Comfort-driven Prosthesis Design.

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ABSTRACT

Diabetic foot complications are commonly recognized as the most common cause of "non-traumatic" Lower Limb Amputation (LLA) internationally. In Singapore, diabetes is the leading cause of amputation. Following an amputation, the provision of a prosthesis aims to facilitate the return to a pre-morbid condition. For a prosthesis to achieve this, it must not only fit well against the residuum but be comfortable to wear and add value to the user's quality of life (QOL). Despite the improvements in technology, the prosthesis remains uncomfortable and disused, or worse, abandoned.

The focus of the thesis is to develop a comfort-driven prostheses design methodology (CPDM) to address the clinical gap in the provision of lower limb prostheses. This thesis aims to 1) understand what comfort means for LLA prosthesis users, and 2) develop a methodology for designing prostheses for comfort. In response, research was undertaken to investigate the phenomenon of comfort. Through a literature review, interviews, questionnaires, and experiments, an understanding of 'comfort' was developed. Further experiments and surveys were conducted to understand how the potential use of sensors and other potential digital technologies could improve the design process.

In response to these findings several solutions were developed with prosthesis users to address various comfort factors. This involved the design and development of a sweat reducing liner to improve thermal comfort, and the design and development of a method to capture Lines of Non-Extension which can result in designs to mitigate discomfort pressures and other discomfort factors, and a case study describes the use a human-centered design methodology combined with a digital technology process to provide further insights into the design and development the CPDM.

The CPDM was designed and developed for providing guidance to the design of comfortable prostheses. The CPDM consists of six design phases and necessary tasks to complete in each phase. Several tools and measures were developed to aid in understanding comfort and its influence on the QOL for the prosthesis user including the AEIOU framework, Requirements Checklist, and the Prosthetic Comfort Assessment Metric (PCAM). These tools and measures were incorporated into the CPDM which was evaluated by experienced prosthetists who were involved in the generation of prostheses. Following the positive feedback of CPDM, the methodology is now being used in a new research study to design and develop an integrated prosthetic liner and socket.

Keywords: Comfort, Amputation, Prosthesis/Prosthetics, Design, Methodology,

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LIST OF ABBREVIATIONS

ADL	Activities of Daily Living
AEIOU	Activities, Environment, Interaction, Objects, User
AFO	Ankle Foot Orthosis
AM	Additive Manufacturing
ASG	Amputee Support Group
BMI	Body Mass Index
CAD	Computer Aided Design
CADCAM	Computer Aided Design and Manufacturing
CLASS	Comprehensive Lower Limb Amputee Socket Survey
CP	Category Partitioning
CPDM	Comfort-driven Prosthesis Design Methodology
DIY	Do-it-Yourself
DM	Diabetes Mellitus
DRM	Design Research Methodology
DT	Digital Technology
DTI	Deep Tissue Injury
EMG	Electromyography
FEA	Finite Element Analysis
FQA	Forequarter Amputation
GCQ	General Comfort Questionnaire
GPS	Global Positioning System
HCD	Human Centred Design
HCPTB	Hand-Casted Patella Tendon Bearing
HCTSB	Hand-Casted Total Surface Bearing
IQR	Inter-Quartile Range
IRB	Institutional Review Board
LLA	Lower Limb Amputation
LoNE	Lines of Non-Extension
MDD	Medical Device Design
MJF	Multi Jet Fusion
NRS	Number Reporting Scale
P&O	Prosthetics and Orthotics
PCAM	Prosthesis Comfort Assessment Metric

PCM	Phase Change Material
PEQ	Prosthesis Evaluation Questionnaire
PLA	Polyactic Acid
PPA	Prosthetic Profile of the Amputee
PPP	Physical, Physiological, Psychological
PTB	Patella Tendon Bearing
PVD	Peripheral Vascular Disease
Q-TFA	Questionnaire for persons with Transfemoral Amputation
QFD	Quality Function Deployment
QOL	Quality of Life
QUEST	Quebec User Evaluation of Satisfaction with Assistive Technology
ROM	Range of Motion
RTCQ	Radiation Therapy Comfort Questionnaire
SCS	Socket Comfort Score
SD	Standard Deviation
SDT	Signal Detection Theory
SOAP	Subjective, Objective, Action, Plan
TAPES	Trinity Amputation and Prosthetic Experience Scale
TCCS	Therapists Cultural Comfort Scale
TLS	Traffic Light System
UCD	User Centred Design
US	United States
VAS	Visual Analogue Scale

1 INTRODUCTION

Diabetic foot complications are commonly recognized as the most common cause of "non-traumatic" Lower Limb Amputation (LLA) (Lazzarini, Clark, & Derhy, 2011). The amputation rate is increasing, primarily due to chronic diseases such as diabetes. Approximately 537 million adults (20-79 years) are living with diabetes, and this number is predicted to rise to 643 million by 2030 and 783 million by 2045 (International Diabetes Federation., 2021). The present trend indicates that more than 60% of the world's diabetic population will be in Asia (Nanditha et al., 2016). Singapore has one of the highest prevalence of diabetes mellitus (DM) in the developed world, with 11.3% of residents aged between 18-69 years living with diabetes since 2010, a significant increase from 8.2% in 2004 (Ministry of Health Singapore., 2010). As a result, annually in Singapore, there are 700 amputations from diabetic foot complications alone (Ang, Yap, Saxena, Lin, & Heng, 2017). Following an amputation, many will require a prosthesis as part of their rehabilitation. Given the low numbers of prosthetists per 100,000 in the world (Ridgewell, Clarke, Anderson, & Dillon, 2021; Ridgewell, Dillon, O'Connor, Anderson, & Clarke, 2016) with the rising rates of disease, the demand will require significant growth of the workforce.

The rehabilitation process with a prosthesis focuses on the key goal of functional mobility. For a prosthesis to achieve this, it must not only fit well against the residuum but be comfortable to wear and add value to the user's quality of life (QOL). Lower limb prostheses connect to the residual limb and act as an extension of the missing skeletal system to transfer loads. It is designed for use in a variety of tasks and movements in different environments. However, despite the benefits, a substantial number of persons with amputations do not use their prostheses. Lower limb prosthesis non-use or low use rates (<9 hours per day) are currently reported to be as high as 15% (Baars, Schrier, DIjkstra, & Geertzen, 2018; Gailey et al., 2010; Raichle et al., 2008), and up to 20% (Raichle et al., 2008; Webster et al., 2012) respectively.

The reasons for the abandonment and low use are due to various reasons including socket fit. The coupling between the mechanical prosthesis and the human limb has benefited from significant technological advancements and an understanding of human physiology. Prostheses have gone from having no joints (Macpherson, Bowlby, Wallace, & English, 2005) to mechanical joints (Michael, 1993) and microprocessor controllers (Ramstrand, Rusaw, & Möller, 2020), and from wood to carbon fiber and lightweight plastics. This has led to users having more active lifestyles and better QOL. However, as much as these devices aim to be an extension of the skeletal system to improve functional outcomes, their lack of comfort limits their ability to serve as an extension of the human behind the system, failing to create a level of human autonomy for the user (Anderson, 2022; Walker, Goddard, Stephens-Fripp, & Alici, 2020).

1.1 Designing Comfort

Comfort as a design driver significantly affects user interaction with a product. It has been shown to reduce muscular-skeletal injuries (Kuijt-Evers, Groenesteijn, De Looze, & Vink, 2004), impact satisfaction scores and outcomes (Fuoto & Turner, 2019), improve well-being and emotions (A. M. Williams et al., 2017), and enhance device usage (Burnfield, Shu, Buster, Taylor, & Nelson, 2011). Several researchers have investigated these effects on various products, from hand tools (Fellows & Freivalds, 1991; Kuijt-Evers et al., 2004), airplane seats (Vink & De Looze, 2008; Vink & Hallbeck, 2012), and car seats (Kamp, 2012) to shoes (Meyer, Mohr, Falbriard, Nigg, & Nigg, 2018; Mills, Blanch, & Vicenzino, 2010). Various methods for qualitative and quantitative feedback can be used to obtain data on comfort levels which provides insights into ways comfort could be incorporated and measured in prostheses.

Most comfort measurements are subjective due to the nature of comfort itself. Users require time to adjust to the prosthesis so that they can provide effective feedback on comfort levels, as comfort needs to be experienced (Coelho, Parola, Escobar-Bravo, & Apóstolo, 2016). According to the comfort models of (Moes, 2005) and (Vink & Hallbeck, 2012), evaluating (dis)comfort through the use of qualitative and quantitative methods could enhance the critical understanding of the holistic effect comfort has on the prosthesis user.

Only the user can evaluate the comfort of a product since the influencing factors are context sensitive. Special attention must be paid to ensure the user is involved in every aspect of the design and ongoing rehabilitation process. Qualifying comfort by asking the user “Do you think it will be comfortable"? or “Is it comfortable when you use it"? will not give enough input for a design (Vink, 2004), while staying aware of the prosthesis users’ needs and expectations of their prosthesis when prescribing individual components is essential (Klute, Kallfelz, & Czerniecki, 2001). The generation of a prosthesis is based on many factors such as personal needs, general health, physical ability, and specific functions, which are user dependent. These needs and requirements may change with environmental changes, aging, evolving health status, and changing lifestyles (Anand, 2000), all of which alter comfort levels with the prosthesis.

When designing a prosthesis to achieve sustained comfort throughout the changes in a person's life, three main issues arise: firstly, if comfort is achieved, the exact cause of comfort is unknown; secondly, the perception of comfort is heavily subjective between individuals and across time; thirdly, there is no design process capturing and incorporating the comfort driving factors to guide toward designs that optimize comfort (Vink, 2004).

1.2 Motivation

The research theme of prostheses comfort stemmed from over 20 years of practicing, mentoring, and collaborating as a certified prosthetist/orthotist across private and public institutions. During this period of designing and fitting hundreds of prostheses, an understanding of the lived experiences and perspectives held by the users was developed. The number one improvement on their wish list was a greater comfort level. Comfort in prostheses is essential to satisfaction, QOL, and preventing prosthesis abandonment (V. Agrawal, Skrabek, Embil, Gross, & Trepman, 2014; Ebrahimzadeh, Moradi, Bozorgnia, & Hallaj-Moghaddam, 2016; Gailey et al., 2010; Gholizadeh, Abu Osman, Eshraghi, Ali, & Razak, 2014; Schaffalitzky, Gallagher, MacLachlan, & Wegener, 2012). The main complaints with prosthesis comfort relate to socket fit that causes skin breakdown (Dudek, Marks, Marshall, & Chardon, 2005; Meulenbelt, Geertzen, Jonkman, & Dijkstra, 2009), affecting the residuum health and rehabilitation process (Butler et al., 2014; Huff, Ledoux, Berge, & Klute, 2008; Legro et al., 1999).

A clear understanding of comfort can help clarify the factors contributing to comfort and their relative importance (Ramirez Patiño, Gutiérrez Rôa, & Correa Espinal, 2015). If all the factors contributing to the user's comfort perceptions are identified and ranked in terms of importance to the individual, more appropriate designs and interventions could be developed. Technological advances in sensing, bionics, materials, and 3D printing fields have significantly influenced the design of prosthetic components and sockets over the years in assisting the user to regain their independence and ultimately improve their comfort. Nevertheless, despite the industry's best attempts to rehabilitate individuals through technological advances, the issue of comfort remains.

The design process for prostheses is geared towards providing function first and addressing other needs second. Current outcome measures reflect the walking ability and the potential to return to pre-morbid status, with little attention given to the holistic approach to the generation of a prosthesis. While functionality has become a focus of research over the past ten years, prosthesis comfort should not be discounted in the design and development of future prosthetic devices (Smail, Neal, Wilkins, & Packham, 2021). The need to incorporate greater comfort into the design process is evident, but how to do this effectively and efficiently should be further explored. With demand for value-based healthcare rising as organizations look for cost-effective ways to improve health outcomes, the concept of enhancing comfort in the design of prostheses could go a long way to reducing healthcare costs. To provide more comfortable prostheses, it is necessary to remember that the generation of a prosthesis is only part of the prosthetists' service. There is a strong need to remember the human using the device. Hence, this Ph.D. was undertaken to redesign the process of generating a prosthesis that revolves around the optimization of comfort.

1.3 Aims and objectives

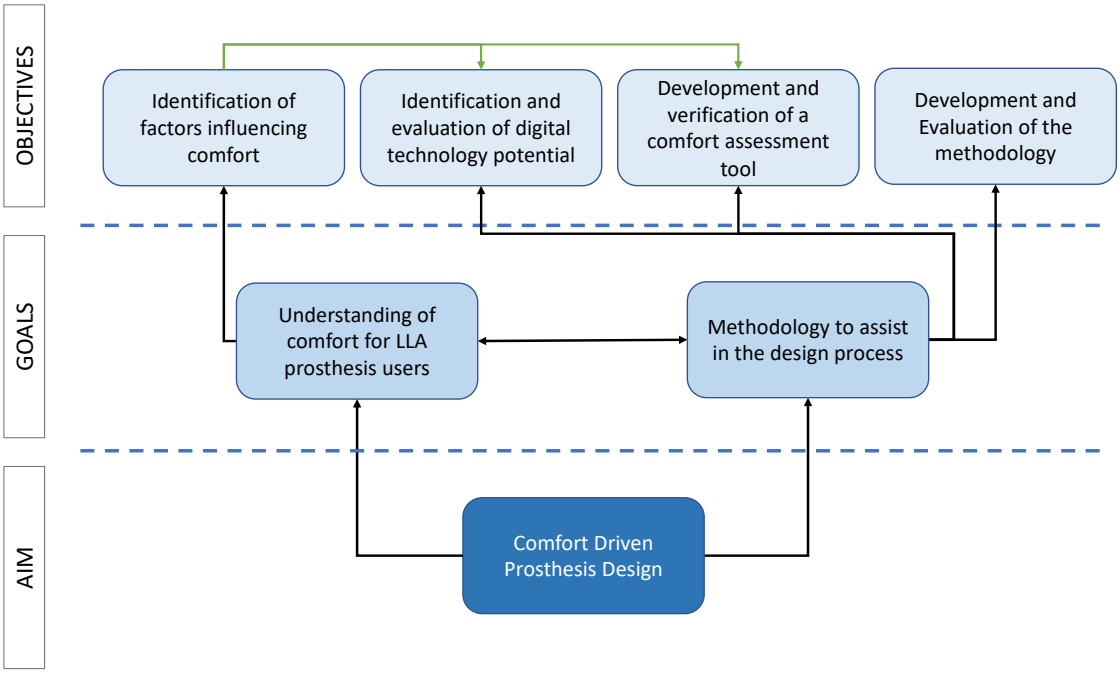

Figure 1-1. Schematic overview of aims and objectives encompassing the thesis

The main aim of this thesis is to develop a methodology for prostheses design driven by the phenomenon of comfort (Figure 1-1). As discussed in this introduction, the lack of comfort often cited by the users is a reason that leads to device abandonment. By incorporating comfort as a design driver, it is hoped that the use of the prosthesis and the QOL of the prosthesis user can be improved. Few – if any – descriptions of prosthesis design explain the need to incorporate users in the design process, nor inform the best approach to involve users in maximizing outcomes.

The goals and objectives are derived from the main aim. There are two primary goals. The first goal is to develop an understanding of what comfort means for LLA prosthesis users from their perspective. The second goal is to develop a methodology to assist the prosthesis design process.

To achieve these two goals, four objectives need to be met. The first objective is a qualitative study with prosthesis users to identify key factors of comfort and their influence on the QOL. These same factors form the basis of the research into the second objective to determine digitalization potential, as well as inform the third objective to develop a Prosthetic Comfort Assessment Metric (PCAM). The last objective is the development and evaluation of the Comfort-driven Prosthesis Design Methodology(CPDM). Greater detail on how the aims, goals, and objectives will be met can be found in the research methodology sections of Chapter 3 - see 3.2 and 3.3.

1.4 Thesis Outline

The following outlines the structure of the main body of this thesis.

Chapter 2, *Literature review:* This chapter presents a review of the literature in 3 areas, namely, (1) definition and factors of comfort; (2) metrics for measurement of comfort; and (3) design process of comfort. Various limitations and research gaps found in the literature are presented and discussed.

Chapter 3, *Research approach*: This chapter describes the approach taken to address the research objectives from a Design Research Methodology perspective. It details the following phases of research clarification: Descriptive Study 1, Prescriptive Study, and Descriptive Study 2.

Chapter 4, *Users' perspectives of comfort:* Issues with comfort from the user's perspective are investigated further to augment the understanding of comfort derived from the literature in Chapter 2.

Chapter 5, *Designing comfort – Process improvement:* Following the identification and verification of the nature of comfort identified in Chapters 2 and 4, this chapter builds on the knowledge by focusing on process improvements when designing prostheses. This chapter describes the combination of quantitative and qualitative methods to determine comfort levels. It then provides information gathered through a survey, on the adoption of digital technology (DT) processes in the prosthetics and orthotics industry, to assess the profession's readiness for DT as part of the design process.

Chapter 6, *Designing comfort – Product improvement*: This chapter focuses on condensing the findings from chapters 2, 4 & 5 into three potential solutions to improve comfort. The first solution focuses on the identification of the Lines of Non-Extension (LoNE) to improve comfort at the residuum-socket interface. Then to help mitigate physiological issues such as thermal regulation (sweating), a new concept for a liner is discussed. This chapter finishes with the use of digitalization in the design and development of a 3D printed forequarter prosthesis.

Chapter 7, *Designing Comfort - PCAM*: . This chapter includes the development and evaluation of the Prosthetic Comfort Assessment Metric, PCAM, which was constructed through the knowledge derived from Chapters 2,4-6. PCAM is an approach to measure the various comfort factors and their importance to the design.

Chapter 8, *Development of CPDM*: This chapter discusses the development of the Comfort-driven Prosthesis Design Methodology (CPDM). Detailed descriptions of the step by step process are provided

along with the influences of the Pahl and Beitz engineering design methodology, the Kano Model, and the Prosthesis Comfort Model on the final CPDM.

Chapter 9, *Evaluation of CPDM*: The evaluation of the CPDM is presented and commented upon. Through a user trial of CPDM, insights are gathered on its usability and usefulness. Particular attention is given to differences between the appropriate and ideal prescription of a prosthesis to identify barriers to the generation of solutions and future areas of innovation to enhance comfort levels.

Chapter 10, *Conclusions and Further Research Work*: This chapter concludes the thesis with a discussion of the original contributions, the evaluation of the initial objectives, and outlines future research work.

2 LITERATURE REVIEW

This chapter presents a review of the literature in 3 areas, namely, (1) importance, definition, and factors of comfort; (2) metrics for measurement of comfort; and (3) the prosthesis design process.

The process to identify common understandings of comfort examines mainly scientific definitions with the aim to select an operational definition that can form the basis for the planned design methodology (Section 2.2). Through investigating influencing factors of comfort, underdeveloped concepts regarding comfort in prosthesis design are identified. The review on different metrics used to qualify and quantify comfort aims to demonstrate different approaches to measure comfort (Section 2.3). Reviewing the prosthetic design process (Section 2.4) and its influence on comfort highlights the artisan approach to prosthetics, its challenges to incorporate comfort and the potential of digitalization to enhance comfort. Finally, a summary is presented on the evidence of gaps and knowledge in the area of comfort-driven prosthesis design (Section 2.6).

2.1 Importance of Comfort

Once an amputation is performed, there is a considerable variation in size, shape and physical features of the residuum, which ensure difficulties in establishing a comfortable and secure prosthesis (Sanders, Greve, Mitchell, & Zachariah, 1998). Many LLA prosthesis users do not consider the prosthesis useful due to pain, ill-fitting designs, or discomfort (Poljak-Guberina, Živković, Muljačić, Guberina, & Bernt-Živković, 2005; Sherman, 1999). With up to 30% of prosthesis users being provided with prosthesis inappropriately designed for their functional mobility (Gailey, 2006) and 50% of prosthesis users unable to achieve ambulation levels after one year (Chopra et al., 2018; Schoppen et al., 2003), increasing comfort could improve outcomes. 57% of prosthesis users are dissatisfied with the level of comfort, and over 50% report pain while using their prostheses (Berke et al., 2010; Dillingham, Pezzin, MacKenzie, & Burgess, 2001). One could argue that 43% are comfortable with their prosthesis; however, understanding what that means and how it was achieved remains elusive.

Everyone pays attention to comfort. It is seen in many aspects of life as a basic human need pursued by all human beings (Malinowski & Stamler, 2002). Comfort remains a must-have, not a nice-to-have in the design of the prosthesis. Understanding what comfort means to the prosthesis user is important for an optimal design (Van Twillert, Geertzen, Hemminga, Postema, & Lettinga, 2013). As mentioned in Section 1.2, the comfort of the prosthesis is a necessity to restore function (Blake et al., 2007) and is essential to user acceptance, improved gait efficiencies (Jaegers, Vos, Rispens, & Hof, 1993) and usability (Hagberg, Brånemark, & Hägg, 2004; Ramirez Patiño et al., 2015). Comfort has been shown to be extremely important to satisfaction, quality of life, and preventing device abandonment (Agrawal et al., 2014; Ebrahimzadeh et al., 2016; Gailey et al., 2010; Gholizadeh et al., 2014; Schaffalitzky et al., 2012) and, is therefore considered a fundamental requirement.

Comfort depends on the personal experience and the physiological, physical, psychological (PPP) state of the person over time in a contextualized environment (Anjani et al., 2021; Vink & Hallbeck, 2012). The user's physical use with the device (Kuijt-Evers, Twisk, Groenesteijn, De Looze, & Vink, 2005; Veisi, Choobineh, Ghaem, & Shafiee, 2019) such as how the device is used and how often it is used can indicate whether the device is comfortable or not (Diment et al., 2022). Comfortable products decrease the risk of injury (Baby, Mathur, & DenHartog, 2021; Klute, Glaister, & Berge, 2010; Nigg, Baltich, Hoerzer, & Enders, 2015). The physiological responses between the human and environment or device (Vink & Hallbeck, 2012) vary between genders (Schellen, Loomans, de Wit, Olesen, & Lichtenbelt, 2012), resulting in different comfort experiences. In cases where comfort was absent, many prostheses cause skin breakdowns (Binedell, Ghazali, Wong, Subburaj, & Blessing, 2022; Klenow & Schulz, 2021) or deep tissue injuries (DTI) (Graser, Day, & Buis, 2020; S. Portnoy et al., 2008). Increasingly, psychological comfort is becoming equally important given the increase in qualitative research that has investigated the expectations of the users, the effects of the prosthesis in their life, and adaption to social challenges (Donovan-Hall, Yardley, & Watts, 2002; Horgan & MacLachlan, 2004; Ostler, Ellis-Hill, & Donovan-Hall, 2014; Sousa, Corredeira, & Pereira, 2009). The service that accompanies the prosthesis provision can address all these life dimensions.

The prosthetist provides comfort in prosthesis design by addressing both technical and human factors. Comfort research in the product design industry is useful for enhancing knowledge and understanding in technical design, such as contours of seats, types of foams used, and types of material combinations used in seating (Califano et al., 2021; Hiemstra-van Mastrigt, Groenesteijn, Vink, & Kuijt-Evers, 2017; Kuijt-Evers et al., 2004; Vink & De Looze, 2008). These technical features are optimized to provide comfortable experiences and are relevant to the design of prostheses. Similarly, inspiration can be taken from the wider healthcare industry, in particular the nursing profession, which emphasizes the human aspects of comfort such as mental wellness (Kolcaba & Wykle, 1997), enhanced self-esteem (Apóstolo & Kolcaba, 2009), and increased communication (Kolcaba, Dowd, Steiner, & Mitzel, 2004; Kolcaba, Schirm, & Steiner, 2006). These factors are central to the patient experience (O'Neill, 2021) and critical to ensuring patient care, including for those with a need for prosthetic devices.

Comfort is a complex concept that involves multiple dimensions of human experience and is subject to considerable variation across people and time (Pinto, Caldeira, Martins, & Rodgers, 2017). Persons with an amputation are so individual in their needs, and the conditions to be met are so variable that it is difficult to establish precise needs for any one situation (Slater, 1986). It is important to understand the parameters that define comfort and their impact on functional mobility, social life, ability to work, and mental and physical health, in order to improve the outcomes of prosthetic design and use.

2.2 Definitions and Factors of Comfort

Many authors have been fascinated by the concept of comfort and, as a result, attempts to define it have emerged from diverse perspectives but are often limited to the academic or professional background of the researcher (Ahmed-Kristensen & Stavrakos, 2012). Being a subjective phenomenon makes comfort challenging to quantify or define, however all agree that it comprises many factors (Ahmadpour, Robert, & Lindgaard, 2016; Bouwens, Mastrigt, & Vink, 2018) and is particularly influenced by the environment (Vink, 2004).

While various debates remain around the definition of comfort, the following characteristics are generally accepted in the literature: (i) comfort is a construct of a subjectively defined personal nature; (ii) comfort is affected by factors of different nature (physical, physiological, and psychological); and (iii) comfort is a reaction to the environment (De Looze, Kuijt-Evers, & Van Dieën, 2003; Slater, 1986; Vink & Hallbeck, 2012).

The following section (2.2.1) concerns the ambiguity in the definition of comfort and seeks to identify an operational definition in relation to prostheses.

2.2.1 Ambiguity in definition

The terms comfort and discomfort suggest two ends of a linear scale from extreme comfort, through a neutral state, to extreme discomfort and was described early on by (Richards, 1980). It is still thought similarly today in prosthesis comfort (Hanspal, Fisher, & Nieveen, 2003). However, comfort and discomfort could also be based on independent factors. This was evidenced in a study by (Zhang, Helander, & Drury, 1996), who sought to define these variables of comfort and discomfort in a seated workplace. They concluded comfort was associated with feelings of relaxation and well-being (Zhang et al., 1996) and can be grouped as emotional experiences (Vink & De Looze, 2008). Discomfort, on the other hand was associated with physical aspects which can lead to pain, tiredness, soreness, and numbness (Vink & De Looze, 2008). These discomfort factors are similarly described for the residuum interaction with the prosthesis (Diment et al., 2022), however additional factors were noted such as phantom limb pain, muscle achiness, rubbing and friction, itchiness, and heat and sweating. Heat and sweating were described as the most severe discomfort factor. Low values for discomfort factors in (Helander & Zhang, 1997) were associated with a wide range of comfort ratings, with comfort ratings falling with increasing discomfort scores. This suggests comfort factors become secondary when discomfort factors are present, affecting overall comfort levels.

Given the need for the prosthesis to address both technical and human factors, it is worthwhile to assess the definitions used in both product design and healthcare such as nursing to compare to the

completeness of current prosthetic definitions (Table 2-1). In product design, definitions address the three PPP overarching contexts of comfort and is described in terms of the physical harmony of the human being within an environment (Gopalakrishnan, Anbazhagan, & Aravindhan, 2006). Whereas healthcare definitions are predominately focused on end-life care which leads to definitions that have a strong psychological component such as relief, embodiment, and well-being. The definitions of comfort directly concerning prostheses are inclined towards viewing discomfort and comfort as a linear continuum such as the socket comfort score (SCS) (Hanspal et al., 2003) or freedom from pain or constraint when wearing the prosthesis (Gailey et al., 2019), but do not address the three contexts of comfort.

The various comfort definitions suggest that comfort should be considered independent of discomfort and is best described and experienced by the user; there is a strong reaction to the environment; and comfort occurs in the PPP multidimensional context. There remains a need for a more comprehensive definition to help clarify the factors which contribute to comfort with prostheses and their relative importance such that user experience and human-prosthesis interactions can be improved (Ramirez Patiño et al., 2015).

Table 2-1. Domains and their definitions of comfort

Domain	Author	Comfort Definition
General	(Dictionaries, 2018)	the state of being comfortable, healthy, or happy
	World Health Organization	a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity
Consumer Product	(Slater, 1986)	a pleasant state of physiological, psychological, and physical harmony between a human being and their environment.
	(Vink & De Looze, 2008)	is an experience
	(Vink & Hallbeck, 2012)	a pleasant state or relaxed feeling of a human being in reaction to its environment
Healthcare/Nursing	(Wensley, Botti, Mckillop, & Merry, 2017)	relief from physical discomfort and feeling positive and strengthened in one's ability to cope with the challenges of illness, injury and disability
	(Mcilveen & Morse, 1995)	an outcome or function of nursing care
	(Gropper, 1992)	a basic human need
	(Morse, Bottorff, & Hutchinson, 1994)	a state of embodiment that is beyond awareness...best recognized when the person first leaves the state of discomfort
	(Morse et al., 1994)	a final state of well-being that comes from therapeutic interventions
	(Kolcaba & Fisher, 1996)	a holistic experience lived by those who received comfort care
	(Nigg, Nurse, & Stefanyshyn, 1999)	allows the user to re-establish a preferred pattern of skeletal motion for a given task, thus facilitating optimal muscle activity, and decreasing energy expenditure and fatigue
Prosthetics	(Hanspal et al., 2003)	A lack of nociceptive stimulation travelling through neural networks to the cerebral cortex
	(Gailey et al., 2019)	a state of physical ease and freedom from pain or constraint while wearing the prosthesis
	(Rybarczyk et al., 1992)	a fundamental aspect of the satisfaction with using the prosthesis

2.2.2 Multi-factorial Comfort

A prosthesis can never be deemed fundamentally ‘comfortable’ or ‘uncomfortable’, as it is the user’s unique relationship and experience with the prosthesis that defines its comfort or discomfort (Vink, 2004). To create a comfortable experience with the prosthesis, the prosthetist must first understand the multiple factors of comfort within the PPP context for the individual (Ahmadpour et al., 2016; Bouwens et al., 2018). The prosthesis factors that influence comfort identified in the literature can be seen in Table 2-2 and are indicated in red. Comfort factors from product design and healthcare identified in literature are also included in the red items, but additionally identified factors from these areas are added in black. This shows the gaps and potential factors to enhance prostheses comfort.

Table 2-2. List of factors contributing to (dis)comfort. (Red – refers to factors for prostheses comfort)

Physical	Physiological	Psychological
Posture • Stability • Safety • Speed Alignment • Force distribution Components • Shock absorbers • Materials Contour • Socket fit • Design/Trimline • Tissue spread • Shape capture method Functionality • suspension, • ROM, • ease of fit, • walking, • sitting, • standing, • climbing stairs • easy to clean • Easy to bring along Surface roughness Activity Movement High Quality Environment Interaction Fatigue/stiffness	Body temperature • Thermal regulation Pressure • Sensation • friction Pain • Body part ache • Inflammation • Numbness • Cramping • Blisters Phantom limb pain Volume • Residuum shape Gender Age Muscle Activation Humidity	Visual input • Aesthetics • Color • Solid design Acoustic Perception Amount of time worn Satisfaction QOL Communication Social relationships Reliable Easy to use • Nice feeling Experience • Short • Long • Previous Size Space Perceived control Environmental stimulation Personal attention Personality and temperament Value system/beliefs Culture Sociodemographic Expectation Cost

The ***Physical*** factors of prosthesis design were well represented when compared to the physiological or psychological contexts as indicated by the number of factors in each column. Given the large technical component in the role of the prosthetist and the focus to return users to their pre-morbid functional levels, heavy emphasis is naturally given to the physical context. Users have rated comfort as the most significant factor to affect functional levels (Ramirez Patiño et al., 2015). However, prosthetic function was not strongly correlated to prosthetic use, suggesting that frequent use of a prosthetic limb is not equivalent to high-level prosthetic physical function (Hagberg et al., 2004) or improved comfort levels, but it is correlated with improved prostheses satisfaction (Diment et al., 2022).

When designing a prosthesis, most attention is paid to the fit between the residuum and prosthetic socket, with good reason. Socket comfort and fit are related: the poorer the fit, the worse the comfort, with improved comfort obtained by adjustment of the prosthesis or the prescription of a new one (Hanspal et al., 2003). Socket comfort can also be enhanced through various physical changes to the prosthesis such as minimizing tissue spread (Flandry et al., 1989) and maximizing joint range of motion in the

proximal joints while wearing the prosthesis (Hagberg, Häggström, Uden, & Brånemark, 2005). This is particularly important when sitting or climbing stairs. The risk for discomfort when seated with the prosthesis increased more than six times if the individual had less than 90 degrees of hip flexion motion in use with the prosthesis, with 44% of subjects in one study recording such discomfort (Hagberg et al., 2005). Other socket designs such as those with an open socket concept (sockets with large areas removed to facilitate donning and doffing) offer greater ROM, which was found particularly comfortable for overweight users (Otter, Postema, Rijken, & Van Limbeek, 1999) and in ascending and descending stairs (Hachisuka et al., 1999). Despite designs such as these, changes in socket designs from an existing design tended to lower socket comfort levels (Manucharian, 2011).

To achieve an optimal socket fit and to reduce the number of adjustments, it is necessary to choose the appropriate socket design methods. The use of hand-casted total surface bearing sockets (HCTSB) were tolerated significantly better than patella-tendon bearing sockets by subjects with longer and more volumetrically stable residual limbs (Manucharian, 2011). However, in the same study, the HCTSB sockets reduced in comfort with an increasing number of adjustments. The authors suggest this was due to the early stages of their rehabilitation causing changes to the residuum and fit with the prosthesis. Conversely, they found the hand-casted patella tendon bearing sockets (HCPTB) increase in comfort the longer the time since amputation. This could suggest that the user experience and feedback to the prosthetists may help to determine more comfortable designs, or the user has an altered level of expectation after using the prosthesis for a period of time, leading to acceptance of small discomfort issues. The careful selection of the type of technology to use when making the socket has been shown to influence comfort. (Hsu, Ou, Hong, & Gao, 2018) compared traditional fabrication methods to digital methods and found users were more comfortable with traditional methods, while being inferior in terms of mobility. This suggests that comfort and mobility may not be correlated, and that mobility may be an important factor when considering whether to use new digital processes and technology.

Designing the socket to fit intimately with the residuum provides stability for the user, improving posture and walking speed (Hachisuka et al., 1999). Loading of the tissues to achieve this should be done accurately, as any subtle changes to the tissue loading can effect on socket stability leading to a meaningful impact on comfort levels (Fatone, Dillon, Stine, & Tillges, 2014). An uncomfortable prosthesis was shown to lower confidence in walking and increased prosthesis abandonment (Rosenblatt, Stachowiak, & Reddin, 2021).

Various components and materials have also been used to improve physical comfort of a prosthesis. The appropriate selection of components such as shock absorbers have demonstrated improved comfort for 67% of patients requiring stair ascent or 78% for stair descent (Popielarz et al., 2014). However, alignment changes to the prosthesis does not seem to effect comfort as much as the author anticipated.

A study by (Jonkergouw et al., 2019) attempted to assess comfort scores using the SCS after altering alignment of the prosthesis, and found that users tended to change their pattern of walking to overcome these alignment changes, negating the effects of any discomfort. This led to no significant changes in SCS, although the authors note the SCS may not be sensitive enough to detect the force changes felt by the user. While the addition of these components adds to the weight of the prosthesis, with appropriate selection of materials, comfort factors such as weight can be improved (Boutwell, Stine, Hansen, Tucker, & Gard, 2012). Materials such as copolymers and silicone elastomer liners improve the suspension and stability inside a prosthesis (Hachisuka et al., 1999) and is beneficial to improving standing and sitting comfort (Boutwell et al., 2012).

Given the functionality of a prosthesis and the presence of discomfort factors, comfort may be dominated by discomfort. The prosthetist may be focused on mitigating discomfort factors in much the same way as in the design of hand tools (Kuijt-Evers et al., 2005). In hand tools functionality, physical interaction, and appearance were found to be important for discomfort as well as comfort suggesting a continuum. The factors that had the closest relationship to comfort when using hand tools were identified among 27 descriptors, such as good fit in hand, surface roughness, functional, easy to use, and reliability. When considering physical factors, choices need to be made to either mitigate discomfort factors or focus on the emotions and "luxury" to increase comfort (Vink & De Looze, 2008).

Most ***physiological*** factors related to prosthesis comfort were also observed in product design. Temperature and pressure were two more common factors across disciplines. Given the occlusive nature of current prosthetic sockets, comfort levels can be affected when there is little thermal regulation to control excessive temperatures (Klute, Rowe, Mamishev, & Ledoux, 2007). An increase of just 1.9 degrees Celsius has been shown to lower comfort levels (Williams, Takashima, Ogata, & Holloway, 2019). (Diment, Thompson, & Bergmann, 2019) observed that after exercise, thermal discomfort ranked higher on the amputated side than on the contralateral side, due to the enclosed nature of the socket. Heat and perspiration issues as a result of the enclosed environment were found to occur in 54% of prosthesis users across 27 studies (Ghoseiri & Safari, 2014) and 71% of users describe the temperature discomfort in tropical climates (Diment et al., 2019). These issues not only affect comfort, but can affect tissue health, activity levels, and prosthesis suspension (Ghoseiri & Safari, 2014), indicating that comfort factors in different PPP contexts show causation.

Socket comfort is achieved through the loading and off-loading in the socket design of the residuum (Sashwati, Mathew-Steiner, & Sen, 2020). The comfort perceived by the patient could be based on the locations of these loaded regions of the residuum (Henao, Orozco, & Ramírez, 2020). When surface and volume matching is accurate, users report greater comfort and improved QOL (Sanders et al., 2018). However, inaccurate loading can result in pain or pressure issues related to skin breakdown, deep tissue

injuries, or wounds (Binedell et al., 2022; Graser et al., 2020; Klute et al., 2009). Furthermore, the effect of volume fluctuations or long-term changes in the residuum can alter socket interface pressures leading to similar issues (Safari, Tafti, & Aminian, 2015; Sanders et al., 2018), and could lead to prosthesis disuse (Sashwati et al., 2020). Therefore, to address these pressure related issues and improve comfort levels, (Sanders et al., 2018) advises to add socks over the residuum to maintain socket fit and mobility. Another way to improve pressure distribution and comfort is through the use of a prosthesis liner. The liner aims to reduce peak pressures and improve the socket fit and comfort. The use of thicker interface liners was demonstrated to significantly reduce fibular head peak pressures by an average of 26 ± 21% (Boutwell et al., 2012).

Issues of pressure and temperature have also been observed in product design particularly in seating and hand tools. The way a hand tool is used can determine the physiological response. When comfortable, the hand tool will not lead to musculoskeletal injuries, sensations of pain, or other internal body responses (de Korte, Huysmans, de Jong, van de Ven, & Ruijsendaal, 2012). Though, the length of time a hand tool or seat is used could influence comfort levels. Literature testing of pressures when seated, do so in a continuous pattern (Alessandro & Sandro, 2009; Helander & Zhang, 1997; Hiemstra-van Mastrigt et al., 2017; Kamp, 2012; Smulders et al., 2016; van der Voort, 2018), however, the prosthesis undergoes repeated pressure loading with each step, making the translation of these results difficult.

A less known physiological factor identified was gender (Schellen et al., 2012; Shooshtarian & Ridley, 2016). Female whole body responses to thermal sensations in an environment were found to be more uncomfortable and dissatisfied than their male counterparts and suggest that particularly for females, skin temperatures of the extremities have a significant influence on thermal comfort (Schellen et al., 2012). No studies have specifically addressed gender and comfort in the prosthetic literature, but these results suggest it is worth exploring as a possible means to optimize comfort levels for the individual.

Attention to the ***psychological*** factors is equally important. In prosthetic literature, the list of psychological factors that influenced comfort was the shortest. This suggests the impact of such factors is minimal compared to the physical and physiological factors of prosthetic design. However these factors may be the most impactful to overall comfort levels since comfort is closely related to emotional experiences (Vink & De Looze, 2008) and improved comfort has a positive effect on the QOL, and satisfaction for the user (Diment et al., 2022).

For many users, the amputation and subsequent rehabilitation journey can lead to levels of anxiety, depression, and reduced self-esteem (Donovan-Hall et al., 2002). Feeling positive about the way the prosthesis looks may help to address any social discomfort the users experience, with social discomfort

and avoidance having been identified as “markers” for poor adjustment of prostheses users (Rybarczyk et al., 1992). To improve the perception of the prosthesis, the introduction of visually pleasing cosmetic covers has been shown to significantly improve comfort levels (Ramirez Patiño et al., 2015) but these should match the sound limb as accurately as possible for maximum benefits (Cairns, Murray, Corney, & McFadyen, 2014).

The perception of sounds coming from the prosthesis have been shown to lower satisfaction with the prosthesis (Ali et al., 2012). Sounds can indicate a structural problem with the prosthesis that may be catastrophic or increase the fear of falling. Sounds were considered a comfort factor within a larger comfort questionnaire by (Hsu et al., 2018) who compared traditionally fabricated sockets with rapid prototyping and reverse engineered sockets. Although the participants did not notice any sounds, the inclusion within the comfort assessment indicates that sounds may affect their perception of comfort levels.

In the product design industry, (Vink & De Looze, 2008) demonstrates the experience of comfort is influenced by soft factors, such as personal attention. This is supported by (Kamp, 2012) who measured the emotional reaction to a tactile experience. Kamp demonstrated that it is possible to increase comfort by rating current experience and designing new seats which have the ability to elicit a better emotion as a reference seat for a specific use (e.g. sports car vs. a van). From nursing, (Pinto et al., 2017) adds several personal aspects that influence the experience of comfort: an individual’s personality and temperament, age, sociodemographic characteristics, clinical condition, culture, value system, and beliefs (religious, political, or sociocultural). (Siefert, 2002; Silva et al., 2020) stated that comfort attributes comprise effective communication, the presence of family and significant relationships, keeping functionality, personal features, physical relief and psychological interventions, spirituality, and feeling safe. Communication and relationships, in particular, seem to be essential to achieving comfort (Pinto et al., 2017). Differences in experience also appear when consideration is given to short-term and long-term conditions. The short-term experience is centred on the visual aspects of the design but long-term effects are important in the use of the product (Vink & De Looze, 2008).

Overall, the limited attention given to psychological factors by the prosthetist to address comfort issues suggests a need to develop greater understanding towards the user and their needs through additional attention, communication, and understanding how and why the user may or may not use their prosthesis.

2.3 Metrics for Measurement

Measuring comfort is necessary to understand and improve design. Efforts have been made to understand the holistic assessment of comfort and to define the different aspects of comfort and

corresponding test methodology for using human beings as measurement tools (Frohriep, 2019). A holistic approach is critical to develop a need into an active element of the design (Tzanidakis et al., 2018). Given the three broad categories of factors are different in nature which lead to various design decisions, using the correct measuring method for each category can help to build a comfort profile of the user and be useful in comparing improvement to comfort levels.

Qualitative methods are enough to know whether comfort was experienced, as comfort can be defined as a qualitative phenomenon. However, in the design of a prosthesis, if explanations are needed, it is useful to have quantitative methods as well (Vink & De Looze, 2008). "In simple terms, the measurement of psychological factors are usually carried out only in qualitative ways, the measurement of physical ones are usually carried out in quantitative ways, and the measurement of physiological ones can use either qualitative or quantitative methods, depending on the type of response sought" (Slater, 1986).

It is easy to measure the weight or size of an object, but it is much harder to measure comfort, happiness or other emotions. Humans are not good in sensing absolute values, but are better when sensing differences between two conditions (Vink, Anjani, Smulders, & Hiemstra-van Mastrigt, 2017). A prosthesis is tested only at the end of the design process and multiple adjustments are needed (Manucharian, 2011). Testing the prosthesis earlier helps to provide a comparison between the two conditions. In measuring factors related to comfort, it is necessary first to decide whether a particular situation needs a qualitative or quantitative method of assessment, then to determine what experiment needs to be carried out, and, finally, to ascertain how many times it must be repeated to be sure that an accurate answer is obtained. Finally, due to the numerous factors in various categories (Table 2-2) the literature suggests to focus on the main factors which can be compared between two devices (prostheses) (Vink & De Looze, 2008).

There is a large range of qualitative and quantitative P&O measures available, many of which are difficult to contextualise or compare. Attempts to compared are discussed in the next sections (2.3.1, 2.3.2). There is a lack of consensus around which measures should be used and when, which only adds to a high data collection workload on busy clinicians (Condie, Scott, & Treweek, 2006). This is indicative of a larger problem, as extensive research on how we measure outcomes might distract us from evaluation of what defines a meaningful outcome for the different stakeholders in P&O services (Dickinson et al., 2019).

2.3.1 Qualitative Measurement

Assessment of comfort, as a complex concept, should include multiple factors and awareness or subjectivity of the experience. As a dynamic and individual process, the individual responses should be considered. Instruments developed to study or document comfort (Table 2-3) must enable these individual interpretations (Pinto et al., 2017).

Often designers will simply ask a version of "how comfortable is it?", without elaborating on which aspects of comfort they should reply to. The way the designer is wording questions differently from one another could produce different results, undermining effective comparisons (OECD, 2011). Consumer products tend to focus on the physical attributes and functionality of the product in their assessment, undervaluing the role qualitative assessment provides. In determining a products comfort and associated comfort experience, a frequently used method includes the use of interviews, surveys, and questionnaires (Mansfield, Naddeo, Frohriep, & Vink, 2020). Responses are either recorded or marked using a Likert type scale. Evidence suggests measuring comfort using an ordinal scale will introduce errors to correlations between comfort and other variables such as biomechanical variables that are measured on continuous scales (Mündermann, Nigg, Stefanyshyn, & Humble, 2002). However, there is evidence to suggest that the use of a visual analogue scale (VAS) system provides more meaningful outcomes (Kolcaba, 1992; Mündermann et al., 2002). It consists usually of a line 0-100mm with anchor descriptions (in comfort context) "not comfortable at all to most comfortable imaginable". Capturing all aspects of the comfort in any given instrument is difficult. The VAS might better represent the personal uniqueness and richness of comfort compared to a traditional questionnaire because the meaning of comfort is not constrained to specific items (Youngblut & Casper, 1993).

Various questionnaires have been used to measure posture and seating comfort. (Groenensteijn, 2015; Smulders et al., 2016) used the Localized Posture Discomfort score to determine postural discomfort. They suggest the use of a benchmark product could be used to test comparisons between an existing and new design as part of this approach. The advantage of this method is that it reveals the location of the areas to be improved, which provides input for redesign (Mansfield et al., 2020). The scale is still very subjective as the researcher knows what is 10 for the user. It that sense, it reflects an experience and an individual's threshold. The CP-50 category partitioning scale (Shen & Parsons, 1997) has shown the best overall reliability and validity for pressure intensity and discomfort ratings (Shen & Parsons, 1997). This has been used by (Franz, Durt, Zenk, & Desmet, 2012; Mergl, 2006) for instance to collect feelings of discomfort after sitting for a certain amount of time.

In assessing the human factors of comfort, healthcare questionnaires have been developed, mainly for nurses providing end-life comfort care – General Comfort Questionnaire (GCQ), Radiation Therapy

Comfort Questionnaire (RTCQ) (Kolcaba, 1992), and pain score (Wong & Baker, 2001) being the more common, showing validity with the VAS (Garra et al., 2010). Kolcaba's development of the RTCQ was based upon the GCQ she had previously developed with subtle changes to the number of questions and to the four categories. The GCQ originally had 48 questions which had been reduced to 26 in the RTCQ despite the response categories increasing from four to six. This change was shown to improve sensitivity with the anchors remaining the same. In the study by (Mündermann et al., 2002), they found that the reliability of a comfort measure can be considerably improved by adding a control condition to the testing protocol. This gives the user, a point of reference for comparison and reinforces the factor of experience in comfort and reinforces the earlier point made about the importance of testing (Vink & De Looze, 2008) Furthermore, (Mündermann et al., 2002) suggests that for long term comfort the repeated assessment of comfort up to 4-6 times is necessary.

In the prosthetics field the most common qualitative tool to assess comfort is a questionnaire. Literature provides many such questionnaires, ranging from 1-70 questions which take between a few seconds to 25 minutes to answer. Individual factors are assessed using specific terminology e.g., to assess weight. The scale ranges from heavy to light (Cavaco, Durães, Ramalho, & Pais, 2020) or ranks satisfaction from very dissatisfied to very satisfied (Safari et al., 2015). Problems could arise when the same factors are using different terminology i.e., weight: heavy to light, or weight: obese to underweight.

The most commonly used questionnaire to assess comfort is the SCS (Fatone et al., 2014; Hafner, Morgan, Askew, & Salem, 2016; Hanspal et al., 2003; Jonkergouw et al., 2019; Kahle, Klenow, & Highsmith, 2016; Manucharian, 2011; Safari et al., 2015; Sanders et al., 2018). This is a one-question tool that asks the individual to rate how comfortable their prosthesis is on a scale of 0-10, 10 being the most comfortable. A one question tool does not appear to give sufficient understanding to the prosthetist about which of the physical, physiological, or psychological comfort the user is referring to. Of the remaining questionnaires, the Comprehensive Lower Limb Amputee Socket Survey (CLASS) (Gailey et al., 2019), Prosthetic Evaluation Questionnaire (PEQ) (Legro et al., 1998), Prosthetic Profile of the Amputee (PPA) (Gauthier-Gagnon & Grisé, 1994), Trinity Amputation and Prosthetic Experience Scale (TAPES) (Gallagher & MacLachlan, 2004), and the Questionnaire for persons with transfemoral amputation (Q-TFA) (Hagberg et al., 2004) were the most-documented alternatives to the SCS. Therefore, these will be described in more detail.

All five involve self-reported outcomes, though each focuses on different areas of the patient's experience with their prosthesis. Of the five questionnaires, both the CLASS and PEQ directly address comfort with three questions regarding the function of standing and sitting and a third relating to the amount of daily activities they can complete. The CLASS assessment of comfort is in much greater detail as it is one of its four main themes: stability, suspension, comfort, and appearance. The CLASS

addresses comfort in sitting, standing, walking, ascending and descending stairs, running or jogging, and overall satisfaction. Notably, despite its relative refinement and validation as reliable, no other articles have used CLASS to assess comfort, suggesting either the results still do not provide sufficient detail to value-add to the consultation with the user or simply the SCS is quicker and easier to administer. The Prosthetic Profile of the Amputee measures factors related to prosthetic use, providing a broad assessment of the user, their physical condition, and other general information, but does not assess socket comfort in any way. For the TAPES, the authors (Gallagher & MacLachlan, 2004) do address the comfort of the limb as a whole, but the relevant question is embedded in a section of the TAPES and is not available for use as an individual item, unlike the PEQ, and cannot communicate perceived comfort or the resulting impact of socket adjustment on perceptions of comfort and discomfort. The Q-TFA addresses discomfort in one of four sections, but only pertaining to sitting (Hagberg et al., 2004).

Table 2-3. Abbreviated list of qualitative tools for product and healthcare, and complete list for prostheses used to assess comfort

Name	No. of questions	Type of scale	Scale range
PRODUCT			
Local posture discomfort questionnaire (+ Borg scale) (Borg, 1990)	12 regions	NRS	0-10 Borg Rating of Perceived Exertion (0–10)
CP-50 category partitioning scale (Shen & Parsons, 1997)	50	NRS	Category portioning - 5 categories: very' slight, slight, medium, severe, very severe. 1 to 10 indicates very slight discomfort, 11–20 slight discomfort, 21–30 medium discomfort, 31–40 severe discomfort, and 41–50 very severe discomfort. Scores of 51 and 52 are for anything exceeding this.
Self-made (M. Li et al., 2020)	2 Driving 15 min Driving 90 min	NRS	1-10 1=low comfort 10=high comfort
Thermal Sensitive Voting scale (TSV) based on ASHRAE 55 standard			7- point range ‘Very satisfied’ to +3, ‘Very dissatisfied’ to −3, and the middle position to ‘neutral’
Self-made (Groenensteijn, 2015)	4	NRS	10-point scale (10=high, 1=low)
HEALTHCARE			
General Comfort Questionnaire (Kolcaba, 1992)	48	VAS	Strongly agree to strongly disagree on a 10 cm line (with four anchors)
Radiation Therapy Comfort Questionnaire (Kolcaba, 1992)	26	VAS	Strongly agree to strongly disagree on a 10 cm line (with 6 anchors)
Comfort visual analogue scale (Kolcaba, 1992)	3	VAS	Strongly agree to strongly disagree on a 10 cm line • Relief • Ease • Transcendence

Pain Score	1	NRS	0-10, 0=no pain to 10=worst pain
Therapists Cultural Comfort Scale (Pérez-Rojas, Bartholomew, Lockard, & González, 2019)	13	Likert	1-6, ranging from 1 (strongly disagree) to 6 (strongly agree)
Nurses with comfort touch scale (Pedrazza, Trifiletti, Berlanda, Minuzzo, & Motteran, 2015)	Not determined	Likert	7-point scale, ranging from 1 (not at all) to 7 (very much). Five subscales: Task-Oriented Contact, Personal Care, Physical Comfort, Reassurance and Emotional Containment.
Comfort behavioural scale (Ambuel, Hamlett, Marx, & Blumer, 1992)	7 categories	VAS	1-5 various descriptions for each category
Comfort-Support assessment tool (Mündermann et al., 2002)	6 scales	VAS	All six scales 100mm in length Items 1-4: 0=not comfortable at all, 100 most comfortable condition imaginable Items 5&6: 0=no support at all, 100= too much support
PROSTHESES			
Socket Comfort Score (SCS) (Hanspal et al., 2003)	1	NRS	0-10
Comprehensive lower limb amputee socket survey (CLASS), (Gailey et al., 2019)	15 (4 subscales = stability, suspension, comfort, appearance	NRS	1=Strongly disagree, 2=Disagree, 3=Agree, 4=Strong agree, 0=NA
Trinity Amputation Prosthesis Experience Scale (TAPES) (Gallagher & MacLachlan, 2004)	45 (9 subscales = 3 psychological, 3 activity restriction, 3 satisfaction	NRS	Psychological = 0-5 (strongly disagree, disagree, neither agree nor disagree, agree, strongly agree) Activity restriction = 0-3 (not at all limited, limited a little, limited a lot) Satisfaction = 0-5 (very dissatisfied, dissatisfied, neither dissatisfied nor satisfied, satisfied, very satisfied)
Prosthesis Evaluation Questionnaire (Legro et al., 1998)	10 subscales including Ambulation, Residual Limb Health, Utility, and Well-Being	100mm VAS	0-10 for each question within the subscale
Comfort Test (Ramirez Patiño et al., 2015)	30 - appearance, well-being, pain, functionality, psychological health, and social health.	NRS	0-6 (ratings depend on topic)
Transfemoral amputee questionnaire (Q-TFA) (Hagberg et al., 2004)	70	NRS	Prosthetic Use Score (Use), Prosthetic Mobility Score (Mobility), Problem Score (Problem), and Global Score (Global)
Short Q-TFA (Hagberg et al., 2004)	1	Likert	0 = no trouble, 1 = slight trouble, 2 = moderate trouble, 3 = considerable trouble, 4 = a great deal of trouble
Short comfort questionnaire (Salazar-Salgado, Valencia, Uribe, & Rendón-Vélez, 2021)	6	NRS	1-5 focusing on fit, pain in leg, back, sweat
Social Discomfort scale (Rybarczyk et al., 1992)	3	VAS	1=not at all, 2=somewhat, 3=definitely

Engagement in Everyday Activities involving Revealing the Body scale (EEARB) and (Discomfort - EEARB) (Donovan-Hall et al., 2002)	10 items - EEARB 11 items - Discomfort EEARB	NRS NRS	0='not applicable', l='never', 2='l to 3 times a month', 3='once a week', 4='l to 3 times a week', 5='4 to 6 times a week', and 6='daily Discomfort EEARB - 1 (very uncomfortable) to 4 (totally comfortable)
Pain Sensation Comfort Sensation Global Perception Questionnaire (GPQ) (Cavaco et al., 2020)	1 1 8	VAS VAS VAS	0 -3 (no pain to very painful) 0-3 (very comfortable to very uncomfortable) "1. Stand up comfort (very comfortable, comfortable, uncomfortable, or very uncomfortable); 2. Sit down comfort (very comfortable, comfortable, uncomfortable, or very uncomfortable); 3. Energy required to use the prosthesis (not exhausting, slightly exhausting, exhausting or very exhausting) 4. Instability during walking (never, sometimes, many times or always) 5. Sensation/sensitivity regarding temperature and texture (pleasant, slightly unpleasant, unpleasant, or very unpleasant) 6. Easy donning and doffing the interface (easy, slightly difficult, difficult, or very difficult); 7. Sweat rate compared with own prosthesis (no sweat, slightly sweaty, sweaty, or very sweaty); 8. Prosthesis weight (very light, light, heavy or very heavy)."
Self-made (Hsu et al., 2018)	10 – standing, sitting, easy to wear, weight, time and temperature, volume, sounds, skin reaction, footwear, cleanliness	NRS	All subscales are ranked from 1-5. Standing: (1= Absolutely uncomfortable to 5= Very comfortable) Sitting: (1= Absolutely uncomfortable to 5= Very comfortable) Easy to wear: (1= impossible to 5= easy) Weight: (1= very heavy to 5= very light) Time to feel hot: 1= 1 h 2= 1–4 h 3= 4–7 h 4= 7–11 h 5= 12 h and more Volume: 1= Silk socks × 1; silica gel socks × 1; thick quilted socks × 3 2= Silk socks × 1; silica gel socks × 1; thick quilted socks × 2 3= Silk socks × 1; silica gel socks × 1; thick quilted socks × 1 4= Silk socks × 1; silica gel socks × 1; thin quilted socks × 1 5= Silk socks × 1; thin quilted socks × 2 Sounds: (1=Always to 5=Never) Skin reaction: (1=Always to 5=Never) Wear any type of footwear: (1=impossible to 5=possible) Cleanliness: (1=impossible to clean to 5=possible to clean)

Self-made (Otter et al., 1999)	18 - skin problems, hygiene, comfort when sitting, cosmetic aspect, mobility, and donning/doffing	NRS	Skin problems = never present/present sometimes/present most of the time/always present Hygiene = yes/no Sitting = easily/with some difficulty/difficult/not possible Cosmetic = 1 = very good to 5 = very poor Mobility and Don/doff = 1 = easily to 4 = impossible
Self-made (Diment et al., 2019)	1	NRS	0-6 (no discomfort to intense discomfort)
Self-made (Popielarz et al., 2014)	1	VAS	No score mentioned but ratings done from; non-comfortable, not very comfortable, comfortable, and very comfortable
Self-made (Boutwell et al., 2012)	19	Likert	5-point scale to statements. Strongly agree, agree, no change, disagree, strongly disagree

2.3.2 Quantitative Measurement

For a comfortable design, "several parameters have to be correctly evaluated in order to guarantee a good level of safety and well-being of users (humans) and to avoid health problems like muscular-skeletal injuries" (Naddeo, Cappetti, & D'Oria, 2015). There is a need to measure the effects to the internal body and the perception of comfort (physiological factors) in the environment (physical factors) as demonstrated in the comfort/discomfort models of (Mansfield et al., 2020; Moes, 2005; Vink & Hallbeck, 2012).

Measurement of the physiological factors can begin before the prosthesis is made, and then used again to compare with initial readings to inform design decision making. Quantifying physiological comfort is typically achieved with digital tools such as sensors, computer software, and AI. Such tools provide accurate, repeatable, and reliable information from which to design a prosthesis. The most common physiological factor measured in the literature is pressure and its distribution. Pressure distribution is the most clear correlated item to subjective ratings (Vink & Hallbeck, 2012). This is evident across industries from seating (Groenensteijn, 2015; Mansfield et al., 2017; Naddeo, 2017; van der Voort, 2018; Wegner, Martic, Franz, & Vink, 2020), footwear (Mündermann et al., 2002), and prosthetics (Ko, Asplund, & Zeybek, 2021; Laszczak et al., 2015). The use of pressure sensors has been demonstrated in the scoping review of (Ko et al., 2021). They found sensors can be used to evaluate comfort and socket fit, but that these sensors should be developed with prosthetists to ensure the intricacies in the design of a prosthesis can be measured. (Neumann, 2001b) used Signal Detection Theory (SDT) to determine the level of discomfort with regard to pressure changes. The author demonstrated that SDT can be applied to the process of fitting sockets and used to model the ability of patients to make judgments concerning the expectation of discomfort problems. This again highlights the need to generate a baseline for comparison that other authors have suggested.

However, pressure alone cannot evaluate comfort as pressure ratings of comfort change over time (Li et al., 2020). Their study of 17 participants as they drove a car for 2.5 hours. found differences between short-term (15 minutes) and long-term (90minutes) comfort, with comfort levels dropping over time. Interestingly, they found variations to the pressure distribution with some areas increasing after 90 minutes and others decreasing when compared to the 15 minute reading. This suggests there is an internal body response to effect the pressure distribution that changes over time. Muscle activation through EMG signals and posture, can be used to measure the fatigue factor associated with comfort. Fatigue can also be quantified through blood oxygen levels, or lactic acid levels (Slater, 1986).

A study on human posture by (Naddeo et al., 2015) demonstrated that anthropometric parameters can be used to evaluate users' comfort, and that their procedure can be used to build curves that represent comfort values along the entire range of motion of postures (joint angle) for each human joint under consideration. Their findings indicate that similar approaches could be possible to determine the comfortable posture for the prosthesis user. Of course, anthropometric data can also be captured with the use of tape measures, goniometers, and vernier callipers, or with digital tools such as scanners, cameras. Both methods capture shape and size which could be used as a cross reference for subsequent adjustments or socket replacements.

Aspects of posture such as stability and alignment has been compared to comfort in prosthetic literature. Stability and alignment have been tested with mixed results. Stability can be quantified through ground reaction forces, postural sway, or number of falls (Fatone et al., 2014). Both magnitude and direction of moments can be useful (Kobayashi, Orendurff, Arabian, Rosenbaum-Chou, & Boone, 2014). The alignment effects on comfort can be determined through similar measurements, which is important given the limitations in the user perceptions of alignment effects on comfort (Boone et al., 2012) and the lack of details provided by the SCS (Jonkergouw et al., 2019).

Quantifying temperatures within a prosthesis that may lead to wounds and fungal infections can be useful in their prevention or management and can done through the use of thermistors or strain sensors (Williams, Holloway, & Miodownik, 2016). Another study by (Williams et al., 2019) found temperature changes of as little as 1.9 degrees Celsius impacted comfort levels and that assessing the prosthesis users in their natural environments was critical. The temperature recordings are also useful to determine differences between the residuum and sound limbs which could lead to improved designs that increase permeability and breathability (Diment et al., 2019).

To quantify physical comfort, measurements need to record the users within an environment such as home, work, or doing activities. Tools such as step trackers, activity monitors, and GPS trackers would provide valuable information to the use and user environments. Functional timed tests such as the Timed

up and Go, 6-minute walk test and L test, provide information that can be repeated to test stability and balance but are generally reported by the physiotherapists and not routinely tracked by the prosthetists. These tests provide only a snapshot of the moment the users are in the clinic and may not represent real world situations well. The use of step trackers and activity monitors have been successful in determining the use of the prosthesis in the real world (Stepien, Cavenett, Taylor, & Crotty, 2007). This is important given the risk of prosthesis users overstating their abilities, which could lead to an inappropriate functional level of prosthesis (Stepien et al., 2007). However, as (Dickinson et al., 2019) points out, the use of such technology should be explained to users to allay fears they are being tracked in an effort to take away their prosthesis or downgrade them to something less functional. This fear also reinforces the need to communicate with the users to address their psychological comfort.

2.3.3 Summary

Therefore, we can conclude that qualifying and quantifying correlate to comfort. The use of questionnaires with a VAS reporting system is applicable to measure prostheses comfort as demonstrated in section 2.3.1. Furthermore, the use of additional domains increases the sensitivity of the results, allowing scope for a longer and more detailed assessment tool which covers the broad areas physiological and psychological comfort. The use of a control condition, in this case, a prior prosthesis, may be necessary for comparison of comfort levels and comfort should be tracked long-term.

Many methods to quantify comfort were identified in the literature. Currently prosthesis comfort is addressed in the short term through standard outcome measures, however, comfort could be enhanced by tracking activity levels with GPS or similar monitors, or by using sensors to determine physiological comfort which will lead to design optimization of the socket shape and pressure distribution, mitigating temperature and fatigue changes over time. Digitally capturing the residuum data may also enable easier comparisons of the shape for subsequent designs.

2.4 Design Process

The goal of the prosthesis design process is to restore an amputees gait symmetry and effort to pre-morbid and able-bodied levels (Price, Beckerle, & Sup, 2019) and to ensure prosthesis use, function, and satisfaction (Bukowski, 2006; Pitkin, 2013; Sinha, Van Den Heuvel, & Arokiasamy, 2011; Van Der Linde, Geertzen, Hofstad, Van Limbeek, & Postema, 2004). However, goals of the user may vary. Some users may prefer function over aesthetics, whereas a cosmetic prosthesis designed for a non-ambulant user would prefer the opposite (Van Der Linde et al., 2004). The individuality of the design should be able to be captured within the design process and be addressed by human and technical approaches. Historically, the prosthetist has been an craftsman, using intuition and heuristic experience

to create properly fitting sockets (Dean & Saunders, 1985). Each prosthesis is supposed to be a tailor-made device, designed to fit the unique geometry of the user's residual limb. While this is true, the similar designs of sockets with regards to materials and trimlines can be seen for the young or older prosthesis user, with components often the only variable. Even though the design is based on artisan techniques (Chevalier & Chockalingam, 2012), the prosthesis remains largely similar in its overall design. The prosthetists relies on previous experience and bias with previous prosthesis users when deciding on the prescription to optimize results (Anderson, 2022). This could leave the prosthesis user with a less than ideal comfortable design due to limitations in the solutions offered. Furthermore, the users may not have had an opportunity to communicate their perception or expectation about the prosthesis, leading to unmet needs and an assumption that the final prosthesis delivered is comfortable.

The current design process has not been described in detail in the literature as far as this author is aware but it seems it is mostly focused on the end product – the prosthesis. The detailed descriptions of how prosthesis are digitally produced seems to support this opinion as those processes are often well described in detail in comparison to the traditional process (Binedell, Meng, & Subburaj, 2020; Sengeh & Herr, 2013). The design of a prosthesis typically involves 6 phases (Figure 2-1). Each phase is elaborated below.

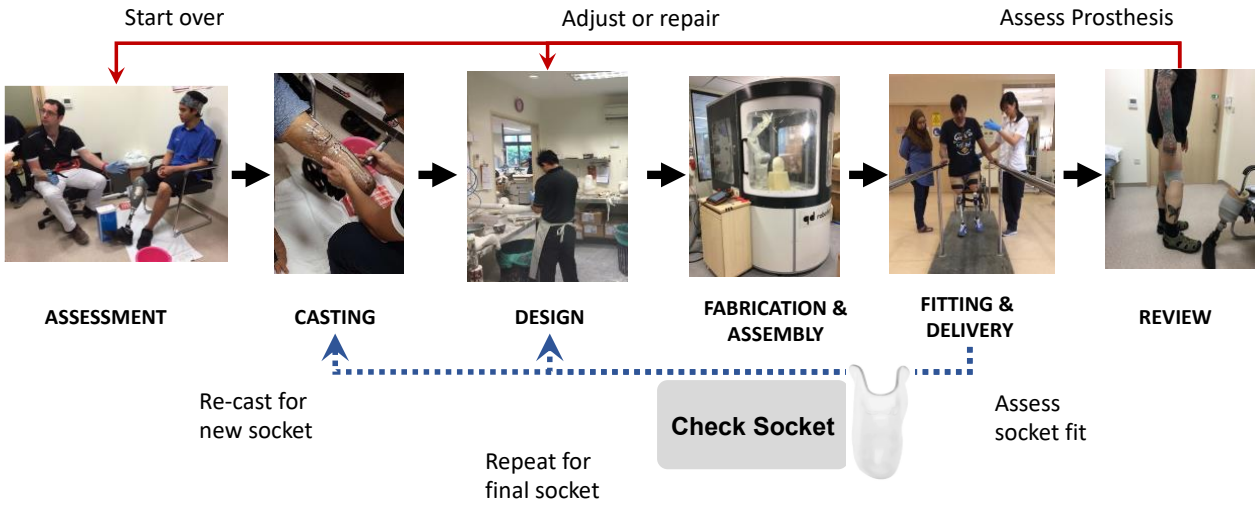

Figure 2-1. Common prosthetic design process phases

Assessment of the user includes assessing their needs, physical characteristics of the residuum and whole body, functional mobility, and goals. The use of mobility predictors has shown validity and reliability to the prescription of device components (Gailey et al., 2002). Background information is sometimes provided from the rehabilitation team including Doctors, Physiotherapists, Occupational Therapists, Podiatrists, and Social workers but is more general by nature than specific to the prosthesis design (Donaghy, Morgan, Kaufman, & Morgenroth, 2020). When determining comfort factors or

comfort levels, there is a lack of any evidence for tools or methods to provide such information. The current state of the art for assessment fails to adequately capture and address all the user needs and does not directly involve them in the design process.

Casting of the user's residuum. This is done through hand casting with plaster of Paris bandage or 3D scanning of the limb to capture the residuum shape or through measurements with hand tools to collect anthropometric data (Safari, 2020). In hand casting, constant pressure is applied to pressure tolerant areas such as para-tibial regions and popliteal fossa until the plaster sets to triangulate the residuum for better stabilization and rotation control. In scanning of the residuum, only surface anatomy is captured by recording images in a circular pattern until all angles of the residuum are captured. This can also be done through photogrammetry with overlapping photos at incremental angles until 360 degrees of the residuum is capture. The anthropometric data is digitally recorded during the scanning process or generated when the file is transferred to the modification software. However, anthropometric data can be recorded manually using goniometers, vernier callipers and tape measures. This data is then transferred into a template in a digital modification software to create the model. This method is the least detailed and most prone to error and socket fit issues.

Design (Modification) of the prosthesis is done by the prosthetist. In this stage, the negative prosthesis cast is filled to create a positive model for modification. In the case of digital process, the file is transferred to a software that has overlays, templates, and tools like traditional modification tools for modification. Sensitive areas such as bony prominences are relieved with build ups over these areas, whereas pressure tolerant areas are further adjusted to apply forces that control limb rotation and allow for stabilization within the socket. Finally, the model is checked against the measured data as differences often occur between measured data and the captured data or it necessary to reduce the model further by a graduated percentage depending on the type of socket design. The model then is smoothed to ensure quality and good contact between the inner socket and the residuum and is ready for fabrication.

Fabrication & Assembly begins with the finished positive model and is either physical, or digitally produced and is often the role of the technician. There may be a need for the prosthetist to be involved for aspects of fabrication such as the location of lamination anchors or to assist with two person tasks. Fabrication may include processes such as lamination, plastic draping or if using digital processes – computer aided manufacture and 3D printing. Technicians usually follow instructions on a job sheet specific to the user and type of prosthesis needed e.g., materials, trimlines to follow, and components to use. The final prosthesis is assembled accordingly, is bench aligned according to manufacturing specifications, and is ready for the fitting.

Fitting and delivery; In this stage, the prosthetist will fit the prosthesis to the user. Socket fit, static prosthetic alignment, and dynamic alignment are all checked. It is not uncommon for an interim prosthesis to be fitted in many countries (Bukowski, 2006; Uustal, 2009). However, in Asian countries this is not commonly practice due to the increase in costs and the difficulties for many users to travel to the clinic regularly for reviews in developing nations (Andrysek, 2010; Meanley, 1995; Shutze et al., 2021). Therefore, the alternative practiced for complex residuum's, is to provide a check socket to ensure an optimal fitting socket before making a definitive prosthesis. The check socket is fitted in the clinic and only worn during the time of consultation to check for pressure issues and comfort. After a check socket is fitted, the process from modification is repeated to complete the definitive prosthesis. Where the check socket is not suitable at all, a new cast is taken.

During the fitting users are taught how to wear and care for the prosthesis and their residuum and to identify problems. Once competent, the users can bring the prosthesis home to practice. Users are required to attend several gait rehabilitation sessions with the physiotherapists until they are stable and safe to use the prosthesis independently. Once the prosthesis is fitting well with the correct alignment and the user has completed their rehabilitation, the prosthesis is covered for aesthetics if needed and a review appointment is schedule with the prosthetist.

Review of the prosthesis is typically scheduled for one month after delivery with the prosthetist. The review is necessary to ensure optimal fitting of the socket to the residuum, provide any alignment changes, troubleshoot issues that may have resulted from the use of the prosthesis, and provide additional supplies of interface socks and education to ensure optimal fit and function throughout their use (Binedell, Subburaj, Wong, & Blessing, 2020). Following this first review, subsequent reviews are scheduled at regular intervals. The prosthetists have an expectation that a new prosthesis socket will be needed within 6-9 months due to on-going residuum volume changes for primary LLA.

It is important in the review process to address comfort changes over time and the individuality of the user, such as a need for new components to address functional mobility barriers (Major, Twiste, Kenney, & Howard, 2011; Rommers, Vos, Klein, Groothoff, & Eisma, 2000). The users' needs and requirements also change with environmental changes, aging, health status, and lifestyles (Anand, 2000). When designing a prosthesis to achieve sustained comfort throughout the changes in a person's life, three main issues arise: "firstly, if comfort is achieved, the exact cause of comfort is unknown; secondly, the perception of comfort is heavily subjective between individuals and across time; thirdly, there is no design process capturing and incorporating the comfort driving factors to guide toward designs that optimise comfort" (Vink, 2004). For this reason, it is important to know what the minimum requirements of comfort are for the user and what makes the prosthesis comfortable. This is not

currently tracked and would help to reduce the number of visits to the clinic which ranges from 4-9 visits per year (Dillingham et al., 2001; Rommers et al., 2000).

There are several limitations to the design process that limits the ability of the prosthesis to be comfortable. Firstly, there is a lack of user participation to develop the needs thoroughly. Participation in the design process has been identified to encourage the user to communicate their needs and expectations of the prosthesis which is a contributing factor of comfort (Klute et al., 2001). Several design processes support the increased participation of the users e.g., user-centred design (Binedell, Meng, et al., 2020) and human-machine-interface design (Beckerle et al., 2017). The recent development of a shared-decision aid for prosthesis design (SDA) (Anderson, 2022) supports this growing body of literature. The SDA was developed to address the complex issue of matching the prosthesis prescription given the abundant options with the prosthesis users characteristics. Evidence suggests a prosthesis user may place various importance on the factors of comfort, and have different preferences for some factors over others (Elwyn et al., 2012; Ryan & Deci, 2000). Without understanding what these are the prosthesis design is limited. Capturing the user needs during the assessment is critical to comfort in the design (Chapter 6). However, it is important to translate these needs into technical requirements of the design (Beckerle et al., 2017). If not, there is a risk of repeating the entire design process.

Secondly, attention to the initial phases of the design process may improve outcomes and comfort by incorporating tools that can predict user performance metrics to optimize the device (Price et al., 2019).

Thirdly, in order to optimize prosthesis design, clinicians must combine the best available evidence around prosthesis design options, their clinical expertise, patient-specific factors, and patient values to guide decision-making (Andrysek, Christensen, & Dupuis, 2011; Geil, 2009; Ramstrand & Brodtkorb, 2008). However, matching the optimal prosthesis design option with a prosthesis user's values, expectations, and functional potential remains a challenge, potentially affecting patient outcomes (Borrenpohl, Kaluf, & Major, 2016; Van Twillert et al., 2013). The abundant options for prosthesis design makes it difficult for prosthetists to accurately match the prescription to the user (Anderson, 2022). One way to overcome this is through the provision of an interim prosthesis to address volume changes at the residuum and socket interface tolerance in early post-amputation stages, as well as usefulness and usability of the prosthesis in completing activities of daily living (ADL). Interim prosthesis tend to focus on the physical and physiological factors of comfort, with little attention paid to the psychological. With perception and experience known contributing comfort factors, it seems the interim prosthesis may help to address such factors. The use of interim prostheses may also address the issues that prosthesis users tend to overstate their function and expectations to return to pre-amputation

levels (Ostler et al., 2014; Sansam, O'Connor, Neumann, & Bhakta, 2014). It can also provide design opportunities for adjusting to life with a prosthesis (Klute et al., 2009).

Lastly, in complex situations, should a comfortable fit be achieved, there remains difficulties in replicating the exact fit a second time should the need arise (Nguyen, Benabou, & Alfayad, 2018). Digital processes has been shown to overcome some of these limitations, although there is not widespread adoption (Binedell, Subburaj, et al., 2020). By investigating alternative design processes we can identify possible means to overcome some, if not all of these challenges.

2.5 Alternative Design Processes

Many design process models over the years have been developed, yet no single model can address all issues in design and are diverse in focus and formulation (Wynn & Clarkson, 2018). There have been several literature reviews conducted on the design and development process and medical device design (MDD) processes, both of which are relevant to the prosthetic industry, due to the nature of the practice. A summary comparison of the design phases are presented in (Table 2-4), for a more detailed comparison see Appendix 1.

Table 2-4. Comparison of phases for the design and development processes

Normative Design	**Design and development process**		**Medical Device Design "Biodesign"**	**Prostheses Design Process**
(Ogot & Kremer, 2004)	(Gericke & Blessing, 2012)	(Pahl, Beitz, Feldhusen, & Grote, 2007)	(G. Herr, 2010)	
Needs Assessment/ Problem definition	Establishing a need		Needs Finding / Empathy	Assessment
	Analysis of task	Task Clarification	Needs Screening / Define	
Conceptualization	Conceptual Design	Concept Generation	Concept Generation / Ideate	Casting
Preliminary Design and evaluation	Embodiment Design	Embodiment Design	Concept Screening / Prototype	(Design) Modification
Detailed Design and testing	Detailed Design	Detailed Design	Strategic Development / Test	Fabrication and Assembly
Production	Implementation		Business Planning	Fitting and Delivery
	Use		Project Launch	Review
	Closeout			

A literature review by (Ogot & Kremer, 2004) performed a comparative analysis of relevant literature and defined five phases for the normative design process. Later, (Eisenbart, Gericke, & Blessing, 2011)

did their own study on 124 models across 9 disciplines of the design process and found similarity in design stages on an abstract level. They also generated a list of eight phases based on their literature review (Table 2-5). Their review, of the 124 models, indicated "a categorisation regarding different aspects (whether the models are phase-based or activity based, solution-oriented or problem-oriented, and whether they are design-focused or project focused)". Given the current prosthesis design approach, which is more solution focused, it appears like the solution-orientated model. This model emphasises the analysis of the product idea (Blessing, 1994) and follows a simple problem – concept – product approach. However, to truly create comfort in the prosthesis a problem-orientated model may be applicable. In this model, emphasis is placed on analysing the problem and after an initial proposal for a solution, the requirements list is abstracted, before other solutions are explored i.e., Problem – Abstraction – Concept – Product. In the review of (Wynn & Clarkson, 2018), they determine this problem approach part of their micro-level model processes. In their model, analysis involves focusing on a problem and structuring it into a set of objectives, then generating a range of solutions before evaluating these against the objectives. By removing constraints and attempting to reframe the problem a wider range of solutions may be generated (Wynn & Clarkson, 2018). This may help in reducing the bias of the prosthetist during the prescription phase and create new designs customized to the user. Regardless of the wordings used, most design models resembled earlier design process models (Gericke & Blessing, 2012).

Table 2-5. List of the design phases and their description (Gericke & Blessing, 2012).

Phase	**Description**
1. Establishing a need	initiation of the design process by a product idea, or the identification of a need or a problem
2. Analysis of task	detailed analysis of the initial description of the task/need/product idea; additional information is gathered
3. Conceptual design	development of abstract/principle solutions (concepts) which solve the problem
4. Embodiment design	detailing of the conceptual solution
5. Detailed design	integration of sub-solutions, refinement, and finalisation of the solution
6. Implementation	integration, manufacturing, installation, test, approval, launch of the product
7. Use	operation, monitoring, maintenance of the product
8. Closeout	recycling, disposal, update/evolution of the product

The addition of the phase "Analysis of Task" is an extension to understanding the needs of the user. As (Wynn & Clarkson, 2018) suggests, it turns the needs into objectives or requirements in the design, which is important as a cross-reference when verifying and validating the design. The "closeout' phase is from systems engineering and does not seem to apply to prosthesis design. However, the explanation for "use" is relevant to address long term changes in a prosthesis users life. By addressing the

maintenance/repair issues in the design, it may reduce the needed number of clinic visits. The design and development processes are for a variety of engineering disciplines including industrial, mechanical and systems. Though the prosthesis design process may appear similar in aspects to these processes, it is also important to compare with common medical device design (MDD) processes for completeness, given the professions nature in healthcare.

For the medical device development, the process is more complicated (Medina, Kremer, & Wysk, 2013). Empirical research has demonstrated the importance of following a complete process in the design of medical devices, showing a significant correlation between the number of stages followed in the development process and the success of the new devices" (Rochford & Rudelius, 1997). The extensive regulatory control over medical devices presents the need to develop separate, adaptive models for MDD. Furthermore, MDD is more focused on mass production, patents, product launches and market ready products, rather than a customized prosthesis for one individual. As a result not all phases of the process are relevant e.g., regulation. Medical devices impact human life positively by prolonging it, sustaining it, improving it or supporting it or negatively as a threat to human health because of the potential risk of illness or injury (Medina et al., 2013). The prosthesis is classified as a class 'A' medical device, meaning it has a low risk to the user and their health, further lowering the usefulness of the MDD process.

The Biodesign process, first introduced by Stanford University in 2000, is one of the more popular processes used today in medical design and innovation. The design process is a systematic approach for the identification of important unmet healthcare needs (Herr, 2010), the development of novel technologies to address them, and the subsequent development of business and commercialization plans to bring them into patient care. It is derived from the design thinking process of empathize, define, ideate, prototype, test, with additional two steps for regulation and reimbursement, these two do not apply to the prosthesis design process, although reimbursement may depend on the country of practice. The need to empathize with the user is relevant to the prosthesis design process given it addresses aspects of their psychological comfort by building participation and motivation for the user. Definition of the problem can be compared to analysis of task which again would translate to objectives and requirements in the design. While the ideation and prototype phases could be executed through interim prosthesis which as mentioned earlier seeks to provide an early experience of comfort. This process is limited by the lack of review and does not seem to address any long-term aspects of comfort.

Despite the similarities of both the design process and MDD to the prosthesis design process, the differences in phases meant it was necessary to review original design processes to see if an optimal design process could be developed. We reviewed one of the earliest models produced in 1977 by Pahl and Beitz (Pahl et al., 2007). It is one of the most detailed and widely referenced prescriptive models

of designing is the 'Systematic Approach', and has been used the world over and is available in numerous languages suggesting a huge presence in design culture (Kannengiesser & Gero, 2017). Steps are included in (Table 2-4) for comparison. The methodology is divided into four phases: task clarification, concept generation, embodiment design and detailed design. Of note, is the task clarification. In this model, the need is interchanged with the task. For a prosthetist this could mean that the prosthetist is to be more focused on how the prosthesis will or will not be used. It would be important to expand this step to include a full needs analysis to develop the requirements that would include any specific tasks the user mentions. By adopting this model however, there is the freedom to add any additional steps to customize the process for prostheses.

There are an incredible number of products being designed and becoming available every year, but these are not always tested and iteratively designed for comfort (Vink & Hallbeck, 2012). Although there are a few papers explaining the concept of comfort ((Moes, 2005; Naddeo, 2017; Vink, 2004)), approaches to comfort which have been developed lack a generalized approach and there is a need for a generally accepted comfort design process (Ahmed-Kristensen & Stavrakos, 2012).

The problem-orientated approach provides a useful base on which to develop an improved comfort-driven prosthesis design process. Both the design and development processes from engineering and MDD have useful attributes, that when combined would structure the prosthesis design process and further enhance the comfort. The basis for improving this process is adopted from the general model of (Pahl et al., 2007) and describe in more detail in Chapter 8. This thesis will focus on increasing the user's involvement in the design process, developing a greater understanding of their needs, converting these needs into requirements, which can then be used to verify and validate against the final design. The use of digital technologies could aid in various phases of the design process to provide a greater level of understanding, verification, and validation of the physical and physiological comfort factors.

2.6 Emergence of Digital Technologies

The current prosthesis design process as demonstrated in Section 2.4, is limited in its ability to provide enhanced levels of comfort in the short-term and over the long-term periods. The design is still subjectively obtained through previous experiences and interpretation (Ribeiro, Cimino, Mayo, Ratto, & Hitzig, 2021). All these factors may lead to inconsistent results affecting comfort levels. The emergence of digital technology (DT) opens new possibilities for design by removing these inconsistencies and inefficiencies. DT requires re-imagining of the prosthetic design and development process and removes the subjectivity from the prosthesis process, making it theoretically possible for the entire prosthesis to be generated from objective data using quality-controlled production methods (Raschke, 2022).

However, adoption remains patchy across the globe, with countries growing DT as part of their service at various rates (Binedell, Subburaj, et al., 2020). There also appears to be a need to understand how DT brings value to the user and the prosthetist (Ribeiro et al., 2021). Barriers such as cost, education, lack of training, and an inability for long term monitoring remain (Binedell, Subburaj, et al., 2020; Chadwell et al., 2020).

Despite the barriers, there is evidence that the use of DT in the design process may be seen as beneficial in the coming years (Raschke, 2022). Three of the design phases identified in this literature review where DT appears especially applicable are the shape capture, fabrication, and review. Given the need for prosthetists to design down to the 1mm (Ng, Lee, & Goh, 2002) the use of DT offers significant potential (Wagner, Dainty, Hague, Tuck, & Ong, 2008). During the **shape capture** of the residuum as part of the task clarification phase, the use of DT such as scanning or other 3D imaging techniques e.g, Finite Element Analysis (Nayak, Singh, & Chaudhary, 2017), photogrammetry (Taqriban, Ismail, Ariyanto, & Putra, 2019), can create an accurate representation of the residuum surface (Barrios-Muriel, Romero-Sánchez, Alonso-Sánchez, & Salgado, 2020; Diment, Thompson, & Bergmann, 2017; Ribeiro et al., 2021; Taqriban et al., 2019), allowing the device to fit more comfortably (Lee et al., 2017; Swartz, Turner, Miller, & Kuiken, 2018). Furthermore, the information is stored and can be used as reference for any replacement sockets or monitoring (Ribeiro et al., 2021), something the traditional casting process cannot (Herbert, Simpson, Spence, & Ion, 2005). These techniques, however, only capture the surface anatomy and cannot provide a residuum volume matching, a key to a comfortable socket (Sanders et al., 2017). As a result, DT including Computed Tomography scans, Ultrasound, and Magnetic Resonance Imaging, have been developed to provide such information (Haleem & Javaid, 2019; Ranger et al., 2015; Sengeh & Herr, 2013). Still, these are expensive and not easily translated to clinical practice.

Apart from the benefits of consistency and accuracy, DT for **fabrication** alleviates several pain points with traditional fabrication methods. Technology such as rapid prototyping (3D printing) is very attractive for prosthesis design and provides affordable and customizable solutions with the possibility for easy maintenance and repair (Vujaklija & Farina, 2018). Despite material selection being currently limited with most devices uses Nylon, the digital process allows for optimization of weight (Lee Ventola, 2014). Prosthetic sockets fabricated with 3D printing showed better results for comfort than those fabricated with the traditional processes in terms of prosthesis weight and the amount of required prosthetic socks (Hsu et al., 2018; Tao, Ahn, Lian, Lee, & Lee, 2017). The ease of printing and fitting a prosthesis within days is an additional beneficial in clinical practice promoting earlier rehabilitation, reduced hospital length of stay and quicker function recovery (Imanishi & Choong, 2015; Ribeiro et al., 2021). These advantages have physical and psychological comfort effects for the end-users. For

instance, (Zuniga et al., 2015) reported that nearly all their participants demonstrated an increase in their QOL due to low cost, light weight, customizable 3D printed devices. Still, there is a need for additional technological advancements to improve the functionality of 3D printed devices (Ribeiro et al., 2021).

The **review** process is often unpredictable due to user variables such as volume changes, activity level changes, and rates of wear and tear of the various components of a prosthesis (Deans, McFadyen, & Rowe, 2008; Sanders, Harrison, Cagle, et al., 2012; Sanders et al., 2017). The practice of monitoring user's activity levels, physiological changes to the socket-residuum interface, or detection of failures in the design may prove beneficial to first understanding and then enhancing comfort levels, although any monitoring should be thoroughly explained to the user. There are reported mixed results for the measured ambulatory activity against self-reported ambulatory activity levels. There has been strong correlation (Speck & Looney, 2006), medium correlation (Dishman, Darracott, & Lambert, 1992; Smith, Domholdt, Coleman, Del Aguila, & Boone, 2004), and poor correlation (Stepien et al., 2007). This suggests that solely relying on user feedback may not provide sufficient details about the use or disuse of the prosthesis. Activity monitoring when used in conjunction with clinical scores and user feedback, offers insights into the use of the prosthesis and whether the user's requirements have been met (Chadwell et al., 2020).

The residuum soft tissues are not physiologically designed to tolerate excessive forces and moments that does not overstress the soft tissues (Zang et al., 2017). The use of sensor technology to detect physiological changes between the socket and residuum or prothesis and its environment is one method to help determine comfort levels and provide valuable information for socket fit or modifications (Polliack et al., 2000). This technology may be applicable to lower limb prosthesis users to increase the embodiment feeling, improve balance and decrease cognitive burden (Petrini et al., 2019). Wearable sensors are now capable of touch, pressure, temperature, and humidity sensation, which enable the user to interact with the surrounding environment (Gao et al., 2017; Hua et al., 2018; Kim et al., 2014; Rahman et al., 2020; Y. Wu et al., 2018). One study determined the need to detect changes outside of the laboratory, identifying that the user environment is important in any assessment of the prosthesis (R. Williams et al., 2019). Sensors appear to provide a multitude of benefits to assess the residuum's comfort with the prosthesis and its surroundings at review but show potential to determine skin tissue viability during the initial design phase. Sensors could be considered as beneficial to the design process but has not yet become a feasible standard clinical practice (Chadwell et al., 2020; Williams et al., 2019).

There are opportunities for DT in the design process given its usability and usefulness to the capturing, fabricating, and reviewing phases. DT that can objectively monitor the use and fit of prostheses offer a complementary approach to design process phases for understanding the effective of different prosthetic

designs, componentry, and rehabilitation and lifestyle interventions (Balk et al., 2018; Hafner & Sanders, 2014; Prince et al., 2008; Williams et al., 2016). The effect DT has on the manual process of prosthesis design depends on how the DT is integrated into their work practice (Wagner et al., 2008). The use of technology should be appropriate, focus on real world application and consider the cultural context, whilst retaining a clinically acceptable level of accuracy (Dickinson et al., 2019). "The prosthesis of the future will be one that is custom designed and produced for individual end-users using objective design tools and automated industrial production methods and will be fitted and maintained using smart tools that provide objective, close to real time, data" (Raschke, 2022).

2.7 Summary of Research Gaps

Definition of Comfort

The definitions of comfort are related to the type of industry in which comfort is assessed. Product design for example, define comfort in terms of physical and physiological, with less attention given to the psychological comfort. However, healthcare professions such as nursing, emphasize the need to define comfort in terms of the psychological, failing to address the physical and physiological comfort. In prosthetics, the definitions focus on a relief from pain or constraint when wearing the prosthesis, but do not address the three contexts of comfort. There remains a need for a more comprehensive definition to help clarify the factors which contribute to comfort with prostheses and their relative importance such that user experience and human-prosthesis interactions can be improved.

Factors of Comfort

Comfort is an important design attribute and remains fundamental to the use of the prosthesis. While comfort and discomfort can be thought of as two ends of a linear continuum, the individual factors identified with either comfort or discomfort suggest they are independent of each other, although comfort cannot be fully experienced in the presence of discomfort factors. Comfort depends on the user experience and the physical, physiological, and psychological state of the user over time in a contextualized environment. Without comfort, many prostheses cause skin breakdown, leading to device abandonment, depression, and low self-esteem. The prosthetist plays a significant role in providing a service that addresses the human factors that address psychological comfort, and technical factors that address the physical and physiological comfort. Currently, the comfort of a prosthesis is assessed more in the physical and physiological contexts, and little in the psychological context. The list of factors can be seen in Table 2. The limited attention given to the psychological factors by the prosthetist currently in the design process, suggests a need to develop greater understanding of comfort from the user's perspective and is a crucial first step in determining all factors of comfort and their influence on the users QOL. Understanding the factors and reasons on how and why the user may or may not use their prosthesis due to comfort is the focus of the Chapter 4.

Measurement of Comfort

Measuring comfort is necessary to understand and improve the design. Given the three comfort contexts are all different, using the correct measuring method for each context can help to build a comfort profile of the user and be useful in comparing improvement to comfort levels. The use of both qualitative and quantitative methods is necessary to capture all factors and their impact to the prosthesis user. The SCS was the most used questionnaire to measure comfort in prosthetics, but it does not appear to give sufficient understanding to the prosthetist about which of the physical, physiological, or psychological comfort the user is referring to. There is a need for a comfort questionnaire to address all comfort contexts to facilitate the design process. The use of digital tools and measures has potential to quantify some factors of comfort, particularly the physiological factors such as temperature and pressure. Sensors to detect these factors have been limited to research, therefore there is a need to track comfort in a clinical setting with appropriate digital technology to bring comfort to the point of care.

Designing Comfort

The current design process involves artisan approaches to create customized one-time devices and is a solution-orientated approach. There remains limited input from users in the design process significantly reducing their chances to express comfort levels, experiences, expectations, and impact of the prosthesis in the life. The current artisan prosthetic design process presents both strengths and weaknesses in its approach. On one hand, being specific in the design and incorporating limitations in muscle strength, stability, and skin tolerance may help to improve comfort levels, on the other hand, the approach is labor intensive. The specific individual focus is often central to the design of the socket and the prescription of components, usually chosen from only a few options due to hospital constraints or prosthetists bias in prescription. It does not tend to consist of the intended use of the prosthesis and truly address the user needs. Current designs remain similar regardless of age or gender with only variations in the functionality of components provided. The prosthetist relies on previous experience and bias with previous prosthesis users when deciding on the prescription to optimize the design and results, resulting in possible limitations to an enhanced comfortable experience for prosthesis users. It is important that the design process considers the changing nature of comfort and the evolving needs of the user. Many other models of design have been developed, yet no single model can address all issues in design. The problem-concept-product approach as suggested by Blessing 1994, appears to provide significant advantages to the comfort-driven design approach in prostheses.

3 RESEARCH METHODOLOGY

3.1 Introduction

An outline of the research approach taken for the entire thesis is given in this chapter and is derived in part from the evidence described in the literature (see Chapter 2). The research described in this thesis aims to establish an approach to assess and develop comfort in prostheses designs that result in better physical, physiological, and psychological comfort for the user. This chapter also describes the methods used to inform, develop, and evaluate a comfort-driven prostheses design methodology (CPDM). The research approach followed the *Design Research Methodology (DRM)* framework set out by (Blessing & Chakrabarti, 2009), a widely used methodology for performing design research. The following section explains the DRM in more detail. The actual approach taken for this thesis is detail in Section 3.2.

3.2 Design Research Methodology

The DRM aims to provide a systematic and generic framework for conducting design research (Blessing & Chakrabarti, 2009). DRM consists of four main research phases as shown in Figure 3-1. Each of these phases will be described in more detail.

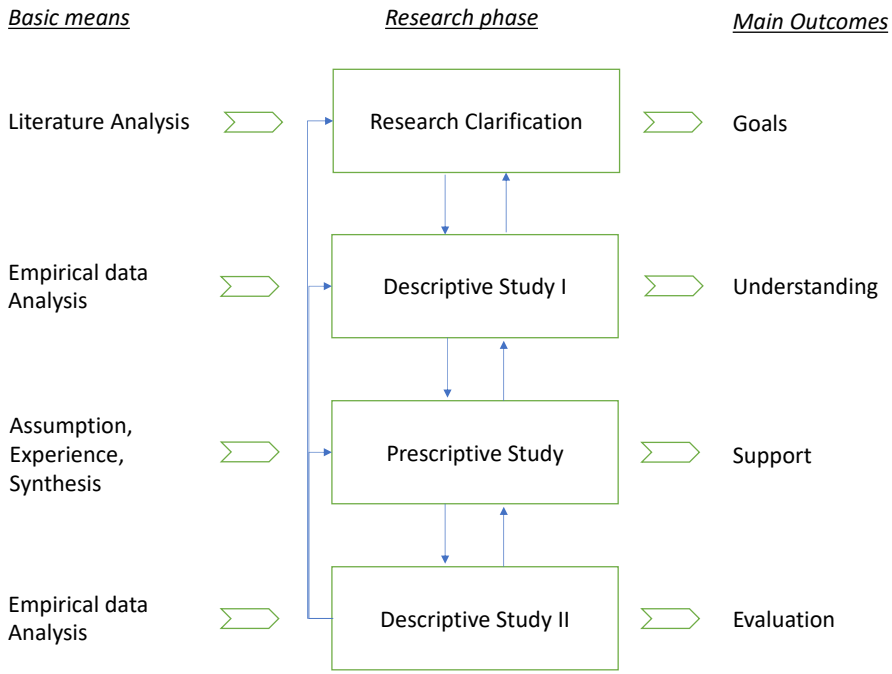

Figure 3-1. General Design Research Methodology framework. Adapted from (Blessing & Chakrabarti, 2009)

Research Clarification. The purpose of this phase is to find evidence of indications that support the assumptions in order to formulate a realistic research goal. This is mainly achieved through literature searches for factors that influence task clarification and/or product success. The findings assist in

forming an initial description of the situation and a description of the desired situation. The researchers develop success criteria to which the outcomes of the research can be measured.

Descriptive Study I. To improve the task clarification as effectively and efficiently as possible, this phase involves further review of the literature to determine which factors should be addressed. To aid in the information gathering, the use of interviews and observational analysis may be needed to better understand the current situation. The findings should sufficiently describe the current situation before moving on to the next phase. The need to sufficiently define the problem in the task clarification is important to reduce work in the later phases.

Prescriptive Study. In this phase, the researchers, using a combination of assumption and experience, elaborates on the initial description of the desired situation and a method or tool is developed. "This description represents the vision on how addressing one or more factors in the existing situation would lead to the realisation of the desired, improved situation" (Blessing & Chakrabarti, 2009). It should ultimately influence the success criteria.

Descriptive Study II. This phase is concerned with the evaluation of the support, method, or tool etc. It investigates the effects and effectiveness to achieve its impact or desired situation. The evaluation of the results includes: "to determine whether the goals have been achieved; to inform improvement of the support; to increase our understanding of design; and to suggest how introduction should take place" (Blessing & Chakrabarti, 2009). The emphasis is on *use* and implies that the human factor and the actual introduction and maintenance of the support in the user environment have to be considered.

The reality when using the DRM approach, is that the design is never linear and as different discoveries are made about throughout the research, there may be a need to revisit a previous phase or to verify and validate the results against other phases. This may result in many iterations which is reflected by the arrows which point in multiple directions.

3.3 Research Questions

There are four objectives this research aims to achieve (Section 1.3). These are

- Identification of the influencing factors of comfort
- Identification and evaluation of digital technology potential
- Development and verification of a comfort assessment tool, and
- Development and evaluation of the CPDM

To achieve these objectives, it is necessary to also understand the context of the prosthesis design process (Section 2.4). In doing so, three research questions were generated along with their hypotheses.

***RQ1*. What are the factors that contribute to the comfort of lower-limb prosthesis users?**

- *H1. Comfort is multifactorial.*

***RQ2*. How could current product design methods be transferable to prosthesis design to increase comfort?**

- *H2. Using existing product design methods provides sufficient structure to improve comfort in the current prosthetic design process.*

***RQ3.* What design methodology would enable the prosthetist to provide comfort to the prosthesis and evaluate the outcomes?**

- *H3. Design methods developed to understand, capture, and incorporate comfort aid in the development and evaluation of a comfortable prosthesis.*

***RQ4.* Does using the Comfort-driven Prosthesis Design methodology provide usability and usefulness to the prosthesis design process?**

- *H4. The prosthetic design process will be enhanced by incorporating the CPDM, leading to higher comfort levels for the user.*

3.4 Research Approach

The following section provides an overview of the studies conducted in this thesis and corresponding stages in the general design research method (DRM). The approach indicates how each of the objectives and their associated research questions will be addressed.

3.4.1 Research Clarification

The use of a literature review (Chapter 2) was used to achieve the first objective and provide evidence for RQ1 and RQ2. The literature review was conducted through research of journals, books, and reports on generic definitions, understanding, measuring, and use of comfort in the design industries, healthcare, and specific to the prosthetics industry. Section 2.2.2 highlighted the multifactorial nature of comfort. Apart from comfort being subjective in nature, the factors of comfort were addressed in three areas: physical, physiological, and psychological. As these factors are influenced by the design process, various design processes were examined for comparison. The results of Descriptive Study II addressed the findings of this phase to be deemed successful.

3.4.2 Descriptive Study I

The descriptive phase of the research is carried out to understand in depth the factors that influence the comfort of the prosthesis. To provide details on the task clarification and success criteria a number of research methods were employed to understand the influence of physical, physiological, psychological factors, and reliable measurements to detect these. Furthermore, a survey investigating the digitalization in prosthetics and orthotics was conducted to assess the readiness of the workforce for adoption of these technologies.

Literature review (Chapter 2) was conducted through a search of electronic databases, journals, books, and secondary sources identified from the original search. Given that comfort has not been widely researched in prosthetics, it was necessary to search design databases to develop greater understanding of comfort. This information helped to answer RQ1.

Interviews with prosthetic users (Chapter 4) is beneficial in understanding the user perspective and perception of comfort. To achieve further understanding a phenomenological study design was used. This type of study design requires the interviewer, to bracket their assumptions about the phenomenon of comfort to understand and explore views of those who have experienced it. This user perspective insight could then be used to guide practice and help prosthetists design more comfortable devices. The captured data with prosthetic users would shed some light on the alignment or misalignment of definitions of comfort, the importance of varying factors of comfort, and expected or actualized problems from a lack of comfort. The data collected from interviews was used to corroborate and weigh the factors contributing to the comfort of a prosthesis found in the literature (Chapter 2) and further elaborate on other factors that have not been identified yet. This information would help to answer RQ1 and RQ2.

Experiments were of great help to understand various physical and physiological factors of comfort. Much of this information was combined with Chapters 2 & 4, to further provide insights for RQ1 and RQ2. Three experiments were conducted, one to investigate process improvements is described in Chapter 5, and two solution improvements are described in detail in Chapter 6. They include: the use of a pressure sensor to measure comfort within a prosthesis socket to assess process improvements to prosthesis design (Chapter 5); the design and capture of the Lines of Non-Extension (LoNE); the design, development and evaluation of a new prosthesis liner that provides thermal improvement (Chapter 6). The information gained from these experiments were useful in determining possible designs that minimized skin movement, to improve comfort and prevent skin breakdown from excessive sweating and provided information to enhance the design process.

Surveys were used specifically to assess the readiness of the prosthetic industry workforce to adopt digital technologies (Chapter 5). 83 respondents from around the world were a great help in understanding current adoption rates and practice. The respondents included 13 prosthesis users that could validate information from Chapter 4 and provide new insights into their interest in using digital technology to enhance comfort. This information was particularly useful for answering RQ1 and provided background knowledge for RQ2.

Finally, a **case study** (Chapter 6) was used to present the design of a prosthesis that demonstrated the usability and usefulness of digital technology in the design process. Seven various comfort factors pertaining to the individual were addressed in a forequarter prosthesis and the results were essential to demonstrate the potential of the emerging digital technologies. This information further substantiated earlier results from Chapters 2,4-6 and helps to address RQ2.

An overview of the methods and results from the methods in this stage, in relation to each chapter is shown in Figure 3-2.

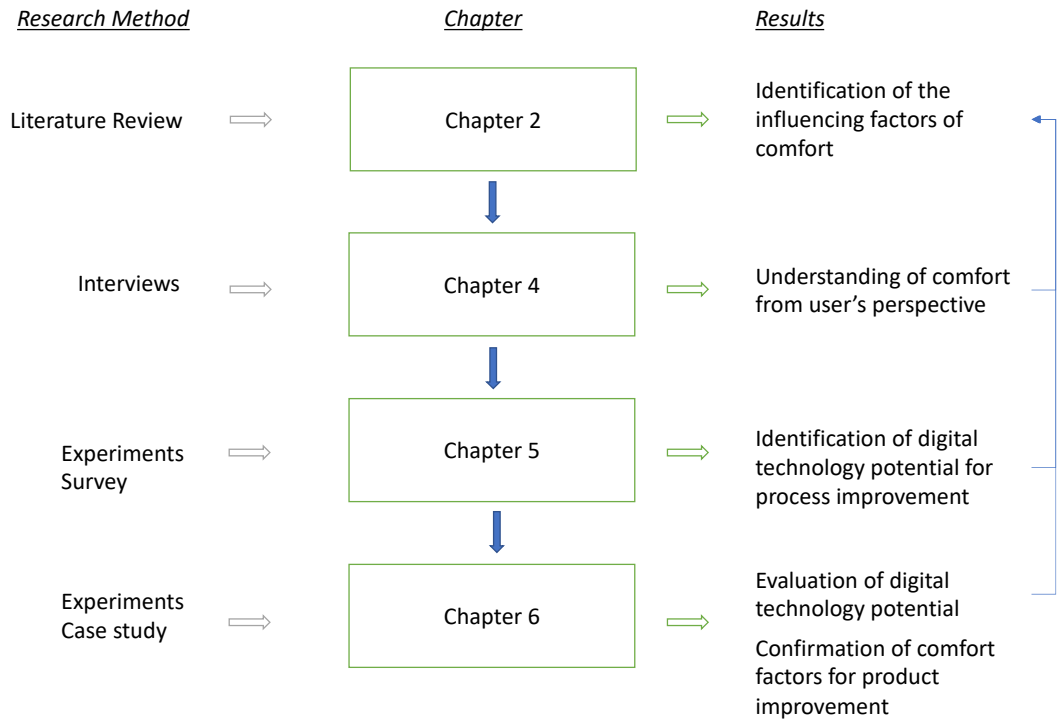

Figure 3-2. An overview of the methods and results in relation to each chapter.

3.4.3 Prescriptive Study

In response to the need for a more robust method to deliver consistent and enhanced comfort results for prosthesis users, the Comfort-Driven Prosthesis Methodology (CPDM) was developed which included the development of the Prosthesis Comfort Assessment Metric (PCAM), which is used to assess comfort levels. These two items address the objectives 3 & 4 and seek to support with additional information to answer RQ1, RQ2 and RQ3.

The PCAM (Chapter 7) was developed through a series of focus groups, interviews, and testing. An initial draft of the PCAM was determined from Chapters 2, 4-6. This was presented to a group of 10 prosthetists during a focus group where consensus on items to include was reached. Testing was conducted on 17 prosthesis users to determine usefulness and consistency. A final consensus provided the definitive version of the PCAM, which was then used as part of the evaluation of the CPDM.

The CPDM (Chapter 8) was developed through a series of six steps (see Section 8.6), findings of Chapters 2, 4-7, findings from a focus group with 10 prosthetists, and interviews with 10 prosthetists. Briefly it involved: **defining** the scope; **talking** with stakeholders e.g., focus groups, interviews, also reviewing results of Chapter 4; **assessing** comfort in the current design process by using focus groups, journey maps, personas; **developing** tools and measures to evaluate comfort e.g., PCAM, Requirement list, AEIOU framework; **framing** of the methodology using focus groups, interviews; and **evaluating** the usability and usefulness through application and interviews. It contains 6 determinants of comfort that can be assessed and addressed for the individual prosthesis user. Feedback was sought through pre and post surveys with both open and closed questions, and interviews.

After the development of the CPDM and PCAM, these were evaluated in the Descriptive Study II phase.

3.4.4 Descriptive Study II

Chapter 7 describes the approach to evaluate the PCAM with prosthetists and prosthesis users. PCAM was evaluated by 10 prosthetists on 17 users to collect insights into its applicability and usefulness in determining comfort levels. This was helpful to ascertain if there were any changes to the understanding of comfort, whether it was useful in their clinical practice, and the possible changes needed to the metric. Pre and post surveys were conducted, with follow up interviews for the prosthetists.

Chapter 9 describes the approach used to evaluate the CPDM with prosthetists and prosthesis users. To evaluate the CPDM, 4 prosthetists were divided into two groups of similar experience and further subdivided into one who would provide a consultation using the standard assessment form, which

contains Subjective, Objective, Action, and Plan (SOAP) fields of information the other who would use the CPDM approach. The CDPM was explained in detail to the appointed prosthetists where any clarifications were made. Each group of prosthetists was asked to provide a consultation with the same patient on the same day. The prosthetists using the SOAP format would consult first to avoid influencing the replies to the methods adopted in the CPDM. All consultations were timed and audio recorded for analysis.

Following the consultations, each prosthetist prescribed and documented the appropriate prosthesis for the user. Statement evaluation forms with VAS, range (0-100) were given to the prosthetists who used the CPDM for detailed evaluation. The prosthesis users were also given a small set of evaluation statements. Each prosthesis user and prosthetist were then interviewed using semi-structured interviews to obtain any verbal feedback. The prosthetists were then asked to describe their ideal prosthesis for the user they assessed if no constraints were applied, and answers compared to their actual prescription. This sought to answer RQ4 and H4 as well as address the assumptions made in the research clarification stage.

A summary of the characteristics of the research methods in this thesis is given in Table 3-1.

Table 3-1. The approach taken to perform Descriptive Study I.

Ch	Research Method	Study Design	Participants	Format of results	Research Question
2	Literature Review	PRISMA	NA	Report	RQ1
4	Interviews	Phenomenological Semi-structured	16 Users	Audio Recording	RQ1, RQ2
5	Experimental	Experiment - Pressure	16 Users	Sensor readings SCS	RQ1, RQ2
5	Survey	Exploratory	83 (70 Prosthetists, 13 Users)	Electronic	RQ1, RQ2
6	Experimental	Experiment - LoNE	5 Users	Video recording Computer mapping	RQ1, RQ2
6		Experiments - Liner	1 User	Physical readings of sweat absorption User feedback	RQ1
6	Case Study	Digital Design Process	1 User	Scanned data, 3D printing, Survey	RQ2
7	Focus groups, Interviews, Questionnaires	Mixed methods	10 Prosthetists 17 Users	Comfort factors, Comfort levels	RQ2
8	Focus groups, Persona's, AEIOU	Mixed methods	10 Prosthetists	Design process, Tools to use	RQ3, RQ4
9	Interviews, Questionnaires	Mixed methods	4 Prosthetists 2 Users	Usability and Usefulness feedback	RQ4

Given the complexity of a prosthesis user's journey, the time necessary to evaluate all aspects of the methodology was compromised. The methodology was assessed in the early design phases with a longitudinal study planned as part of the future research work to assess the later design phases.

3.5 Summary

A summary of the research approach taken is given in Figure 3-3.

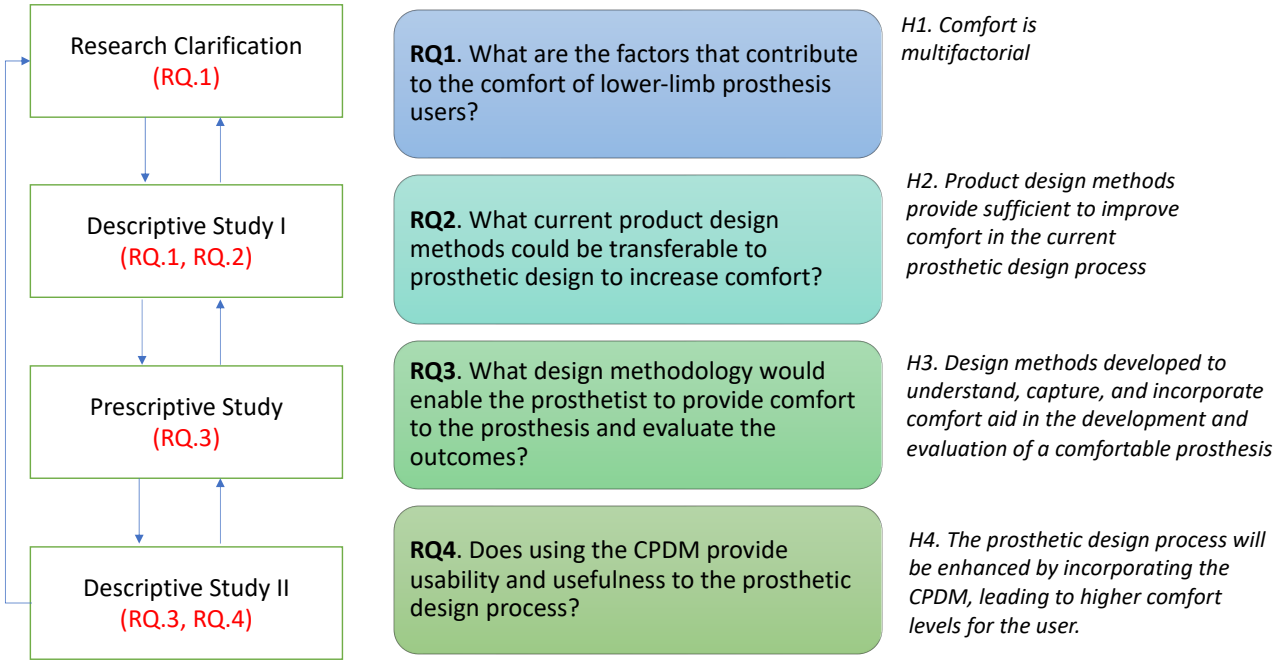

Figure 3-3. The approach taken in following the Design Research Methodology.

4 USER'S PERSPECTIVE OF COMFORT

4.1 Introduction

Lower limb amputation (LLA) is a life-changing event affecting multiple aspects of an individual's quality of life (QoL) (Ostler et al., 2014). "For individuals with limb loss, the prescription of a prosthesis is the most common form of intervention in their rehabilitation" (Jefferies, Gallagher, & Philbin, 2018). Lower limb prostheses have been shown to improve the quality of life beyond other assistive devices such as walking sticks and crutches, highlighting their importance (Sinha et al., 2011; Sinha, Van Den Heuvel, & Arokiasamy, 2014). Despite this importance, prostheses remain challenging to fit and use, with common complaints of comfort issues and limitations in physical functioning, leaving individuals disappointed with the state of the technology (Jefferies et al., 2018). Turner and McGregor (Turner & McGregor, 2020) found that issues related to socket fit were identified as the most significant factor affecting rehabilitation by 48.0% of amputees and 65.7% of clinicians. Other literature reports 57% of prosthesis users are dissatisfied with the comfort of their devices, and over 50% report pain while using their prostheses (Berke et al., 2010; Dillingham et al., 2001). Most of these studies have focused on the factors affecting the overall QoL but have not investigated the relationship with the patient's comfort experience in using the prosthesis (Ramirez Patiño et al., 2015).

Despite the frequent use of the term comfort, there is no widely accepted definition of comfort (Section 2.2). Comfort in the prosthetics and orthotics industry sees a mixture of definitions, mainly focusing on comfort as an interaction of the socket and residual limb or a subset of the physical and social well-being of the prosthetic user (Bosmans et al., 2007).

Comfort with a prosthesis extends beyond the users' experience with a socket and includes physical, physiological, and psychological factors (Figure 4-1). When designing a prosthesis to achieve sustained comfort throughout the changes in a person's body and life, three main issues arise as identified by (Vink, 2004): 1) if comfort is achieved, the exact cause of comfort is unknown; 2) the perception of comfort is heavily subjective, differing between individuals and across time, and 3) no design process or approach captures and incorporates elements potentially affecting comfort to guide prosthetists toward optimizing designs to maximize comfort. The prosthetists seek to understand the importance of each comfort aspect for the user to match the prosthesis to their expectations better.

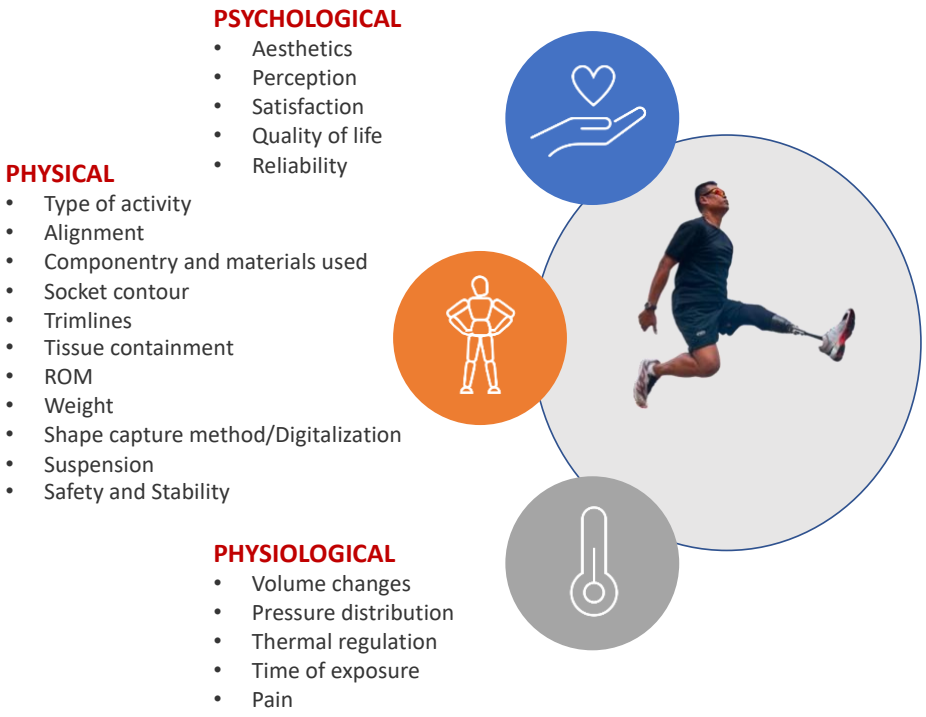

Figure 4-1. List of comfort factors identified in the literature review of Chapter 2

Reported studies in the P&O literature have investigated the effects of prosthetic design believed to directly influence the user's comfort and performance, such as mechanical properties, alignment and pressure distribution, socket fit and appearance, adjustability, suspension, and even cultural factors (Section 2.2.2). A significant innovation to the comfort of the residual limb and socket interface has been the development of prosthetic liners. However, little empirical evidence exists to support the liners presumed usefulness in improving comfort, particularly from the end-user's point of view (van de Weg & van der Windt, 2005).

Despite extensive research into factors supposedly influencing comfort perceptions there remains a rift between academic research outcomes regarding prosthetic comfort and patients' actual experiences in day-to-day activities. As comfort is thought to be an individual situated experience, it has been typically assessed as a user-related outcome measured through questionnaires (Section 2.3.1). Quantitative assessment of comfort remains challenging (Slater, 1986), although recently, comfort improvement has been quantified with sensor technologies that track pressure and temperature (Section 2.3.2).

Amputation is a uniquely traumatic experience for the patient, and the issues of loss and replacement have different meanings for each person (Legro et al., 1999). There has been an increase in qualitative studies looking at the prosthetic experience from users' perspectives to seek a greater understanding of the issues and challenges faced (Section 2.3.1). Still, no previous research has investigated the

expectations of the patient's comfort and how it affects their QoL. (Murray & Forshaw, 2013) conducted a meta-synthesis that describes the difficulties many face when adapting to limb loss and prosthesis use and sheds light on how individuals perceive their experience of living day-to-day with artificial limbs (Ostler et al., 2014). Unfortunately, as mentioned earlier, a prosthesis can cause discomfort, which lowers user satisfaction and influences functional status (Klute et al., 2001).

The advancements in digital technology attempt to improve comfort by accurately capturing the residual limb's geometry and characteristics. However, this alone cannot guarantee comfortable designs without decoding what an individual perceives as comfortable. Thus there is a need for a deeper understanding of comfort that can help elucidate the physical, physiological, and psychological factors contributing to comfort and their relative importance to the user's perception of comfort. (Ramirez Patiño et al., 2015).

Exploring various aspects of comfort from a user perspective provides the necessary insights into their expectations and experiences, which we will use for the development of clinical practice guidelines for designing comfort in a prosthesis. Therefore, this research aims to address the following question through a phenomenological study; (a) How is comfort experienced by patients with LLA, and (b) what are the contributing factors towards comfort with their prosthesis following rehabilitation?

4.2 Research Methods

4.2.1 Interview Methodology

Participants

Users were recruited using purposive sampling from the Singapore Amputee Support Group (ASG) in Singapore, applying the following inclusion criteria:

1. Lower limb amputation > 2 years ago
2. Either bilateral or unilateral amputations
3. Without motorized mobility
4. Currently using a prosthesis
5. Living in Singapore

The sample included 15 users (11 males, 4 females), of whom 8 had a transtibial amputation, 2 transfemoral, 2 quadrilaterals, 2 hip disarticulations, and 1 bilateral transtibial level. The interviews were performed in 2021, and informed consent was obtained before participation. The study protocol was approved by the Institutional Review Board of the Singapore University of Technology and Design.

Procedure

An email invitation was sent to the ASG to invite interested users to participate. Those that fulfilled the criteria were invited to participate. Before the interview, the user was briefed about the focus of the interview, which was on comfort and whether the user experienced any discomfort with using their prosthesis, either currently or in the past. The interview was audio-recorded, lasting between 30-50 minutes. This was performed via a video conferencing tool at a time convenient to the participant. In the first part of the interview demographic data was collected to investigate links with the comfort experience. Open-ended questions were used to stimulate detailed accounts of the user's experience (Appendix 2). The questions were based on the three areas identified in the literature that contributed to the comfort experience: physical, physiological, and psychological. General questions were included such as "What does comfort mean to you?" and "What factors do you consider affect your comfort?" to facilitate discussions. The socket comfort score (SCS) (Hanspal et al., 2003) was obtained from all users to identify any correlation with their answers.

4.2.2 Data Processing and Analysis

A phenomenological approach (Moustakas, 2011) was employed in analyzing users transcripts, following (Creswell, 1998) guidelines for assembling the textual and structural descriptions. The transcripts are read several times to obtain an overall understanding. From each transcript, phrases or sentences pertaining directly to the comfort experienced with a prosthesis are identified. Meanings are then formulated from the significant phrases or sentences and clustered into themes to allow for commonality between transcripts to be identified. These significant phrases and themes are then used to describe what the users experienced and describe the context that influenced how the users experienced comfort. Once the descriptions and themes have been obtained, the researcher approached three participants a second time to clarify the findings. Any new information was included in the final description.

Methodological rigor was attained by applying verification strategies to determine reliability and validity (Morse, Barrett, Mayan, Olson, & Spiers, 2002). Verification was fulfilled through literature searches, adhering to the phenomenological method, bracketing past experiences of the interviewer to better understand the phenomenon from the user experience, keeping field notes, and interviewing until data saturation was achieved (Frankel, 2012; Meadows & Morse, 2016). Validation was performed throughout the interviews, coding, and data analysis.

4.3 Results

4.3.1 Demographics

Four females and eleven males were interviewed, and their responses were transcribed non-verbatim. The demographic data of the 15 users is summarized in Table 4-1. The average age of the participants was 50.33 ± 10.33 years [Range 34-74, Median 50], time since amputation was 15.27 ± 10.66 years [Range 2-43, Median 12], hours per use was 11.87 ± 4.72 [Range 2-19, Median 12], and the socket comfort score (SCS) was 7.77 ± 1.52 [Range 5-10, Median 8].

Table 4-1. Demographic data of users.

Subject number	Age at time of study (Years)	Gender	Time since amputation (Years)	Reason for amputation	Level of amputation	Hours of use per day	Socket Comfort Score (SCS)
1	74	M	13	Diabetes	Transtibial	9	9
2	51	M	9	PVD	Hip Disarticulation	12	9
3	58	F	5	Infection	Quadrilateral	2	8
4	53	M	12	Congenital	Transtibial	11	7
5	38	F	30	Trauma	Hip Disarticulation	9	6
6	44	M	22	Trauma	Transtibial	15	8
7	43	M	2	Infection	Bilateral Transtibial	13	9
8	49	F	11	Infection	Bilateral Transtibial	4	6
9	34	M	10	Trauma	Transfemoral	11	6
10	56	M	16	Diabetes	Transtibial	10	8
11	40	M	16	Trauma	Transtibial	19	5
12	53	M	23	Trauma	Transfemoral	16	9
13	45	M	5	Diabetes	Transtibial	14	9.5
14	67	M	12	Diabetes	Transtibial	18	7
15	50	F	43	Congenital	Transtibial	15	10

In the analysis of the interview data, three themes emerged that were critical to the overall evaluation of comfort of the user – Expectations, Context, and Communication. Each of these themes comprises a range of factors that contribute to their experience of comfort. Each theme is discussed below and supported with direct quotes from the users. Table 4-2 includes representative significant statements

with their formulated meanings; in total, 155 significant statements were identified and used to determine the themes.

Table 4-2. Representative significant comfort-related statements of users, and related formulated meanings

Significant Statements	**Formulated Meanings**
Now I wear mid-length skirts to the market, and people might look, but I don't care, but it's probably taken me 40 odd years to get to this stage.	It takes time to adapt and psychologically accept the prosthesis.
What I need is what I need, and it's hard to specify to my prosthetist. It's better to have the same one so they understand over time.	Consulting the same prosthetist helps the user to feel comfortable.
Sometimes, when you are out of the house, and it's uncomfortable, you just bear with it; it's the price you must pay.	Learning to live with discomfort is necessary when using a prosthesis.
Oh yes, it's totally relaxing to take off the leg after 10 hours of wearing.	Removing the prosthesis provides comfort.

4.3.2 Theme 1 – Expectations

BASIC FUNCTIONS

The expectations of comfort were a key theme running throughout most of the discussions. Expectations appeared to change as the users journeyed through the rehabilitation process, which closely matched Maslow's hierarchy of needs. In the early phase of rehabilitation, the expectations of comfort related to the basic level of function the users expect from the prosthesis, such as standing, balance, and being able to walk. Users acknowledged that being able to walk was the focus during this phase, and if the prosthesis was comfortable and did not induce pain they were encouraged to walk more. Being stable while walking and being confident were also viewed as a key to walking better.

> *"My first leg didn't fit very well, and then I had to use it to learn how to walk…*
> *Getting a really good prosthesis from the start can help reduce the pain, and because it's more comfortable, you tend to walk more.*"

Standing comfort was a surprising expectation of the prosthesis. Users stated that it was necessary for activities like toileting or brushing teeth. Users felt that standing was often more challenging to achieve than walking, with one user mentioning that

"*it was easier to stop walking than it was to stop standing."*

Despite some discomfort, there was a strong expectation throughout the rehabilitation process and beyond that the prosthesis would not hinder their mobility. Comfort was a critical factor in enabling mobility. Users reported feeling less tired, more stable, and able to walk faster when using a more comfortable prosthesis.

> *"Stability is the biggest thing, to know my next step won't jeopardize me and I'll fall… When I push out my leg and know I won't fall, it will speed up my walking."*

As users get accustomed to their prostheses, becoming familiar with the experience with a prosthesis and its ability to address basic functional needs, it was noted that the expectations of the prosthesis started changing. Many users acknowledged that perfect comfort is impossible and that one must live with some discomfort.

> *"If the fit is not quite right, I know it will get better over time as long as it's not a bone rubbing, etc.; nothing is perfect."*

ACTIVITIES

When the essential functions of walking and standing have been achieved, the user's mentioned that their expectations shifted to other needs, including squatting (necessary for toileting in Asian culture), running, and cycling. These needs were accompanied by a growing expectation that they could now participate in more activities, traversing longer distances to providing them with a greater independence. However, limitations in comfort sometimes meant that these expectations needed to be moderated.

> *"Going to the market, I will walk and just bring a towel to dry my leg; anything further than 300m, I will drive… I can only walk 2Km without resting. If my leg is more comfortable and I can extend that range, that would be the best."*

Users who wore a prosthesis more than 6 hours/day stated that it was better to use an uncomfortable prosthesis than nothing at all, as the latter option significantly impacts mobility. Users who wore a prosthesis less than 6 hours/day did not find it as necessary to continue using their prosthesis and limited their activities. When comfort levels were low, users sought to employ several coping strategies to maintain mobility, including reduced physical activities and frequent breaks. One user described how he modified the route to run errands depending on the amount of comfort he was experiencing.

> *"If my stump isn't feeling that good, then maybe I'll just go somewhere nearby, get some takeaway, wash my car, or so. And come back home."*

The increased wearing of a prosthesis often worsened the interaction with the prosthesis, such as increasing temperature, sweating, abrasions, and poor suspension. All the users recalled these issues and their adverse effect on mobility. One user remembered a very different experience of using his prosthesis in cooler climates compared to his daily struggles with the prosthesis in hot climates like Singapore.

> *"So, I remember one perfect example. I traveled to Europe for a conference, and the weather there was perfect, literally perfect. I felt very comfortable wearing it, as I did not sweat at all."*

Several users wore silicone liners to improve comfort. While some found them beneficial, others highlighted their contribution to increased temperatures, sweating, and loss of suspension, which also contributed to instability and lower confidence with the prosthesis.

> *"It's so hot; you can pour out the sweat from the liner. The sweat makes the suspension very weak as well."*

Poor suspension often led to less stability and pain within the prosthetic socket. The pain was generally expressed as the antonym of comfort and severely limited mobility. Users tended to modify their actions to reduce pain, such as walking less, applying creams to the skin inside the liner, or altering gait patterns. However, users were willing to endure some pain to overcome environmental barriers to mobility.

> *"Using a wheelchair can be tedious when looking for an elevator, so even if I'm in a little pain, I'd rather use my prosthesis than any other device."*

The users expressed the expectation of the prosthesis's weight at length. While some users found the weight acceptable for the first 500m, the weight of the device became more of an issue as the distance increased. The determination of the correct weight appears to be dependent on individual requirements.

> *"If the leg is too light, I might have this feeling that the leg will break, can it withstand my weight or not… Heavy is more durable; I can do more things…. It feels like I'm carrying weight when I'm walking, though."*

Other users describe a heavy prosthesis as tiring, with some users even refusing to wear a prosthesis that they consider too heavy for periods of the day to allow their legs to rest.

To cope with challenges arising from fit-related issues, users tended to modify their sockets in various ways e.g., adding padding, cut holes inside the liner. These were performed to mitigate the need to

return to the clinics. Padding or cutting holes was viewed as a satisfactory and affordable option; however, when applying the padding was often inconvenient, with users adjusting their devices in restrooms throughout the day. One bilateral user wears the prostheses for 16 hours daily and adjusts his prostheses with the Click Medical Revofit system (Click Medical, USA). A cable system connected to a dial that controls three adjustable panels. He found it extremely useful in the latter part of the day to accommodate socket fit challenges. However, he preferred it be further optimized with larger panels to control more surface area after changes to his residuum shape.

> *"The adjustable panels have a bit of an issue; if they could be 20% wider, that would be great. The string also gets caught occasionally."*

Results also indicated that users expect a new prosthesis to need multiple adjustments before it becomes comfortable. Many felt the prosthetists could further optimize comfort in the clinic before users leave to reduce the number of required adjustments later.

> *"The leg should fit your function and the way you walk. Sometimes when getting a new leg, there are so many adjustments that are needed here and there, and it feels everything is fine in the clinic, and then you go home and find it isn't."*

After a series of adjustments and acceptance, the user's focus shifted to higher-order expectations in areas of their lives such as aesthetics, running, and linked the growing trend of digital technology as a means to support these higher-order expectations. Users also turned their attention to the perceived limitations of the prosthesis.

AESTHETICS

Users who had their amputation over 10 years ago noted their focus shifted from walking, and recreational activities to areas for improvement, e.g., aesthetics or a more customized fit. Users described how the prosthesis should be an extension of themselves when walking, natural and unnoticeable to the passer-by. The use of traditional foam covers did not provide this required level of comfort.

> *"My first leg had a cover, and I was more conscious of that. It looked like I was walking around with a barbie doll leg."*

Several users found that using a custom silicone cover made them feel comfortable. Many had not considered using a cover until this option was made available. One user describing the effect of a natural-looking cover recalled his response on a train one day.

> *"Sometimes, when people don't give up the seat, and they say, "Hey, I didn't notice that he's wearing an artificial leg," I'm happy, and I won't get angry because he didn't give me the seat. Because my limb is made to look like a real one."*

TECHNOLOGY

The use of digital technology is a necessity to produce silicone cosmetic covers. However, users were skeptical about using digital technologies, as they considered it necessary to have a prosthetist using their expertise to provide comfort. Users were comfortable with the current process of casting, suggesting the use of check sockets was suitable to visualize pressure and fit before moving into final manufacturing. When asking about the advantages of technology with one experienced user, she replied by highlighting a current limitation.

> *"I think a human, an empathic human, would really listen to a patient's concerns, but a machine would just say that this is the shape with the assumption that comfort is just purely based on shape."*

There were two viewpoints from the users about the usefulness of digital technology that aids in improving comfort. The first was that the users felt that supporting the prosthetist's expertise, with digital technology and componentry will lead to improved comfort. The second viewpoint is that users do not think digital technology will improve the situation or without proof of its effectiveness there is no need to change. This seems to be caused by a lack of understanding of how this technology will impact the users and its added value when users are already comfortable with the familiarity of current practice. Users who have had their prosthesis longer tended to express the second viewpoint.

> *"I wouldn't be uncomfortable doing digitalized processes to make the leg, but I would be wary of the product and need to check its track record… Theoretically, digital scanning should be a perfect fit, but casting is also a good representation of your leg as well."*

Users mentioned that they had spent years learning one way of walking and were comfortable with their current components. Changing to new technological componentry requires time, effort, training, and a period of adjustment.

> *"I also need that window of time when I'm not working. I need to get a few months only to unlearn and learn how to use the new technology. If I had all the time in the world and no responsibility, then maybe I would think about changing to better technology sooner."*

MINDSET

Users' expectations of comfort appear to be strongly influenced by their mindsets. True comfort can only be achieved when the users are willing to accept the new reality of their amputation and develop confidence in their ability to use the prosthesis.

> *"Initially when I had my leg amputated, I felt ashamed and wanted to hide it.*

And,

> *"Certain functions are about if you want to do it or not. People ask me if I can squat, and I say, "you drop $50 on the floor and see if I can pick it up or not?". We will think of a way to do it if we want to do it."*

Regardless of differences in mindsets, all users felt comforted by positive public sentiment towards their level of functioning following their rehabilitation. This feeling was particularly prominent with users of bilateral prostheses or higher-level amputations.

> *"I feel more comfortable when I get positive reactions from the public about my leg. A couple of weeks back, I went to a weekend program, and some people came up to me and said they were happy to see me so confident to wear short dresses."*

Users in this study remembered how – upon receiving a more comfortable prosthesis – they found a sense of freedom that such comfortable prosthesis offered beyond what crutches, or a wheelchair could offer, with one user describing the prosthesis as *"giving back her sense of dignity."* This freedom provides users with the confidence to participate in a variety of activities and contexts.

4.3.3 Theme 2 – Context

Understanding the users' expectations should include the assessment of the individual context in which the prosthesis will be used. A combination of specific design strategies and users' adaptability influences the comfort levels across the different contexts.

SPECIAL CONSIDERATION ACTIVITIES

Several users emphasized the context of sitting with a prosthesis instead of walking and the issues that arise. The level of comfort was affected by both the socket design and the length of time that sitting is required, as well as the seating height.

Users mentioned that the prosthetic sockets were not flexible enough to allow sitting in one position for an extended time, such as when going to the cinemas or taking a flight overseas. They described feelings of pain, cramping, and restricted blood flow during these periods. One user recounted his trip to the US in economy class.

> *"So, the tough part is when you're sitting in economy class, it gets really, really painful, especially if it's across an overnight flight into the US. And then I must secretly take it off because it's just too painful…I remember sitting in economy class to the US, a 14-hour flight; I had to take my leg off because it was sore, red, and painful because of the sitting angle."*

Users also mentioned that to carry out their activities of daily living (ADL's), they were required to sit on varying heights of chairs, sofas, stools, and even on the floor, i.e., at different seating angles, as well as different widths. To mitigate sitting discomfort, users mentioned searching for seats of certain heights, width, and easy access across the different modes of public transportation or choosing certain positions or models of cars to facilitate comfortable sitting. One user reported that when he takes a taxi, *"the front passenger seat needs to be pushed forward so he can sit comfortably in the back."* Another user preferred to drive higher SUV models over low sports cars as *"it was easier and more comfortable getting in and out."*

CULTURE

The current prostheses designs tend to prohibit extreme ranges, such as those involved in squatting. One user stated that this ability to squat was important when adopting a common position for smoking a cigarette with friends. It was also beneficial when using the standard squat toilets in Asian countries, with one user recommending that new standards for a prosthetic range of motion be explored.

> "*I would love for the back wall to be lower, like an Asian squat standard!"*

Users in our study offered insights into the context of participation in religious rituals. Many users stated that due to a lack of prosthesis comfort, they could not join in floor-based traditional positions like praying and had to sit on low stools at the back of the hall. These low stools would also lead to sitting discomfort, with the trim lines of sockets often pressing into the body. Users felt more comfortable visiting their regular places of worship as the religious leaders were familiar with their situation and tended to ask fewer questions. However, other attendees may not feel this way.

> *"so, I'm Hindu, we go to temples, and temple socks are not allowed. People say you need to take off your socks. And I'm like, No, that's an artificial limb, the socks can't come off… sitting on the floor is very important for most of our ceremonies and things like that. So it gets a little*

difficult when I actually have to sit on the floor… most often, I will remove my prosthetic leg for prayer."

Another user who often speaks and prays for his congregation mentioned that he understands the prosthesis is made for walking, but the need to stand for longer periods is just as critical.

"*Sometimes, in church, I'm giving a prayer or testimony, I need to stand still for long periods, but I keep moving around the pulpit, so I tell the congregation, sorry it's not the holy spirit, it's because I am wearing an artificial leg.*"

As a result of the discomfort in these contexts, users would often remove their prostheses. Having to take off a prosthesis caused users to become "*self-conscious and mentally stressed"*, lowering levels of comfort associated with a prosthesis.

PRIVACY

Many preferred the removal of the prosthesis to be done in private.

"I'm not concerned about people looking at my legs, but I'm concerned about people looking at me removing and putting my legs back on. It's part of my attire; it kind of feels like I'm undressing."

"When you have to remove it, it's quite inconvenient and embarrassing, especially if you are in public. You have to find a private space to take it off and put it back on."

When out in public with friends, one user preferred to find a toilet to remove the prosthesis, yet another stated that he will do so in public if the sensation of discomfort gets to strong.

"If I'm wearing shorts and I'm out but really need to take the leg off, I just will, people will stare, but I've got to make myself feel comfortable."

In hot climates such as Singapore, many users feel compelled to remove the prosthesis during periods of heavy sweating to air the residual limb. After removing the prosthesis, the users describe the feeling as *"removing metal shoes after a long day,"* which provided a collective sigh of relief. One user described the restrictive nature of a prosthesis quite vividly while explaining an urgent sense to remove it.

"It feels like someone's put your hands around your neck the whole day. They're not pressing it too tight. But still, it's there. And it's kind of disturbing."

EASE OF WEARING

Another context factor influencing the comfort users experienced was using the prosthesis at nighttime. Diabetic users and users with bilateral lower-limb amputations had tried to sleep with the prosthesis to reduce the time needed to wear the prosthesis before using the toilet.

"Like, in the middle of the night, especially the diabetic has to get up at least once, you know, to go and urinate. You don't have time to wear the leg because the moment you get up, you are really urgent to go."

Being easy to don was considered convenient, equating to being more comfortable.

"Last time, I liked to crawl at home because I didn't find my leg comfortable, but now it's easy to put the leg on just to get a glass of water."

And,

"I've seen other amputees use the pin type, and they just click it in and look so comfortable."

AFFORDABILITY

Another context factor that users mentioned related to financial costs and budget. 53% (8/15) of the users relied on social support to fund their prostheses, with these users stating they felt ongoing maintenance costs were expensive. They were, however, willing to pay up to $100 for a silicone liner to increase comfort. Still, as silicone liners were several times more expensive than $100 in Singapore, users tended to put up with blisters on their residual limbs if funds were limited.

"It's too expensive for people like us; we don't have incomes, we don't work. We take months to pay it off, and then the socks have wear and tear, and when we finish paying off the loan, we have to take another one."

Limitations of funds available to pay for the prosthesis were viewed as a restriction on comfort. Users felt that clinics recommended readily available componentry to users rather than work with them to determine the most suitable prosthesis for their needs.

"Funding is a big issue as it means you only have a certain amount of funds to make a leg, and that restricts the amount of comfort you can provide to a certain point."

One user suggested that the entire rehabilitation process and the associated costs be considered in totality when making prescriptions. Investing upfront in better quality componentry may improve outcomes and reduce discharge times.

"I think if you can get people into a good liner and good suspension right from the start, the rehabilitation results outweigh these costs."

And as another user summarized,

"If it's comfortable and economical, definitely nobody will complain."

4.3.4 Theme 3 – Communication

RELATIONSHIP

To address the expected user needs and context requirements, users expressed a strong desire for better communication with their prosthetist. There was a strong sense that the relationship between user and prosthetist played a pivotal role in the prosthetists ability to understand needs and context and thus provide support and develop a comfortable prosthesis. Users felt that communication was crucial in determining the individual factors in designing a comfortable prosthesis. Consulting the same prosthetist was seen as key to the repeatability of design and comfort.

"It's better to have the same one, so they understand over time…The relationship you have with your prosthetist is significant; being able to communicate problems without either party being offended by that is really important."

ACCESS

Users indicated that having access to care early and promptly can improve comfort levels and help to reduce anxiety. The availability of a prosthetist (preferably the regular prosthetist) is critical to achieving the desired level of comfort with the prosthesis, failing which users would have to do with DIY solutions.

"Being able to see a prosthetist in a reasonable time is important; you can't have a problem, call the clinic, and they say, we can see you in a month. Because that just compounds the

problem…To adjust the leg, I would sometimes add toilet paper inside (to alleviate discomfort); it wasn't always effective or convenient."

TRUST

Having trusted and timely communication with the prosthetist was viewed as helpful in solving prosthetic-related issues. Continuity of care, as described earlier, is a strong contributor. Experienced users expressed the desire to be more involved in the design and decision process, as they understand what worked and what did not in terms of designing for comfort. They often could tell if the cast seemed appropriate or if the hand positions were correct during the casting process. Opportunities for them to communicate their opinions could lead to better outcomes.

"If patients can learn how to explain to the prosthetist how it fits and what changes are needed, you will end up with a more comfortable result."

FAMILY SUPPORT

The role of supportive family networks and their interactions with the user was another critical area of communication in establishing user comfort. As users sought to regain a level of normality following their amputation, expressions of understanding and support from people close to them could be an essential source of comfort and encouragement.

"*Whenever I see my friends or relatives, and I'm using my prosthetics, you should see the way they pray and be (were) happy (for me); it's very encouraging. It's great moral support."*

"My wife and friends understand that I need to rest a short while, like 2 mins every so often, so I can continue walking with them."

However, when communication was not supportive, users felt a level of fear and embarrassment, with one user even describing the feeling of being *"ashamed."* Users did not necessarily welcome sympathy from others as they sought to reconstruct their lives post-amputation.

"I don't want them to show empathy and concern; I want to be better than them."

SOCIALIZING

Users sometimes felt anxious and concerned about using their prostheses when visiting homes, mainly when the custom is to remove the shoes when entering. This tended to compromise their feelings of safety.

"If I visit other people's houses, I put socks over my shoes to enter, but it's dangerous and slippery."

Communicating with the public was often viewed as an opportunity to educate and dispel myths and stereotypes. Users shared they were willing to be proactive in order to pre-empt any awkwardness in conversation and make others and themselves feel more comfortable.

"If people ask me questions about my leg, I'm happy to answer, especially kids, and it helps to make more people comfortable with people with disabilities."

4.4 Discussion

"Although a growing body of research has illustrated the importance of psychological, social support, and education in facilitating the adjustment process following an amputation, there appears to be little research looking specifically at user expectations" (Ostler et al., 2014). Our study highlights the utility of user interviews in confirming and understanding previously documented issues with comfort and identifying unrecognized needs and concerns. Figure 4-2 is thus updated to reflect the additional factors of comfort identified in this study. These are highlighted in yellow for easier reference. There is considerable new information in the additional three determinants suggesting comfort of a prosthesis and has been underestimated previously and thus, should be considered within the design process.

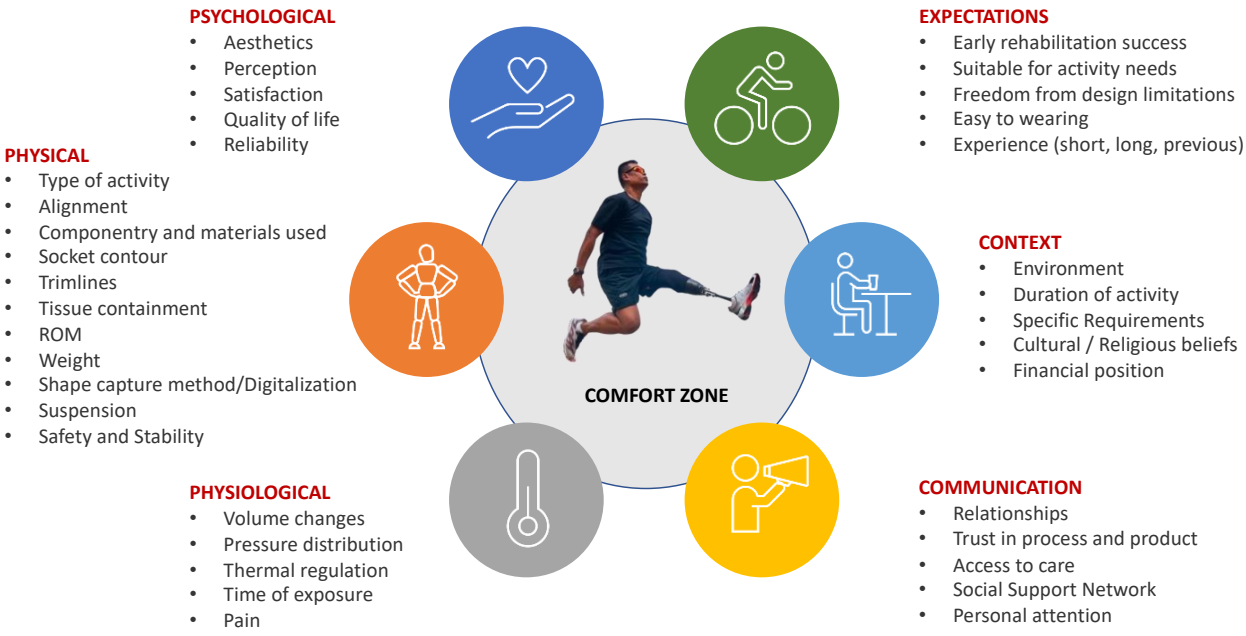

Figure 4-2. Updated list of comfort factors following user interviews.

The following sections discuss the three themes of expectation, context, and communication in detail, followed by a discussion on the comfort zone as an end goal for prosthesis comfort.

Expectations

Users' expectations of the prosthesis impact the levels of comfort they experience. These expectations, some of which may not be explicitly formulated by the user should be part of the requirements for the design of a comfortable prosthesis. The literature points to the simple expectation of returning to normality and simple walking following an amputation (Murray, 2013; Ostler et al., 2014). Gallagher and MacLachlan (Gallagher & MacLachlan, 2004) reported that patients are initially focused on the importance of being able to walk, then face the practical difficulties of transferring the physical act of walking into life, e.g., ADLs. This echoes our results that suggest a change of expectations over time. The initial expectation for basic functions such as walking, and standing is soon superseded by other higher-order functions such as running and improving aesthetics with an enhanced customized fit and adjustability. Our results suggest that a non-adjustable design may only be temporarily fitting because of changes in the residuum or activity related need. Users expect improvements and optimization of the design for their specific requirements, this is improved through communication with the prosthetist.

Users face many limitations daily. Temperature, sweating within the prosthesis, and the weight of the prosthesis were three of the more common complaints. Issues of sweating that led to abrasions, poor suspension, and a need to remove the prosthesis as found in our study are similar to other reported outcomes of prosthetic users (Legro et al., 1999; Quintero-Quiroz & Pérez, 2019; Williams et al., 2019). Our study suggested that the trend to make the prosthesis lightweight may have a detrimental effect on the psychological safety and stability the users experience with the prosthesis. A lighter prosthesis may not necessarily be better (Donn, Porter, & Roberts, 1989). Finding the right balance of weight for the user should be determined with consideration given to the weight distribution throughout the prosthesis and a user's context. Allowing the prosthetist to alter adjust the weight distribution and mass during the initial design and subsequent repeat visits, may help to facilitate better weight distribution (Donn et al., 1989; Lehmann et al., 1998; Meikle, Boulias, Pauley, & Devlin, 2003). Since users report issues walking in the range of 500m-2km, distance has to be taken into account when designing the prosthesis. Thus, when deciding the weight of the prosthesis, the prosthetist must weigh not only its structural, functional, and safety aspects but also pay significant attention to the psychological elements leading to safety concerns of the user.

The need for aesthetics in a prosthesis assists in perceiving one's body image and self-esteem, although not all users require a cosmetic cover to improve the appearance. In Asian societies, it can be important for many users to hide their disability for fear of reproach in the workplace, being stereotyped, or not

being regarded as normal. Using a cosmesis remains an individual preference, not a confounding factor of comfort. Ostler (Ostler et al., 2014) found that some users did not care about the aesthetics of the prosthesis but rather the type of footwear that could be used. Bekrater (Bekrater-Bodmann, 2021) found that a more realistic appearance was more satisfying to the younger prosthesis user. However, the present results suggest that aesthetics is important to facilitate confidence and that prostheses should be designed for the user's size and skin tone, unless explicitly expressed otherwise by the user.

In recent years, technological advances in prosthetics have been directed toward improving comfort, reducing energy expenditure, improving stability, and accompanying functional issues while addressing concerns about aesthetics (Sousa et al., 2009). The use of improved technology was expected to reduce the need for adjustments and related appointments, improving the overall cost-effectiveness and efficiencies (Binedell, Meng, et al., 2020; Ribeiro et al., 2021). However, none of the current prosthetic socket fabrication systems can adequately create a comfortable and functional interface with the human body (S. Li et al., 2019), despite technologies such as 3D scanners or 3D printing, which are being touted as having a potentially huge impact (Comotti, Regazzoni, Rizzi, & Vitali, 2015). This potential tends to be driven by the prosthetists' views and understanding of those technologies. We observed in our study that the users are hesitant in adopting new technology. They remained skeptical about its ability to deliver similar results to that of their current prosthesis that highly skilled prosthetists, whom they trust, delivered. This confirms our finding in an earlier study on leveraging digital technology in prosthetics and orthotics (Chapter 6). The same study suggested that digital solutions are more suitable to aid prosthetists with less experience in delivering similar results.

The use of virtual care has been identified as helpful, e.g., in triaging patients. Our earlier study indicated that prosthesis users were interested to use virtual consultations but with prosthetists they trusted and not for early visits (Binedell, Subburaj, et al., 2020). This finding suggests that while users may understand the theoretical advantages digital technology can offer, they expect a prosthetist they trust to guide them and believe that face-to-face communication in the crucial early visits is essential.

The interviews suggest that users who were generally more accepting of their situations and of the fit and overall function of their prosthesis appeared more comfortable which was confirmed by the higher socket comfort scores they provided. Hamill et al. (Hamill, Carson, & Dorahy, 2010) and Senra et al. (Senra, Oliveira, Leal, & Vieira, 2012) described this general acceptance as "regaining a sense of normality" in their qualitative analyses of experiences following amputation, something our users also expected. This process of alignment with normality was found to be facilitated by time (Carpenter & Clark, 1994), further reinforcing our findings. Learning to perceive their body positively can be transferred to other domains of social interaction in daily life and might be an element that facilitates social inclusion (Sousa et al., 2009). Oaksford et al. (Oaksford, Frude, & Cuddihy, 2005) suggest that

cognitive-behavioral interventions may be beneficial in aiding people to manage and positively reappraise their amputation, thereby facilitating improvements in psychological adjustment. Such an approach might encourage individuals to adopt positive coping strategies, avoid maladaptive ones, and help develop the attributions of those who find positive meaning following their amputations (Murray & Forshaw, 2013).

Context

The context should be considered in a design process. Comfort is specific to the individual and situation, i.e., depending on the context. We found that special activities such as travelling by air, participating in social activities (e.g., going to the movies or visiting friends) were usually not included in the prescription details for the prosthetist, possibly because this information is not always captured during the initial discussion between the prosthetist and user before the socket is designed. In the interviews users often recounted how these special activities caused great discomfort but had to be performed as part of a life.

Our results confirm the large need for functionality with a prosthesis as found in other qualitative literature (Sousa et al., 2009). Functional independence results from improved mobility, as shown earlier by Franchignoni et al. (Franchignoni, Orlandini, Ferriero, & Moscato, 2004), which enhances the QoL.. The need mentioned in the interviews to use a prosthesis on various seat heights available in the community and at home suggests that testing knee flexion comfort in the clinic should always include different seat heights. Previous studies indicate that user satisfaction and comfort are linked to increased prosthesis use for basic functions e.g., standing (Gailey et al., 2019; Hanspal et al., 2003; Legro et al., 1999; Neumann, 2001a). We found two studies focusing on other activities common in low-income or Asian countries, namely the habit of sitting in a squatting posture for many activities, e.g., the use of the toilet, and sitting in a cross-legged posture on the floor, e.g., for relaxation, having food, and during daily prayers (Chakraborty & Patil, 1994; Craig, 2005). The users in our study emphasized the significant discomfort caused by these special activities which often prevented them from participating.

There was a strong need to remove the prosthesis and a sense of relief after doing so. Many users felt awkward removing their prostheses in public spaces, preferring to find a private space such as a toilet. In the eyes of the others, the person with an amputation may appear disabled and a member of a stigmatized group (Horgan & MacLachlan, 2004). If the discomfort is getting to great and private spaces are not available, users will remove the prosthesis wherever they are as the sense of relief outweighs the glares from the public. This in another strong indicator that comfort levels must be improved. Prosthetists often advocate the removal of a prosthesis to allow the skin to heal and breathe, i.e., for

health reasons, but may not consider the need for privacy to do so, nor the need to do so because of discomfort. Users are generally told not to wear a prosthesis at night to allow the residuum to rest and recover, as loading is limited. However, users in our study felt this recommendation might be superfluous, considering that many do not even wear their prostheses the entire day. Our study indicates that being able to wear the prosthesis comfortably for many more hours, including the night, makes it easier and faster to get to the toilet during the night or to leave an apartment due to an emergency. Many studies highlight the need for a prosthesis to be easy to wear (Legro et al., 1999; Pezzin, Dillingham, MacKenzie, Ephraim, & Rossbach, 2004; Schaffalitzky et al., 2012), but lack details as to when, where and why this need is important and how it will impact their daily lives that could help develop better solutions.

With the increasing importance of accessibility and feasibility in prosthetics, the cost of the prosthesis impacts the users' comfort levels. Beyond the initial cost of the prosthesis, our study suggests the cost burden to the user (at least in Singapore) is enhanced through modifications deemed necessary to increase comfort, facilitate donning and doffing more easily, ongoing maintenance and repairs, and the replacement of socks and liners. As some respondents mentioned, potential costs can be a barrier to seeking care and leads to often unsatisfactory DIY solutions (Binedell, Subburaj, et al., 2020; Shutze et al., 2021). It is incumbent upon a health care system to address this possibility and its impact on patient function and QoL (Legro et al., 1999). Funding structures remain important in usage and satisfaction with prostheses (Biddiss, McKeever, Lindsay, & Chau, 2011). We also believe that being able to achieve comfort at an earlier stage, potentially through a slightly more expensive solution, will reduce costs caused by follow-up visits for adjustments, reduced use and hence independence, as well as skin and other health issues.

Communication

Comfort has a significant psychological component. Our results suggest that open communication and a trusting relationship between the prosthetist and patient can significantly influence comfort. Our users cited increased psychological comfort and assurance in the case of timely communication and access to care with their prosthetist in times of discomfort. This trust can begin early on following an amputation but can only be established over time and after consistent user results. The dialogue between the prosthetist and user allows the prosthetist to understand the activities and context of the user in more depth, and the user to understand the possibilities in the design and adjust their expectations. This type of dialogue is likely to instill a greater sense of involvement in their care and trust (Murray & Forshaw, 2013). Trust in the prosthetist will leave the user feeling comfortable that the prosthetist has their best interests at heart, potentially leading to improved outcomes.

Nevertheless, Murray (Murray, 2013) found that even when the user-prosthetist relationship was more established, amputees still did not know what to expect from the interaction with the prosthetist. Ostler (Ostler et al., 2014) reasoned that this could lead to passivity, communication issues, disappointment, and lack of service engagement. Our study, as well as common sense, suggest that from the user's point of view, to build trust and improve communication and understanding. They should continue seeing the same prosthetist who can then better appreciate and solve individual requirements (Murray & Forshaw, 2013) to achieve comfort. As mentioned earlier in the design process the prosthetist understands the expectations, context, concerns, obstacles, and requirements of the user – using technology or other methods – the earlier comfort can be realized. At the same time, these change over time. Hence, having the same prosthetist is crucial to capture and adjust to these changes.

Comfort also relates to self-worth. Social activities enhance a person's sense of self-worth, but often include barriers for prosthesis users, such as the need to homes, or to remove the prosthesis for religious rituals e.g., praying. This seriously affects the ease or even the possibility of participating, thereby lowering the users' QOL. Ferguson, Richie, and Gomez, (Ferguson, Richie, & Gomez, 2004) highlighted the significant role of societal barriers in the daily lives of people with amputations. As highlighted in chapter 2, users can feel socially isolated after amputation and that even just one negative social interaction can have severe emotional and behavioral consequences. A study by Gallagher and MacLachlan (Gallagher & MacLachlan, 2004) found that amputees often described feelings of insecurity and apprehension in the early stages following amputation and that the provision of physical and psychological support and information about the amputee rehabilitation process at this point was necessary for addressing these concerns (Ostler et al., 2014). In our study, users tended to surround themselves with a social network of friends and family to overcome some of these barriers. This network provides a morale boost to the user when these members react positively to their progress or accept their prosthesis use. It is our belief that the communication early in the process that is better focused on better understanding the user, their expectations, and context provide a very important starting point in the design process for a prosthesis. A comfortable prosthesis as early as possible in the rehabilitation process will enhance this process, as it will support functional independence in daily life, allow participation in social life and provide a new sense of normality. The role of the community could have an impact on users in accepting and feeling comfortable about their level of function and self-worth.

Comfort zone

Total comfort currently does not exist. According to White (White, 2008), the comfort zone is a behavioral state within which a person operates in an anxiety-neutral condition, using a limited set of behaviors to deliver a steady level of performance, usually without a sense of risk. In our context, the

comfort zone is a state where the users feel they can use the prosthesis when and where they like with a feeling of normalcy. The prosthesis is so seamlessly integrated into their lives that it becomes unnoticeable to the user and those around him/her.

The 'prosthesis comfort zone' for an individual user is defined by a range of experiences (physical and physiological) and physical interactions with a prosthesis that are deemed comfortable for an individual user. This zone is a utopian view of the prosthesis. The users in our study state expressed a desire to reach this zone although this is not possible currently, as the wish of users to not notice they are wearing a prosthesis is unattainable. The "prosthesis comfort zone" could be a useful concept for the development of prostheses that are as comfortable as possible for the user. Differences in amputation, body, context, preferences, and needs implies that comfort zones are user specific. Some users prefer more stability and safety, while others prefer a cooler prosthesis with more functions. The prosthetist and user must work together to define the comfort zone as early as possible in the rehabilitation and design process.

4.5 Conclusions and Limitations

The comfort experience for lower limb amputees is determined by the various physical, physiological, and psychological factors and enhanced by the prosthetist through 1. Understanding the users' expectations of the prosthesis and its functionality, 2. Identifying the needs-based context that affects comfort, and 3. Communicating the needs and requirements between the prosthetist, the user, and the social network. The comfort experience is individual.

Current prostheses have many desirable characteristics and features, but it appears that they are not meeting all the needs of users. From the data we gathered, we can conclude that overall, many respondents are well served by their prostheses. However, most users were living with prosthetic problems that if could be resolved would elevate their comfort levels. The factors additionally identified from the study according to the three categories of comfort include:

- Physical – Activity, easy to use
- Physiological – Body ache, numbness
- Psychological – Communication, Social relationships, Time of exposure, Personal attention, Cost, Value system/Beliefs, Culture, Expectation, Experience,

The factors indicate a focus should be applied in addressing the psychological factors to enhance the comfort of prostheses. The socket design experiences of prosthetists and user experiences are essential for defining these indicators. These factors add to the literature established in Chapter 2 to provide a

deeper understanding of comfort with a prosthesis and helps to answer RQ1 and affirm our first hypothesis "comfort is multifactorial."

The following are further recommendations that provide insights for the development of the Comfort-driven Prosthesis Design Methodology (CPDM):

- A better understanding of the comfort factors that are important to the individual user, right from the beginning of the rehabilitation process is essential. This would include additional questions during the initial consultation to ascertain all user requirements, needs, expectations and contexts. Better communication between the prosthetics and user is important to understanding these. The continuity of care should be provided by the same prosthetist where possible, while providing easy access to facilitate repairs or maintenance.

- Educating the user about what can be expected during the entire process - from how it should feel during casting, fitting, and the subsequent rehabilitation process to post-discharge monitoring - would help them feel involved and invested in the decision-making process and contribute to a trusting relationship between the user and the prosthetist.

- The comfort zone of an individual user must be identified by the prosthetist and the user as early as possible in the rehabilitation and prosthesis design process. This should lead to a comfortable prosthesis in the shortest period, that can support the rehabilitation process and help the new users in their process of obtaining functional independence in daily life, participation in social life and a new sense of normality. The ultimate experience is where the prosthesis seamlessly integrates into the user's life and lifestyle to such an extent that it becomes unnoticeable by the user and others. A critical issue that remains is the translation of the comfort zone into quantifiable indicators for designing a comfortable socket.

Several limitations are noted in this study. The study only includes persons with lower-limb amputations who had received rehabilitation services in tertiary hospitals in Singapore that generally provide comprehensive rehabilitation by a team including doctors, physiotherapists, prosthetists, and occupational therapists. To be included, the amputation should have been at least 2 years ago, but those participating were long-term prosthesis users with an average of 15.27±10.66 years of use. These factors limit the transferability and generalization of the results. Furthermore, the sample size is small, and the subjects varied in occupation, religion, gender, and activity levels. Although this provides the richness required to understand the many different issues facing prosthetic users, firm conclusions on the relationship between demographics and issues are not possible.

5 DESIGNING COMFORT – PROCESS IMPROVEMENT

5.1 Introduction

To further understand the factors of comfort and to address two of the objectives in this thesis, which are the Identification of the influencing factors of comfort and the identification and evaluation of digital technology potential, this chapter builds on the knowledge from literature and the qualitative study on the user perspective by focusing on process improvement when designing prostheses. Section 5.2 describes a process to measure interface pressure in a clinical setting and linking the pressure readings to qualitative information to verify this approach. Section 5.3 then describes a study that investigated the adoption of digital technology (DT) processes in the prosthetics and orthotics industry to assess the professions readiness for DT as part of the design process.

Parts of sections 5.2 have been published in
Binedell T, Ghazali MF, Wong C, Subburaj K, Blessing L. "Measuring discomfort—An objective method for quantifying peak pressure discomfort and improved fit in adults with transtibial amputation". *Physical Medicine & Rehabilitation*. 2022 Apr 12.

Parts of sections 5.3 have been published in
T. Binedell, K. Subburaj, Y. Wong Y, L. Blessing, "Leveraging Digital Technology to overcome barriers in the Prosthetic and Orthotic Industry – an evaluation of its applicability and use during the COVID 19 pandemic," *JMIR Rehabilitation and Assistive Technologies*, (**2020**), 7 (2), e23827. [PMID: 33006946]

5.2 Pressure and comfort

The quality of fit with a prosthesis can be defined as the ability to provide comfort through accurately contouring the inner surface of the prosthetic socket to the residuum with appropriate force distribution (Moerman, Solav, Sengeh, & Herr, 2016). However, when the socket fit is optimal, improved satisfaction (Dou, Jia, Suo, Wang, & Zhang, 2006), functional mobility and overall comfort is observed (Al-Fakih, Abu Osman, Mahamd Adikan, Eshraghi, & Jahanshahi, 2016)

Poor prosthetic socket coupling with the residual limb can cause discomfort, lowering user satisfaction and influencing functional status (Klute et al., 2001). The socket forces cause high internal strains and stresses in the muscle and fat tissues in the residual limb, leading to deep tissue injury or wounds, and affecting physiological comfort (Bui, Raugi, Nguyen, & Reiber, 2009; Laing, Lee, & Goh, 2011; Meulenbelt, Dijkstra, Jonkman, & Geertzen, 2006; S. Portnoy et al., 2008). Wounds are also a result of poor sock management (D'Silva, Hafner, Allyn, & Sanders, 2014; Sanders, Harrison, Allyn, et al., 2012) as the use of improper socks can lead to skin trauma and inflammation affecting prosthesis use. (Lyon,

Kulkarni, Zimerson, Van Ross, & Beck, 2000). The literature reports a prevalence of residuum wounds varying from 8.8% (Chan & Tan, 1990) to 57% (Meulenbelt et al., 2009).

Socket fit changes over time due to volume reduction of the stump resulting from weight loss or weight gain (Sanders et al., 2018) or muscle atrophy, alter the pressures occurring on the user's residuum, therefore affecting socket comfort that may lower balance confidence and cause prosthesis disuse (Rosenblatt et al., 2021).

Several studies have attempted to assess the distribution of interface pressures to achieve a quality socket fit and prevent residuum wounds (Abu Osman, Spence, Solomonidis, Paul, & Weir, 2010; Dumbleton et al., 2009; Moo et al., 2009; Ming Zhang & Roberts, 2000) highlighting their regular occurrence and lack of solution. These complications severely affect the users' ADL, lowering satisfaction rates and reducing the quality of life (Dou et al., 2006).

The factors influencing the health and healing of wounds can be categorized into three major categories: [1] direct factors: venous supply, oxygenation, and infection; [2] system factors: age, obesity, and nutrition; [3] device factors: excessive pressure, shear forces (Guo & DiPietro, 2010). Clinically, the prosthetist makes physical alterations to the prosthetic socket to alleviate the pressure and discomfort to promote wound healing (Salawu, Middleton, Gilbertson, Kodavali, & Neumann, 2006). However, the prosthetist relies heavily on the qualitative feedback of the user to determine whether the adjustments were sufficient (Gailey et al., 2019). The question is whether it is possible to measure and quantify the residual limb socket interface pressure in such a way that it can act as an indicator to design or adjust the socket such that wounds and discomfort are prevented or reduced.

Pressure can be used to determine appropriate normal stress ranges for individual residual limb sites and evaluate the design or fit and function of sockets (Silver-Thorn, Steege, & Childress, 1996; Springer & Engsberg, 1993). In recent years the use of sensors to determine interface pressures has grown. Several studies have used an array of sensors to detect peak pressures (Beil, Street, & Covey, 2001; Dou et al., 2006; Sengeh & Herr, 2013; Wheeler et al., 2016), while other studies have simulated biomechanical stresses through finite element analysis (FEA) (Faustini, Crawford, Neptune, Rogers, & Bosker, 2005; Nayak, Singh, & Chaudhary, 2015; Nayak et al., 2017).

The information gained has contributed to understanding the prosthetic interface (M. Zhang, Turner-Smith, Tanner, & Roberts, 1998). Peak pressure and average pressure have been used as possible indicators. Interface peak pressures >100kPa are reported as potentially dangerous (Convery & Buis, 1998). Interestingly, several studies presented data where mean peak pressures have been 100-200% higher than this threshold value (Convery & Buis, 1998; Dou et al., 2006; Sanders, Jacobsen, &

Fergason, 2006), although they did not indicate whether this was problematic or not. A peak pressure recording of >400kPa at one point was reported in (Convery & Buis, 1998) without stating any clinical outcome of this reading. The average of pressures over the socket interface would be another approach. However, pressures differ across anatomical structures on the residual limb, and therefore have different pressure thresholds for discomfort. The averaged pressures dilute the importance of the data that quantifies the discomfort over a distinct area, e.g., location of wounds. While wounds do not necessarily preclude weight-bearing (Salawu et al., 2006), they affect the users' mobility and overall comfort levels.

To date, no studies have attempted to correlate the pressures that cause wounds, redness, or pain to socket discomfort. The research questions we want to address are: 1. Can a quantification of socket pressures and discomfort in the presence of wounds, redness, or pain and throughout the healing process, provide an indicator that will help to improve interface comfort. 2. Which quantification of socket pressure is most suitable as an indicator (OR: correlates to discomfort?) Therefore, this study's objectives are:

1) To evaluate if a peak pressure reduction assists in resolving wounds, redness, and pain inside prosthetic sockets in people with transtibial amputation,
2) To determine whether peak pressures measured inside the prosthetic socket due to external forces could be used to quantify the level of improvement in socket discomfort.

5.2.1 Methods

Participants

A convenience sampling of 16 volunteers took place at the prosthetic outpatient clinic in a tertiary hospital between June 2020 and February 2021. The study was performed in the Department of Prosthetics and Orthotics and received approval from the Institutional Review Board. During the study briefing, all participants gave their informed consent. The inclusion criteria for participants were:

- unilateral transtibial amputations due to diabetes, trauma, or cancer.
- used a prosthesis for more than one month with various suspension methods that included pin and lock, seal in, or patella cuff.
- presence of a pressure ulcer in the form of a wound (Category II), redness (Category I), or pain (no category) (K. Agrawal & Chauhan, 2012) over any point of their residual limb.

Instrumentation

Peak forces were recorded with a Loadpad mobile flexible force sensor for prostheses (model No. L3210, Novel GmbH, Munich, Germany). The sensor coverage area is 1.7x 1.7cm, its external dimensions are 3.2 x 3.2 cm, and thickness is 1.9mm. The Loadpad uses a thin, flexible sensor to measure the normal total force at a scanning rate of 100Hz and transfers the data via Bluetooth to the

loadpad software (version 1.5.17, iPad (Apple 5th Gen, iOS version 12.3.1), Model MP2F2NF/A. The peak pressure (kPa) was calculated from the measured Loadpad Forces (N) using P=FxA.

Procedure

Before the experiment, the prosthetists in the study team performed a clinical examination of the leg to document the cause of amputation along with any wounds, redness, or abrasion characteristics. A pressure ulcer was defined as a break in the stump skin of at least 0.25 cm in diameter without additional surgery required (Salawu et al., 2006). Redness was defined as a persistent red area that does not blanch (Shea, 1975), and pain was defined as an unpleasant sensation localized to the residual limb (Jameson; Fausi et al., 2018).

All wounds, redness, and pain were treated as mutually exclusive. Participants who experienced two or more conditions were grouped into the more severe category (Agrawal & Chauhan, 2012), with ulcers categorized as the most severe wound, followed by redness, and lastly pain. .

The examination also recorded the following:

1. Knee range of motion (ROM) measured with a goniometer
2. Muscle strength measured by manual muscle testing (Cuthbert & Goodheart, 2007)
3. Amount of time the leg was worn as reported by the user
4. Type of prosthetic suspension system
5. Weight of the participant with a digital weighing scale
6. Number/type of prosthetic socks the participant was using at the time.

Process steps:

1. Participants provided their comfort levels using the SCS.
2. The sensor was applied over the wound site and directly against the skin where possible (Figure 5-1). Participants with wounds that were producing exudates were dressed in minimal protection. The liner and/or socks were then carefully rolled over the sensor, and the prosthesis was donned.
3. The participants were required to stand up and walk three consecutive steps, turn, and return to the chair/wheelchair at their self-selected pace.
4. Pressures were measured during walking. The average peak pressure across the 6 steps was recorded as their first pressure reading.
5. Adjustments were made to the socket fit by adding socks, heating out of pressure areas, or grinding away some material thickness of the pelite liner. The adjustments were based on verbal feedback, pressure readings from the sensor, and the SCS.
6. After each adjustment, the SCS and pressure measurements were taken as per steps 1-4.

7. Step 6 was repeated until the participant was satisfied that the adjustments had sufficiently relieved their discomfort. The SCS has improved from the first measurements, and the prosthetist was satisfied based on their experience that the adjustments were sufficient to relieve pressure.
8. All steps were repeated at 3-week intervals until the wound, redness, or pain were resolved for a maximum of three visits. Any ongoing issues were reported. The latest SCS and averaged peak pressure readings were recorded as the final scores and used for analysis.

The method of sensor integration in the socket was considered to avoid co-intervention. The authors ensured that the subject felt the socket fit as it would without the sensing system in place (Ko et al., 2021). At no point were the subjects informed of their previous SCS or pressure readings before adjustments were made to reduce bias and treat each point as independent measurements. However, some adjustments were faster to complete, and subjects may have remembered their scores during each session.

Figure 5-1. Sensor applied to the residual limb.

Prosthesis Discomfort

The discomfort reduction was assessed via the SCS (Hanspal et al., 2003). The SCS is a single question with a 0-to-10-point analog scale where the higher the score, the more comfortable the prosthetic socket. The SCS was initially developed to measure patient comfort based on the Visual Analogue Scale (VAS) used to measure pain (Hanspal et al., 2003). Adjusting physical factors like pressure to improve the socket fit and reduce pain often increases the score but does not necessarily mean increased comfort. Instead, discomfort is reduced. Discomfort and comfort are independent variables and do not lie on a continuum. Even though SCS measures the change in discomfort rather than any increase in comfort,

without a suitable scale to measure comfort developed, the SCS was deemed the most suitable for the study purposes.

5.2.2 Data Analysis

Analysis was conducted in R (Version 4.0.5, Vienna, Austria). We calculated the mean, standard deviation (SD), median, interquartile range (IQR), and demographic ranges for descriptive purposes. The paired T-test was used to determine statistical significance between the first and final peak pressures and between first and final SCS measurements. This test was also conducted to evaluate whether the wounds, redness, or pain resolved after the intervention. It was considered significant when $P<0.05$. Pearson's correlation (rho) was used to check for the linear association between variables including socket pressure and SCS, socket pressure or SCS and wound, redness, or pain resolution, and whether the presence of diabetes impacted resolution. Rho value and the significance level were reported, with a rho>=0.4 shown to have acceptable levels of correlation (Fayers & Machin, 2007). Linear regression was used to identify causal relationships between changes to socket pressure or SCS and weight, suspension, number of socks, hours of use, gender, knee ROM, or muscle strength. Greater knee ROM and muscle strength have been shown to reduce falling with a prosthesis (Vanicek, Strike, McNaughton, & Polman, 2009), while the use of improper socks can lead to skin trauma and inflammation (Lyon et al., 2000).

5.2.3 Results

A total of 16 participants were recruited for this study. They presented with wounds (n=7), redness (n=7), and pain (n=2). The demographics of the participants are summarized in Table 5-1. The participants consisted of 15 males and 1 female (p=0.001), with an age range of 27-80 years (mean 57 ± 15.49 years). Diabetes was the leading cause of amputation (p=0.05). In addition, 56% of the subjects were overweight (BMI >25) or obese (BMI >30).

Table 5-1. Demographics

	Participants n=16 N (%)
Ethnicity	
Chinese	11 (68.75%)
Malay	3 (18.75%)
Others (Caucasian)	2 (12.5%)

Age	
21-30	2 (12.5%)
31-40	0 (0%)
41-50	3 (18.75%)
51-60	4 (25%)
61-70	3 (18.75%)
>70	4 (25%)
Sex	
Male	15 (93.75)
Female	1 (6.25%)
Side of amputation	
Left	5 (31.25%)
Right	11 (68.75%)
Etiology of amputation	
Diabetes (PVD)	9 (56.25%)
Trauma	6 (37.5%)
Cancer	1 (6.25%)
Diabetes	
Yes	9 (56.25%)
No	7 (43.75%)
Weight	
Underweight	0 (0%)
Normal	7 (43.75%)
Overweight	5 (31.25%)
Obese	4 (25%)
Reported Wear time	
0-2 hours	6 (37.5%)
3-6 hours	2 (12.5%)
7-10 hours	5 (31.25%)
>11 hours	3 (18.75%)
Min-Max	1-16
Mean (SD)	6.38 ± (5.04)
Median (IQR)	9

Time since amputation (Years)	
Min-Max	0-13
Mean (SD)	5.44 ± (4.46)
Median (IQR)	6.75
Age of prosthetic socket (Months)	
Min-Max	1-35
Mean (SD)	20.22 ± (9.09)
Median (IQR)	10
Prosthetic suspension	
Pin liner	6 (37.50%)
Seal In liner	3 (18.75%)
PTB with cuff	7 (43.75)
Walking aid	
Single point	3 (18.75%)
Quad stick	1 (6.25%)
Crutches	1 (6.25%)
Walking frame	2 (12.5%)
None	9 (56.25%)
Issue with limb	
Wound	7 (43.75%)
Redness	7 (43.75%)
Pain	2 (12.5%)

Table 5-2 compares the wound group (n=7) and the non-wound (i.e., redness/pain) group (n=9). Due to low numbers, participants with pain (n=2) were grouped with redness (n=7). The distribution of the location of wounds were distal tibia (57%), distal lateral tibia (29%), and anterior tibia (14%). Redness was identified on the tibia crest (57%), distal tibia (29%), and distal/lateral tibia (14%), while the pain was located on the fibula head (n=1) and Lateral distal tibia (n=1). The location of the issue was not associated with more favorable results of resolution. 85.71% of participants with wounds were either overweight or obese compared to 33.33% of non-wound cases (p=0.04). The mean first peak pressure for participants with wounds was 292 ± 183kPa. After adjustment, the final mean peak pressure was reduced to 147 ± 84.28kPa. For the non-wound group, the first peak pressure mean was 336 ± 236kPa and, following the adjustments, dropped to a mean of 116 ± 111kPa. A statistically significant difference between the first and the final pressures of each patient was observed for the non-wound

group (p=0.02) but not in the wound group (p=0.19). On the other hand, statistical significance was found between the first and the final SCS for the wound group (p=0.04) but not for the non-wound group (p=0.07).

Non-diabetic participants wore their prostheses on average 9.29 hours per day (SD 4.31) compared to the diabetic participants with 4.11 hours (SD 4.54). Similar peak pressures and comfort scores were observed when compared with diabetics despite the higher use per hour. The distribution of diabetics across groups indicates diabetes was not a significant factor in wound healing. We observed that the final pressure was lower than the first pressure, and all wounds, redness, and pain resolved through heat adjustments made to the socket to relieve pressure, grinding some thickness of pelite material, or the addition of prosthetic terry socks, except for one case of redness. The one redness case that did not resolve had a high first peak pressure reading of 596kPa and SCS 5, with a final peak pressure reading of 346kPa and an improvement to a SCS of 9. This participant had some contact dermatitis that may have contributed to the ongoing redness. Due to the high number of wound resolutions and the low number of participants, no correlation could be calculated, and we cannot confirm that a reduced pressure led to the resolutions.

The use of a silicone prosthetic liner did not appear to reduce the risk of a wound, redness, or pain. Out of 16 participants, 4 participants with wounds, 3 participants with redness, and both participants with pain used a liner. No correlation was found with the sensitivity of pressure values predicting wound healing ($p>0.05$). The SCS or the change in pressure did not correlate with weight, suspension, the number of socks, the hours of use, gender, knee ROM, or muscle strength ($p>0.05$).

Table 5-2. Comparison of measured pressure values and Socket comfort scores (SCS)

Participant (D) Diabetic	Location	Suspension & Sock	First Pressure (kPa)	Final Pressure (kPa)	Issue Resolved Y/N	P-value	First SCS	Final SCS	P-value
1 – Wound	Anterior Distal Tibia	Pin liner	62	66	Y		5	7	
2 – Wound (D)	Distal Lateral Tibia	PTB with cuff (1 cotton)	91	212	Y		7	9	
3 – Wound	Distal Tibia	Pin liner	282	59	Y		6	9	
4 – Wound (D)	Distal Tibia	PTB with cuff (1 terry)	300	100	Y	0.19	2	5	**0.04**
5 – Wound (D)	Distal Tibia	PTB with cuff (1 terry + 1 cotton)	319	108	Y		2	10	
6 – Wound	Distal Lateral Tibia	Seal In liner	386	208	Y		8	9	
7 – Wound	Distal Tibia	Pin liner	606	276	Y		7	7	
8 – Redness (D)	Tibial Crest	PTB with cuff (1 terry + 1 cotton)	109	59	Y		7	7	
9 – Redness	Distal Tibia	Seal In liner	141	118	Y		8	9	
10 – Redness (D)	Tibial Crest	PTB with cuff (1 nylon)	159	26	Y		7	8	
11 – Redness (D)	Tibial Crest	PTB with cuff (1 nylon)	221	97	Y		8	9	
12 – Redness (D)	Lateral Tibia	Seal in liner	373	285	Y		5	9	0.07
13 – Redness (D)	Distal Tibia	PTB with cuff (1 cotton)	596	346	Y	**0.02**	5	10	
14 – Redness (D)	Tibial Crest	Pin liner	759	182	N		8	9	
15 – Pain	Lateral Distal Tibia	Pin liner	156	112	Y		0	2	
16 – Pain	Fibula Head	Pin liner	512	270	Y		3	10	

15 out of 16 participants had their issues resolved after the intervention. The mean number of adjustments necessary to achieve this reduction was 2.6 ± 1.4 per participant. Following adjustments, the peak pressure value (Figure 5-2) showed a statistically significant change across all participants (p=0.001). The mean first peak pressure reading was 317 ± 208.9kPa, and the mean final peak pressure reading was 157.75 ± 97.54kPa. The paired T-test results showed the mean increase between the first SCS and final SCS was 2.625 (SD 2.45), (p=0.001) (Figure 5-3).

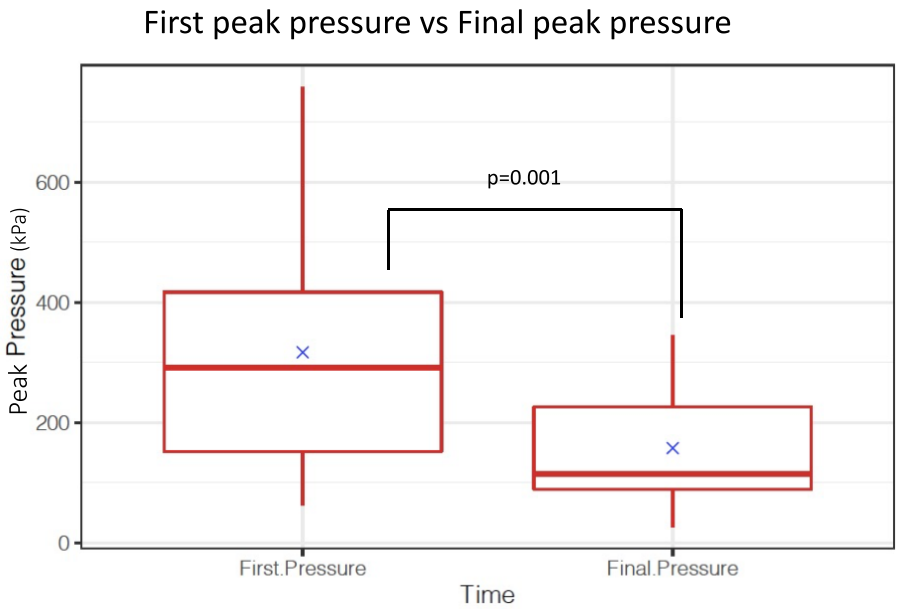

Figure 5-2. Box plot of First peak pressure and Final peak pressures. X indicates mean.

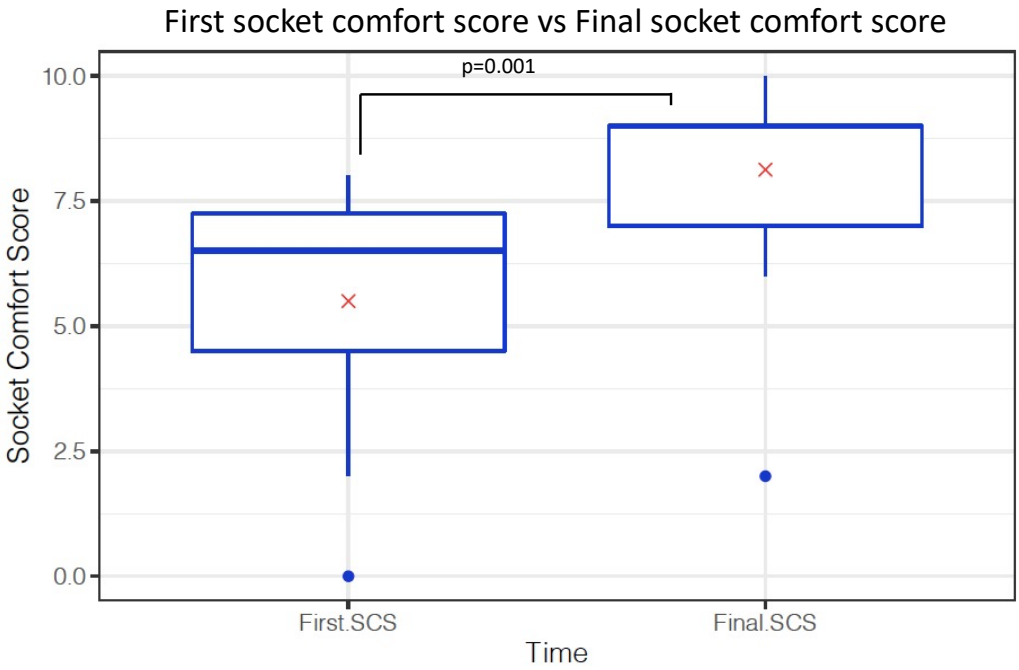

Figure 5-3. First and Final socket comfort score. X indicates mean.

There was normal Q-Q distribution when visually plotted. Pearson's correlation of (r=0.35, p=0.02) suggests a mild correlation between the change in pressure and the change in SCS (Figure 5-4).

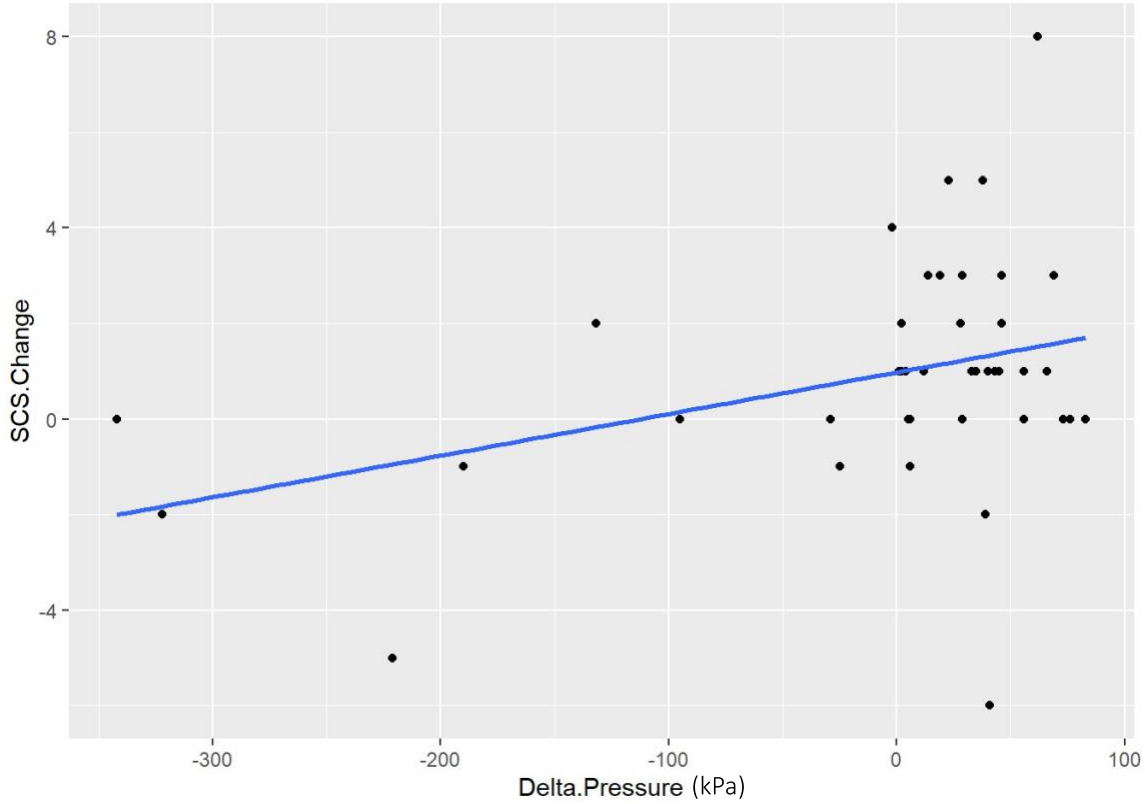

Figure 5-4. Correlation of Δ % change in pressure (kPa) vs. Δ SCS change.

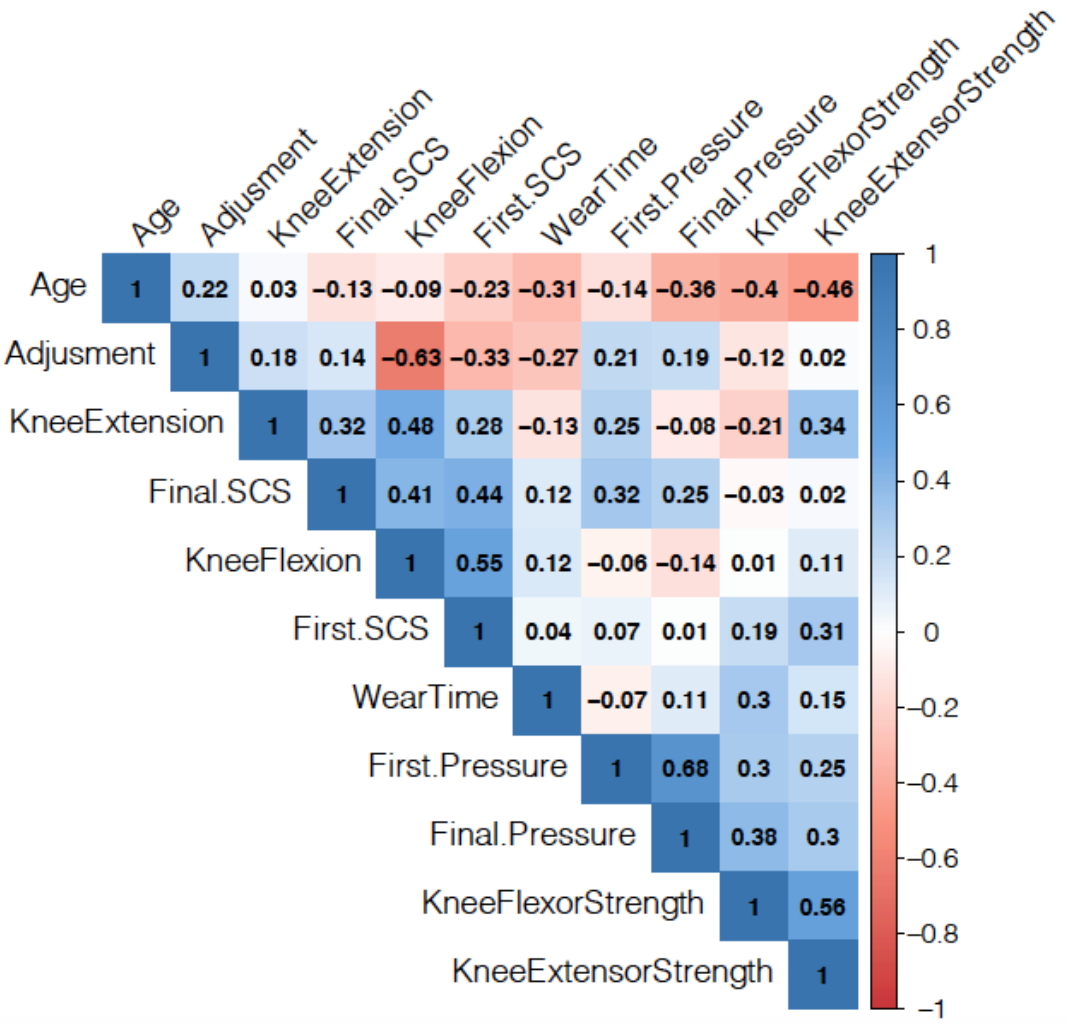

Figure 5-5. Correlation plot of R^2 variables. As the shades of blue deepen, the correlation between variables is stronger.

Further analysis (Figure 5-5) showed a moderate correlation between knee flexion ROM and first SCS (r= 0.55) but less correlation with the final SCS (r=0.41). There was also a moderate correlation between the first and final peak pressure measurement (r=0.68, p=0.001). Similarly, between knee flexion ROM and knee extension ROM (r=0.48), and between knee flexion strength and knee extension strength (r=0.56). Knee extension ROM was not significantly correlated to SCS or pressure values.

5.2.4 Discussion

Our first aim was to determine whether a peak pressure reduction assisted in resolving wounds, redness, or pain inside prosthetic sockets. Peak pressure values could not predict wound, redness, or pain resolving (p>0.05), with all issues resolving at various pressures. However, our results showed 15/16 cases of wound, redness or pain resolving when a reduction of 50% to first peak pressures was recorded (p=0.001). There are many factors affecting wound healing. We cannot state that reducing the pressure of this magnitude will resolve all issues and factors such as vascularization (Moreira & Marques, 2022).

Co-morbidities such as diabetes and arterial and venous insufficiencies (Sen, 2021), pressure, dressings, and nutrition (Gruen, 2010) should be considered. Variations in the extent and localization of perfusion, infection, patient characteristics, and treatment strategies such as offloading, reduced use, or additional gait aids may also be responsible (Eneroth, 1999). Surprisingly, we found that participants with or without diabetes had no significant differences for recovering from wounds, redness or pain, despite diabetes being a determinant for skin problems inside the prosthesis (Meulenbelt et al., 2009). The hours of prosthesis use per day for LLA with diabetes was less than non-diabetes-related amputations and could have assisted with the healing rates. Wound healing has been shown to continue even during exercise and prosthesis use when combined with strategies to relieve direct pressure and shear forces (Salawu et al., 2006). This trend is supported in our study, whereby we did not completely unload the skin breakdown site but instead decreased the pressure load in that area to provide healing and recovery. Our study also supports the growing body of literature (Hoskins, Sutton, Kinor, Schaeffer, & Fatone, 2014; Salawu et al., 2006; M. Zhang, Turner-Smith, & Roberts, 1994) that the prosthesis is safe to use despite the residual limb ulcers with appropriate socket adjustments.

Our results indicated that using a silicone liner did not improve comfort or prevent socket fit issues. 4/7 participants in the wound group and 5/9 participants in the non-wound group used a silicone liner. Such liners have been shown to enhance user comfort in some cases (Baars & Geertzen, 2005; Boutwell et al., 2012; Klute et al., 2010), but it is also associated with issues such as sweating(Klute et al., 2007), blisters (Ghoseiri et al., 2018), and hygiene (Hachisuka, Nakamura, Ohmine, Shitama, & Shinkoda, 2001). Perhaps due to the warmer climates in South-East Asia, the prescription of a silicone liner should be carefully considered, as it may not prevent all socket fit issues. The fact that issues still arise despite using a liner suggests that the shape and fit of the socket play an important role.

Our second aim was to determine whether peak pressures measured inside the prosthetic socket due to external forces could be used to quantify the level of improvement in socket discomfort. We found that absolute peak pressure values are not correlated with the comfort level experienced by the participants as measured via the SCS; however, a reduction of peak pressure at the wound site led to significant ($p=0.001$) improvement in the socket comfort score, improving by 2.6 ± 1.4 points. It could mean that the SCS may not be sensitive enough to such changes or that pressure is not the sole direct factor in determining socket discomfort. While the validation data shows repeatability, validity, and sensitivity of the SCS, the interpretation of the results remains ambiguous (Gailey et al., 2019). Although the SCS is a subjective outcome, when combined with objective measurements from a pressure sensor, it may prove valuable in quantifying change and providing feedback to the prosthetist and user. This is confirmed by another study (Fatone et al., 2014), which compared tissue loading and socket comfort, concluding that suboptimal pressures affected the SCS. Many factors contribute to socket comfort, including functionality, physical interaction, and psychological. However, as one of the goals of the

prosthesis is to provide the optimal stiff coupling for load transfer, careful consideration of interface pressures remains vital in the design.

Interestingly, we found a moderate correlation between knee flexion ROM and SCS. This finding of knee flexion association with SCS may emphasize the importance of function and quality of life in the SCS. Rehabilitation should continue to improve knee extension ROM preventing contractures, but attention should be given to knee flexion strength and ROM post-op to improve outcomes and decrease socket discomfort. This improvement may also facilitate the prosthetic alignment to aid in a better gait and reduce the risk of falls (Vanicek et al., 2009).

Our study showed that using a pressure sensor to quantify pressures within the socket and relating it to the SCS was useful in aiding adjustments and monitoring of wound, redness, and pain resolution. The sensor used in our study had high sensitivity, was lightweight, easy to use, washable, and conformed to irregular shapes. Other studies have been conducted with similar sensors, further reiterating the usefulness of such devices in the potential future care of amputees (Al-Fakih, Abu Osman, & Mahmad Adikan, 2016; Laszczak et al., 2015; Wheeler et al., 2016). By using the sensor to guide the adjustments made to the socket, prosthetists can rely upon the accuracy of the sensor to inform whether the adjustment has been successful and how much it has reduced the discomfort. The low number of adjustments necessary to achieve wound, redness, or pain resolution was 2.6 ± 1.4 per participant supports its efficiency and effectiveness. It would be useful to see if our skills and methods are comparable to other centers or whether improvement can be gained, and faster outcomes obtained.

The feedback from the sensor to the participant was equally valuable, as it substantiates their feelings of discomfort within the socket. Withholding the SCS and pressure readings of the participant until after each adjustment and after their feedback to the adjustment helped to limit the bias in the measurements. However, there is evidence that users may appease their prosthetists' efforts by suggesting an improved socket fit, even if they have not achieved reduced discomfort (Murray, 2013).

There are limitations in our study, and hence we should interpret the findings with caution. The small sample size of this preliminary study resulting from the recruitment difficulties associated with amputee studies limits its statistical power. The sensory deficits from the diabetic participants could have impacted the results. While 44% (4/9) of the participants had no sensory deficits, the remaining 5 participants did not have a sensory status in their clinical documentation. This could have led to the participants understating their discomfort levels and misinterpreting their comfort levels when assessing their SCS. The compromised sensation may also lead to unstated discomfort, depending on the severity of the missing sensation. Another limitation is the type of sensor used. The sensor was 1.9mm thick and may have interfered with the readings to determine peak pressure values. We used a single-point sensor

which indicated the pressure at only one point on the residual limb and did not provide a complete picture of the total pressures in the socket. It also cannot be confirmed that we have measured only the peak force and not the shear force inside the socket. However, the sensor was suitable to determine the pressure at the adjustment site regardless. The pressure recorded was the pressure caused by forces perpendicular to the sensor. It is known that shear forces contribute significantly toward tissue injury (M. Zhang et al., 1994) and cannot be excluded when examining the results. The sensor was also slightly thicker than other sensors in the market as we required enhanced durability and the ability to disinfect the sensor after each use.

5.2.5 Conclusion

Although the peak pressures values did not relate to the SCS score, the reduction in peak pressure saw significant improvement to the SCS. The wound, redness, and pain resolved in 15 of 16 participants regardless of diabetic status. Future care delivery could potentially consider using pressure sensors to quantify some aspects of discomfort. A portable pressure sensor facilitates a fast and efficient means of providing feedback when adjusting the socket fit to both the prosthetist and the user. When combining objective measurements such as pressure, with a subjective measurement scale such as the SCS, may prove valuable in quantifying changes to levels of discomfort.

5.3 Digitalization and Comfort

Digitalization is both a means to improving comfort and an influencing factor of comfort (Sections 2.5.1, 4.3.2). As demonstrated with the pressure sensor study, digital technology (DT) is useful in the quantification of comfort. However, adoption of DT appears inconsistent in its application to prosthetics. Therefore, we conducted an international survey to ascertain the adoption of DT, its perceived usefulness, and barriers, to determine the technological readiness of the industry.

The P&O industry is slowly transitioning into digital technology, whereby clinicians are experimenting with digital design processes and tools such as sensors, scanning, computer-aided design (CAD), and additive manufacturing (AM) to remove the subjectivity in the design process. This has led to end-users receiving innovative devices with enhanced outcomes. However, not everyone in the industry is embracing such practices. Evidence suggests that adopting a naive plug-and-play approach using optical scanning and AM for prostheses is unlikely to produce a satisfactory result (Hofmann et al., 2016; Olsen, Day, Dupan, Nazarpour, & Dyson, 2021), particularly if the user's expectations are not met with a positive experience when using DT and the digitally designed device. Digital technologies such as 3D optical scanning and AM are often presented in the media as ready-to-use solutions for producing low-cost, functional devices. However, public perceptions are shaped primarily by superficial media

representation and advertising (Olsen et al., 2021) and often fail to consider the design elements necessary to achieve an optimal outcome.

Customized prostheses are made to be either functional or aesthetic pleasing in the form of cosmetic limbs and optimized for the user (Pullin, 2009). The diversity of attitudes and attributes of a user and the appeal of digital technology have led to new combinations of materials and socket designs that enhance comfort and function. Prosthetic sockets can be made with AM that incorporates variable stiffness, enhancing static (sitting) and dynamic comfort. Additive manufactured sockets can also be adjustable, with panels that compress the leg using a boa cable system (Weller, Kleer, & Piller, 2015). AM can also be used to produce prosthetic interface liners with silicone that can be custom designed with additional padding, compression, and stiffness.

There are several challenges posed by the standard process (Section 2.4), including the amount of time needed and skills, material wastage due to subtractive manufacturing methods, the accuracy of measurement or fit and its associated discomfort, and the quality of the final product. DT and AM aim to improve these inefficiencies. The figure shows the digital product cycle of prostheses and orthoses, which highlights a manufacturing process that is cleaner and more efficient (Figure 5-6). However, the critical factor in applying digital workflows is that the end device must satisfy the functionality, comfort, and aesthetics requirements while keeping the cost competitive (Wang, Tan, Pu, Boone, & Zhang, 2020).

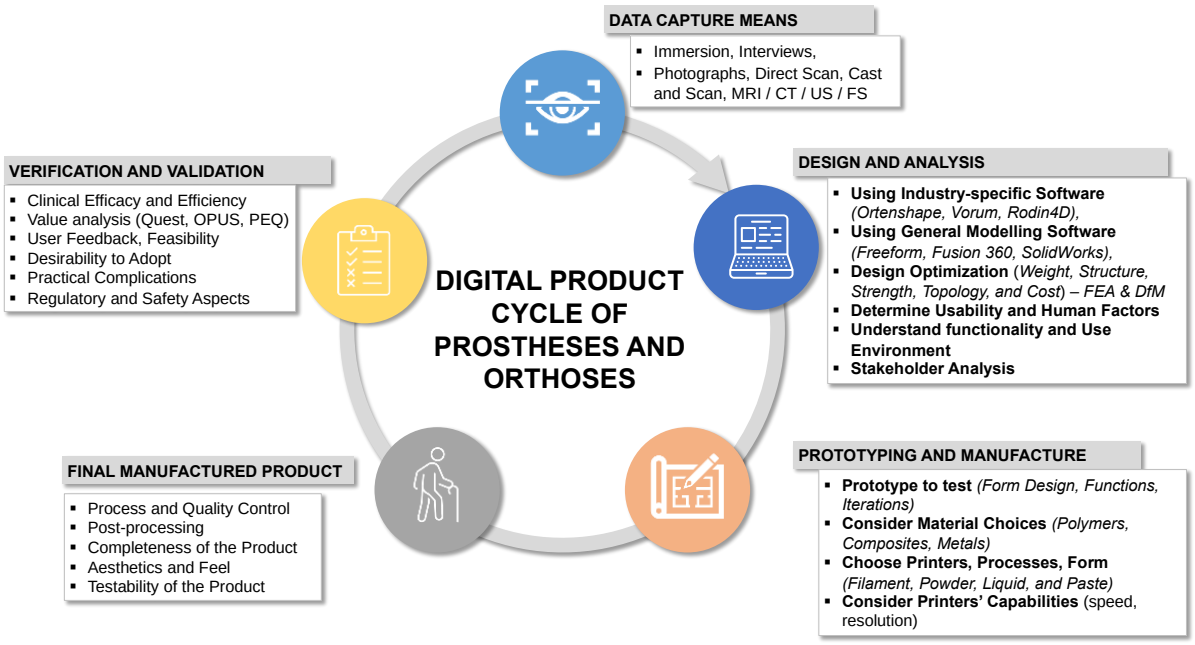

Figure 5-6. Digital Product Cycle and workflow of AM for Prosthetic and Orthotic Devices (Binedell & Subburaj, 2022)

Digital technology in this section refers to 3D scanners, tablets, computers, computer cloud-based software programs, and computer-aided design and manufacturing (CADCAM). Digital technology has successfully provided assistive devices assessment (Cason, 2009; Schmeler, Schein, McCue, & Betz, 2015), therapy services (Hall, Boisvert, & Steele, 2013), and diagnostic evaluations (Georgeadis, Brennan, Barker, & Baron, 2004). They have also eliminated distance obstacles from the health care (Lemaire, Fawcett, Nielen, & Leung, 2003).

5.3.1 Methods

An online survey was designed to survey practicing P&Os and lower limb amputees using a prosthesis on their use and attitudes towards digital technology (Appendix 3). This study was approved by the Institutional Review Board (IRB) at the Singapore University of Technology and Design. Interested participants agreed to a preceding statement of consent. A participant information sheet link was provided describing the survey, including the length of the survey, the purpose of the study, investigators, and how data would be collected and stored. The survey was hosted, and all data was stored on a secure server. Participants were asked for their email only if they agreed to a follow-up interview. This information was stored separately from the responses to maintain confidentiality. Participants were able to review and change their answers before submission. The authors developed the survey in conjunction with ProsFit Technologies (Sofia, Bulgaria) and tested it with 5 Singaporean P&Os. This data was not included in the final analysis but was analyzed to adjust the survey for errors.

The survey was open to participants who met the inclusion criteria. The survey was administered between June and July 2020 via the SurveyMonkey platform and was voluntary to complete. Participants were recruited via IRB-approved social media platforms like LinkedIn, WhatsApp, and social chat groups.

The 68 qualitative and quantitative survey items were divided into three sections, with adaptive questioning routing the participant to questions based on previous responses. The first section of the survey gathered Lower Limb Amputees (LLA) experiences and preferences. This included questions relating to prosthetic use, barriers to care, and opinions on the use of virtual assessments and home fittings. Section two was designed for the P&Os, who did not use digital technology in their facility (P&O-nonDT). Questions included the number of patients seen per day, attitudes towards digital technology, and its importance to the future of the profession. Section three was for P&Os, who currently use digital technology in their facilities (P&O-DT). Additional questions about the use and limitations of technology were included in this section.

All three sections included demographic questions and questions on virtual assessments or fittings. Various formats were used: multiple choice with single or multiple answers, ranking of answer options, 5-point Likert-scale, and open-ended questions. Where options were provided, the option "Other" was included to allow respondents to enter a different answer.

Follow-up interviews were conducted on selected patients and P&O respondents. Interviews were unstructured and conducted *via* face-to-face, phone, and email.

5.3.2 Data Analysis

Survey responses were analyzed with Stata/SE software (StataCorp LLC). Time stamps were collected at the start and end of the survey. All tests were carried out using a 5% level of significance. Answer options were presented as counts (%), mean (standard deviation), or median (interquartile range) as appropriate. Pearson's chi-square test was used to assess the difference between frequencies as observed and expected for certain answers.

5.3.3 Results

We received 113 survey responses, of which 83 were eligible for inclusion (n=13 lower limb amputees (LLA), n=70 P&Os). Surveys were excluded if less than 10% of the questionnaire were answered. On average, the survey took 13 minutes for the P&O to answer and 15 minutes for the LLA to complete.

5.3.3.1 Participants

Table 5-3 shows the demographics of the respondents. Singapore was well represented: although only 18.6% of the respondents (n=13), this constitutes 68% of all P&O in Singapore. LLA were from Singapore (n=12) and India (n=1). Follow-up interviews were conducted with LLA from Singapore (n=3) and with P&O who were using at least one form of digital technology (P&O-DT), Singapore (n=3), Thailand (n=2), Malaysia (n=1), and Cambodia (n=1).

Table 5-3. Demographics of the respondents

	Prosthetists/ Orthotists (n=70) n (%)	**Lower Limb Amputee (n=13)** n (%)
Age range		
18-24	5 (7.1%)	1 (7.7%)
25-34	**33 (47.1%)**	2 (15.4%)
35-44	22 (31.4%)	3 (23.1%)
45-54	8 (11.4%)	**4 (30.8%)**
55-64	2 (2.9%)	3 (23.1%)
Gender		
Male	41 (58.6%)	**13 (100%)**
Female	29 (41.4%)	0
Country		
SE Asia + Asia	n=56 (80%)	n=13 (100%)
Singapore	13 (18.6%)	**12 (92.3%)**
Myanmar	8 (11.4%)	0
Thailand	8 (11.4)8	0
Malaysia	7 (10%)	0
Cambodia	6 (8.6%)	0
Indonesia	4 (5.7%)	0
Sri Lanka	4 (5.7%)	0
India	3 (4.3%)	1 (7.7%)
Hong Kong	1 (1.4%)	0
Philippines	1 (1.4%)	0
Japan	1 (1.4%)	0
Middle East	n=2 (2.9%)	
Yemen	1 (1.4%)	0
Saudi Arabia	1 (1.4%)	0
Europe	n=8 (11.4%)	
Bulgaria	2 (2.9%)	0
UK	2 (2.9%)	0
Germany	1 (1.4%)	0
Ireland	1 (1.4%)	0
Scotland	1 (1.4%)	0
France	1 (1.4%)	0
Other		
Australia	4 (5.7%)	0

Table 5-4 shows the characteristics of the LLA respondents. LLA were primarily of K3 and K4 activity levels in the US Medicare Functional Classification levels (12/13, 92%) and had their amputation due to trauma (62%). They reported a long duration of daily use (mean 8.69 hours, SD 5.12), and a mean socket comfort score of 6.97 (SD 1.15). 11 out of 13 (85%) LLA had their prostheses measured using plaster and only 2 patients used only measurements. Zero LLA used scanning to make their prosthesis. LLA mobility was mostly impacted by pain, followed by the ease of wearing their prosthesis, their ability to access care, and the temperature.

Table 5-4. Characteristics of Lower Limb Amputees

	Lower Limb Amputee (n=13)
K2 – Community ambulator	1 (8%)
K3 – Unlimited community ambulator	7 (54%)
K4 – Unlimited and recreational sports	5 (38%)
Non-trauma (cancer, diabetes, vascular disease,)	5/13 (38%)
Trauma	8/13 (62%)
Mean hours of using prosthesis each day	
Min – Max	0 – 18
Mean (SD)	8.69 (5.22)
Median (IQR)	8 (6.3)
Level of comfort with a prosthesis (0=least comfortable, 10=most comfortable)	
Min – Max	4 – 9.4
Mean (SD)	6.97 (1.15)
Median (IQR)	7.3 (1.5)
Methods of casting	
Plaster wrap	11 (84.62%)
Scanning	0 (0%)
Measurement alone	2 (15.38%)
Mean ranking of factors most impact on mobility (SD)	
Pain	**2.46 (1.89)**
Easy to wear	2.92 (1.85)
Access to care	4.54 (1.51)
Breathability/temperature	4.54 (1.90)
Durability	4.69 (1.93)
Stability	4.85 (2.91)
Weight	4.92 (1.71)
Appearance	7.08 (1.66)

Table 5-5 shows the characteristics of the P&O respondents. The P&O had a mean of 9.33 (SD 7.37) working years. The mean number of patients seen per day was 5.81 (SD 4.28). Almost half of the P&O used digital technology (31/70, 44%). Singapore had (11/13, 85%) of P&O use digital technology compared to Myanmar (0/8, 0%)

Table 5-5. Characteristics of P&O respondents

	Prosthetist &Orthotist (n=70)	
Years of working		
Min-Max	1 – 32	
Mean (SD)	9.33 (7.37)	
Median (IQR)	7 (10.0)	
Number of patients seen per day		
Min-Max	0 – 20	
Mean (SD)	5.81 (4.28)	
Median (IQR)	4 (6.0)	
Using digital technology as part of work	**Yes (P&O-DT) 31 (44.29%)**	**No (P&O-nonDT) 39 (55.71%)**
SE Asia + Asia	n=24	n=34
Singapore	11	2
Myanmar	0	8
Thailand	4	4
Malaysia	1	6
Cambodia	1	5
Indonesia	2	2
Sri Lanka	1	3
India	0	3
Hong Kong	1	0
Philippines	0	1
Japan	1	0
Middle East	n=1	n=1
Yemen	0	1
Saudi Arabia	1	0
Europe	n=5	n=3
Bulgaria	2	0
UK	1	1
Germany	0	1
Ireland	1	0
Scotland	1	0
France	0	1
Other		
(Australia)	3	1
Years using technology	**(n=31)**	
Min-Max	0.5-24	
Median	2	

5.3.3.2 Use and Types of Technologies

The number of years the P&Os who use digital technology have been doing so varies greatly, from 0.5 to 24 years, with a median of 2 years. Many of the P&Os had CADCAM facilities where they worked (23/31, 74%). The iPad with a structure scanner was the preferred method for digital capture (12/31, 39%) with a mix of other scanners used, including Artec Eva Lite, Omega, and Rodin 4D. Geometrical modifications of the scans were performed using various programs, which can be grouped into P&O-

specific software (24/31, 77%) and engineering software such as Rhinoceros or Solidworks (6/31, 19%). One P&O respondent was unsure of the program they use (1/31, 4%).

Figure 5-7 shows the application areas of the technology. Predominantly, the technology seems to show that taking digital photos to monitor care and to inform the design (27/31, 87%) is the most common use, followed by scanning for custom footwear (18/31, 58%). Approximately half of the subjects would scan for an AFO, spinal braces, transtibial or transfemoral sockets.

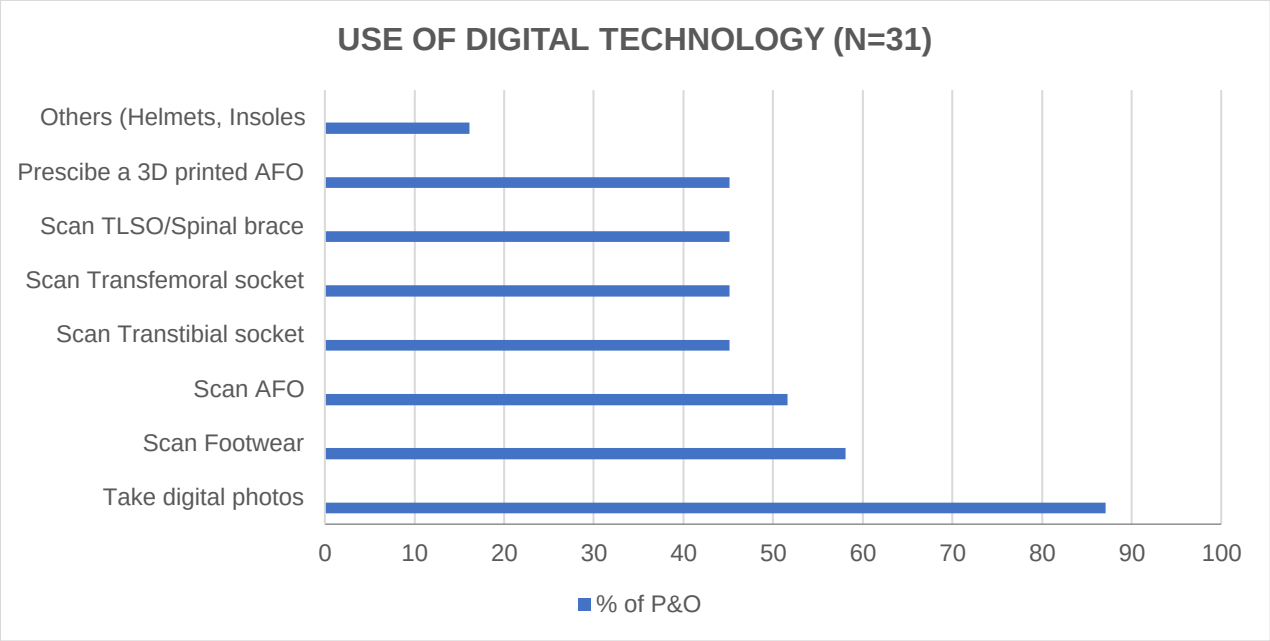

Figure 5-7. The applications of digital technology used in clinical practice.

5-point Likert-scale questions showed that the attitudes towards digital technology among P&O using technology were generally positive (Table 5-6). 24 out of 31 (77%) of the respondents agreed or strongly agreed that it improves patient outcomes. The majority of participants agree that they have the necessary skills to incorporate digital technologies (25/31, 81%) and acknowledge a strong need to continue using the technology to maintain efficacy and improve skills (30/31, 97%), while approximately two-thirds (20/31, 65%) are conscious that patients prefer them to use digital technology for their care. However, just over half (17/31, 55%) agreed that 3D printed devices were cost-effective, and 22 out of 31 (71%) felt that digitally produced prosthetic and orthotic devices did not fit better than traditionally made ones.

Singaporean P&Os who use technology agree significantly less strongly (P=.04) than non-Singaporean P&Os that the future of prosthetics and orthotics is digital. Interviewees from Singapore suggested their current experience with technology has been both positive and negative, limiting their expectations

for the future. They felt a need to use digital technology "for appropriate cases" or "when they improve efficiencies such as casting for a large transfemoral socket or making a scoliosis brace." One interviewee stated that using digital software to "modify such large devices was more efficient and required less physical strength."

The common barriers to greater integration of digital technology (DT) for the P&O-DT respondents as obtained using open-ended questions, can be seen in Figure 5-8. The top barriers were cost (11/31, 35%) and the lack of skills and training (10/31, 32%). The third identified barrier was the effectiveness of technology (6/31, 19%). P&O-DT cited material strength, the need to outsource, and the constant software updates limiting the effectiveness of greater integration. These main barriers were similar to P&O-non-DT, highlighting an ongoing need for continual financial reinvestment and training even when digital services have been established.

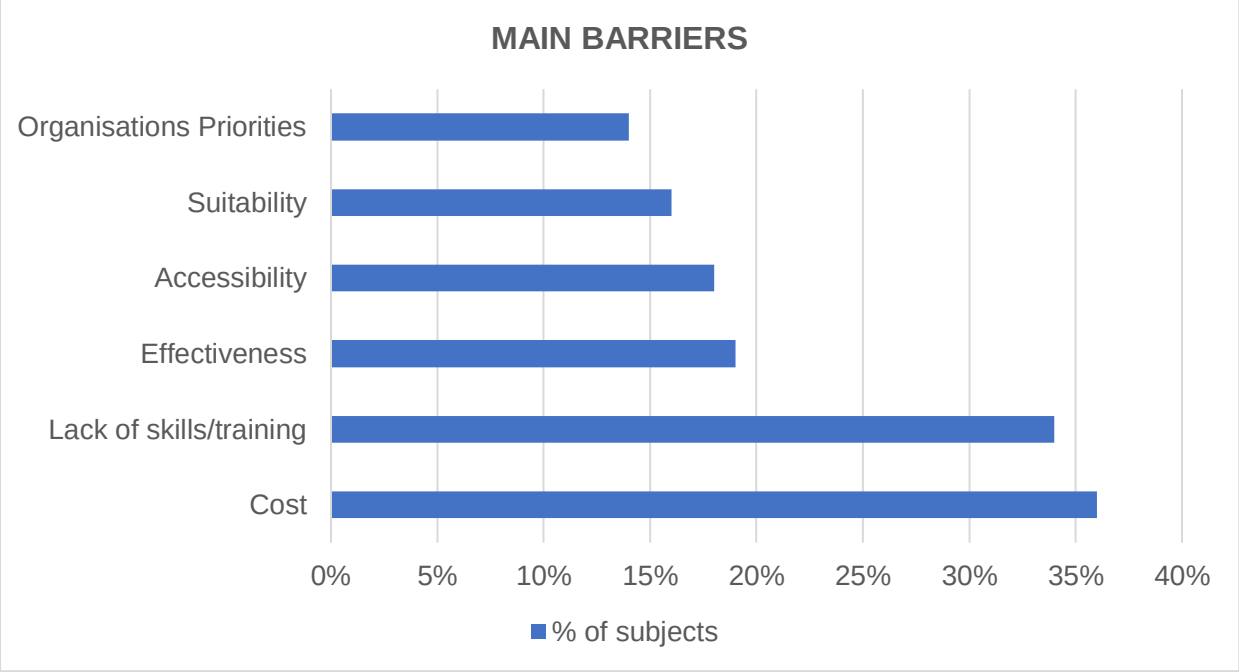

Figure 5-8. Barriers to greater integration of technology (n=31, P&O who use technology).

Table 5-6. Attitudes of P&O who use digital technologies at work

	Total (n=31)	**Singapore (n=11)**	**Non-Singapore (n=20)**	***P* value**
Digital technology improves patient outcomes				
Strongly Agree	9 (29%)	2 (18.2%)	7 (35%)	0.125
Agree	15 (48.4%)	8 (72.7%)	7 (35%)	
Disagree	7 (22.6%)	1 (9.1%)	6 (30%)	
Strongly Disagree	0 (0%)	0 (0%)	0 (0%)	
Patients prefer me to use digital technology when making their devices				
Strongly Agree	4 (12.9%)	3 (27.3%)	1 (5%)	0.123
Agree	16 (51.6%)	6 (54.6%)	10 (50%)	
Disagree	11 (35.5%)	2 (18.2%)	9 (45%)	
Strongly Disagree	0 (0%)	0 (0%)	0 (0%)	
It is important to practice with the hardware/software to be more efficient and effective.				
Strongly Agree	21 (67.7%)	8 (72.7%)	13 (65%)	0.276
Agree	9 (29%)	2 (18.2%)	7 (35%)	
Disagree	0 (0%)	0 (0%)	0 (0%)	
Strongly Disagree	0 (0%)	0 (0%)	0 (0%)	
Missing	1 (3.2%)	1 (9.1%)	0 (0%)	
I do not have the technical skills to use digital technology with my patients.				
Strongly Agree	0 (0%)	0 (0%)	0 (0%)	0.188
Agree	5 (16.1%)	0 (0%)	5 (25%)	
Disagree	20 (64.5%)	8 (72.7%)	12 (60%)	
Strongly Disagree	5 (16.1%)	2 (18.2%)	3 (15%)	
Missing	1 (3.2%)	1 (9.1%)	0 (0%)	
Digitally produced devices always fit better				
Strongly Agree	2 (6.5%)	0 (0%)	2 (10%)	0.554
Agree	5 (16.1%)	1 (9.1%)	4 (20%)	
Disagree	22 (71%)	9 (81.8%)	13 (65%)	
Strongly Disagree	0 (0%)	0 (0%)	0 (0%)	
Missing	2 (6.5%)	1 (9.1%)	1 (5%)	
3D printed devices enable high cost-effectiveness				
Strongly Agree	2 (6.5%)	0 (0%)	2 (10%)	0.394
Agree	15 (48.4%)	4 (36.4%)	11 (55%)	
Disagree	11 (35.5%)	6 (54.6%)	5 (25%)	
Strongly Disagree	1 (3.2%)	0 (0%)	1 (5%)	
Missing	2 (6.5%)	1 (9.1%)	1 (5%)	
The future of prosthesis and orthosis industry and practice is digital				
Strongly Agree	12 (38.7%)	2 (18.2%)	10 (50%)	***0.038****
Agree	16 (51.6%)	9 (81.8%)	7 (35%)	
Disagree	3 (9.7%)	0 (0%)	3 (15%)	
Strongly Disagree	0 (0%)	0 (0%)	0 (0%)	

* $P<0.05$

5.3.3.3 Non-Use of Technologies

Where non-use of technology was common, stable internet was still a problem, particularly in developing countries such as Sri Lanka (2/3, 66%), Cambodia (2/5, 40%) and Myanmar (2/6, 33%). Many of the P&O respondents in these countries did not have computers (35/39, 89%). Other reasons mentioned for not using technology were cost (25/39, 64%) and the lack of awareness and skills (20/39, 51%).

5.3.3.4 Virtual Care

The use of virtual assessments and virtual fittings were analyzed for agreement. A primary benefit of virtual services is to reach those who face obstacles in coming to their appointments. 29 out of 70 (41%) of all P&O respondents felt their patients had difficulties coming for their appointments. The main reasons mentioned were transportation (16/70, 19%), cost (11/70, 13%), and the lack of family members or caregivers to bring them to their appointment (9/70, 13%). P&O respondents found that virtual assessments benefit patients in these situations (59/70, 84%). Interestingly, 11 out of 13 (85%) of LLA did not find access to care an issue and preferred to come to the clinic for their follow-ups.

51 out of 70 (73%) of P&O respondents would use virtual assessments if made available. Most respondents agreed or strongly agreed that virtual assessments would be suitable in rural areas (47/70, 67%), but just over half suggested virtual fittings would improve patient outcomes (38/70, 54%). The potential benefits mentioned were to save clinical time and reduce the need to travel (32/70, 46%), this often reduces costs (17/70, 24%), and – of relevance during this current pandemic – 10 out of 70 (14%) suggested it would be safer for the patient and decrease the risk of infection.

Some confusion arose when P&Os were asked about the format of the virtual assessments. 5 out of 7 (71%) of selected interviewees revealed they had merely agreed to the statement without thinking about how they might apply this service. Suggestions for the service included a "*triage-like*" service or checking "*simple things like whether all is well or not*" to "*assess the problem*" and "*determine whether a trip to the clinic was necessary*." When asked if they felt patients would be willing to pay for this service, many '*did not think so*" unless "*it adds value*." The LLA responses concur with these statements. Only 6 of the 13 surveyed LLA are prepared to pay for this service, with (3/3 100%) of the LLA interviewees agreeing only if their needs were met.

The significant potential challenges with virtual assessment mentioned by the P&O respondents were difficulties in assessing the limb for strength, ROM, palpation, and pain (26/70, 37%). Other problems were concerns about the skills the patient had to use items such as computers (12/70, 17%), the high chance of miscommunication when giving advice (11/70, 16%), and internet connectivity (8/70, 12%).

27 out of 70 (39%) of P&O respondents were open to virtual fittings using a third person 'fitter,' with 15% considering it depending on the fitter's skills and training. The main benefits cited were that it provides greater outreach and maintains the ability to overcome common barriers like the need to travel to the clinic. When the P&Os were asked about patients doing the task of fitting themselves, safety concerns were mentioned during the interviews, despite LLAs feeling confident in their ability (Table 5-7). There were mixed results for the level of confidence LLA have to adjust their own prosthesis with or without internet guidance. We found that those LLA who were less confident with internet guidance than themselves tended to be over 45 years of age.

Table 5-7.The confidence of LLA adjusting their own prosthesis (n=13)

Confidence in adjusting the prosthesis	**By self**	**With internet guidance**
Extremely confident	4 (30.8%)	4 (30.8%)
Very confident	2 (15.4%)	1 (7.7%)
Somewhat confident	4 (30.8%)	2 (15.4%)
Not so confident	0 (0%)	**5 (38.5%)**
Not at all confident	3 (23%)	1 (7.7%)

5.3.4 Discussion

5.3.4.1 Principal Findings

To date, research has focused on developing digital technologies or how new technology can be applied to the industry for a particular application. This survey reports the current use of digital technologies in the prosthetic and orthotic industry and suggests its suitability in practice. Current adoption levels of technology suggest the potential benefits of safer care have not outweighed the limitations of the technology to provide sufficient value to both the patient and P&O. Furthermore, changing organizational behaviors in delivering digital healthcare requires the right skills among healthcare professionals to leverage technology-driven solutions towards technology adoption.

5.3.4.2 Use

Approximately half of the P&O respondents use some form of digital technology. The use of scanners, computers, and CADAM are the most common ones. The use of scanners provides a cleaner and faster means to capture data.

The P&O respondents preferred the more cost-effective iPad with a structure scanner (Occipital) over accurate high-end scanners such as Vorum's Spectra scanner or Artec EVA scanner. P&O interviewees stated that the wireless iPad was easier and lighter to maneuver to capture the limb shape but can be limiting when capturing the posterior view due to the screen's position forcing an awkward posture of the person scanning. This finding is aligned with a study by Brunsman et al., where the positioning of the human body for surface scanning required an assortment of body postures to make all essential areas visible, and the direction the subject faces can affect the quality of the scan (Brunsman, Daanen, & Robinette, 1997). This repositioning may not reduce the prosthetist-patient contact as intended when trying to minimize cross-contamination. The lead author's opinion, as a principal P&O with over 21 years of experience, is that having a small hand-held external camera connected via a cable or wirelessly to an external screen to view the captured image would be a simple solution to overcome these issues.

The use of low-cost cloud-based engineering modeling and analysis software programs such as Rhinoceros (Robert McNeel & Associates, North America), Fusion360 (Autodesk, United States), and Solidworks (Dassault Systèmes, France) was also common due to their affordability, usability, and applicability. The P&O respondents stated that more training and skills are needed to increase the adoption of technology despite such software. The use of point and click options in software (Colombo, Facoetti, & Rizzi, 2013) may remove the need for advanced CAD skills, making the technology more appealing and user-friendly (Barrios-Muriel et al., 2020).

Interviewees appreciated the improved efficiencies of digital scanning and software for making larger casts like transfemoral sockets or spinal braces. Stating that these types of casts can be modified using preloaded templates in the software in a shorter time than physically removing or adding plaster via traditional methods. This process is more convenient, safer for the patient, and faster for the P&O.

The use of 3D printing is often touted as the next big transition for the Industry (Nguyen et al., 2018). Our results suggest its use is relatively low. 3D printing is similar to traditional production methods, where getting throughput, part demand, and production planning is necessary to minimize part manufacturing costs ("The Real Cost of 3D Printing - 3DPrint.com | The Voice of 3D Printing / Additive Manufacturing,"). 3D printing may change how many products are developed and produced and herald an era of "personal manufacturing" (Bogue, 2013). They also provide an efficient and safe manufacturing process; however, unless a facility is consistently 3D printing prostheses or orthoses, outsourcing is more economical.

5.3.4.3 Barriers

The main barriers (cost, lack of skills/experience, and effectiveness of the technology) to adopting digital technology were found to be the same issues preventing greater adoption in facilities already using digital technology.

The initial cost outlay in purchasing scanners, computers, or 3D printers can cause apprehension over the ROI. Interviewees reported that prosthetic and orthotic specific software requires special training, software updates and yearly licensing, often based on the number of modules needed, adding to the cost, and deterring more users from greater adoption. The use of 3D printing is limited by the same factors identified in a systematic review of 3D printed sockets (Nguyen et al., 2018), including the quality of the part, choice of materials available, and cost-effectiveness. Literature also points to associated costs of printing ignored when compared to traditional methods, including; the additional material costs for support structures, machine utilization rates, labor and print preparation, machine maintenance, and error costs ("How much does 3D printing cost? 3D Printing Price Calculator - Bitfab,").

Even though the design and manufacture of highly accurate prostheses and orthoses are possible with the help of digital technology, it was concerning to see that most P&Os who already use digital technology did not find the devices a better fit. This result may be attributed to the need for ongoing training and practice to enhance the skills: most P&Os only used the technology for less than five years. Another reason could be the printing quality, which has increased over recent years but still requires more expensive printers.

The use of scanning for AFOs was high. Still, limitations in contactless scanning were voiced during the interviews, as the P&Os would often need to position the limb on a clear Perspex plastic scanning platform or the ground before scanning. Scanning residual limbs for prosthetic sockets was easier. However – as discussed earlier – positioning the scanner still remains troublesome to obtain a full 360-degree image with multiple positions needed to capture the entire shape (Brunsman et al., 1997).

Our survey suggests a low use of digital technology for transtibial socket design, with the LLA respondents complaining of poor design, fit, and ease of wearing their prostheses as major factors inhibiting their mobility. This is despite digital technology such as Finite Element Analysis, MRI, computer tomography, and photogrammetry showing benefits to improve outcomes by predicting accurate interface pressures through better imaging of the muscles and tissues. It also allows further optimization in the design of comfortable, high-quality devices (Hernandez & Lemaire, 2017; Nayak et al., 2015, 2017; Nehme & Dib, 2016; Rotariu et al., 2015).

5.3.4.4 Virtual Care

Patient

85% of the LLA did not find access to care an issue and preferred to follow-up at the clinic. It should be noted that all but one patient was from Singapore. Almost half of all P&O respondents outside Singapore found their patients had difficulties coming for their appointment. This is at odds with other countries where patients are more comfortable with telemedicine (Sutherland, Stickland, & Wee, 2020). Our study did find support for virtual assessments from the P&O interviewees, who noted it was safer for patients and protected them from possible virus infections.

Questions remain about what types of tasks are suitable for virtual care: all P&O interviewees suggested that triaging a patient or providing education to patients may be most appropriate. The NHS program "Attend anywhere" suggests that virtual care is only helpful if it results in improved efficiencies, significant time savings, reduced need to take time off work, no travel costs, and no technical issues (E. Donaghy et al., 2019). Our study also showed the lack of IT skills and connection issues of the patients as concerns, highlighting the need for reliable infrastructure. Although virtual care would be an excellent solution for patients in remote areas and developing countries, this is also where infrastructure is likely to be poor. These results align with Mihalj et al., who describe five factors that support telemedicine implementation. These include technology (broadband and connection) that must support both the healthcare provider and patient; secured platform; training for healthcare providers; patients need to be educated on privacy, safety, efficacy, and personal benefits; cognitive and hearing impairments are addressed (Mihalj et al., 2020).

In a telehealth consumer study in the US, the authors found that 66% of patients were willing to use telemedicine in 2019, but only 8% had used it previously. The authors suggest that the main reasons were the lack of familiarity with the new technology and a lack of trust in the clinician whom they had not met in person (Portnoy, Waller, & Elliott, 2020). The emotional connection to the clinician is equally important in telehealth adoption. Knowing that the consultation focuses not only on the immediate healthcare needs but the emotional support is critical to gaining loyalty from the patient (Wu et al., 2019).

Both LLA and P&O respondents highlighted this same trust issue in this study. Any change in the care model in an industry that customizes devices should reflect a strong need for such change. By merely moving consultations online, we may overcome some barriers found in this study, such as the travel burden, the lack of support to bring patients to their appointments and reduced overall costs. However, there appears to be a need to develop a rapport between P&O and LLA before the use of virtual care,

and certain P&O tasks may be challenging to fulfill (see next section). A thoughtful application and design of digital technology are needed, considering all stakeholders involved.

Prosthetist/Orthotist

Concerns over how to conduct shape capturing, residual limb assessment, palpation, and gait analysis may limit the effectiveness and adoption of digital technology unless it can be developed to overcome these challenges. The lack of touch and feel was found to be a significant hurdle to adoption. Virtual assessment tools allow implementing triage at the point of need (Bashshur, Doarn, Frenk, Kvedar, & Woolliscroft, 2020), but advice-only consultations may not prove valuable. LLA suggested they may be unwilling to pay for such services. Both LLA and P&O respondents are used to a consultation/physical contact combination. The information garnered through physical examinations, such as tissue consistency, and identifying painful areas or range of movement (ROM), may prove challenging to overcome in a virtual setting.

In rural settings, our survey suggests that the use of virtual care may be more suitable. This study found that P&Os would use virtual care where patients travel long distances for care or are too sick to come to a facility. However, in such rural locations, there may be other challenges, such as internet connectivity and the IT skills of patients, limiting its applicability (Mihalj et al., 2020). Our survey suggested using a third local person to assist with data collection and fitting devices, which might help overcome some limitations. Attitudes towards the use of such a person were mixed. They would need sufficient competencies to ensure the appropriateness and quality of care. In the case of pandemic-related social distancing laws, the viability of such a third-person service would also be affected. Third person or support staff was used as a means to provide care in rural New South Wales, Australia, in combination with video calling for the provision of AFOs (Goodchild, Frain, Chhun, & Fuller, n.d.). In this study, the authors trialed the assessment of the ROM over a video call with a third person performing the task. They found that when using the primary caregiver as the third person, the measurements of the ROM were less accurate than the P&O. However, when a third person has a healthcare background, the results were acceptable, suggesting a possible minimal educational background.

5.3.4.5 Hospital/Facility

The impetus for change and adoption of digital technology varies based on the funds and infrastructure available. Budgets may be too small to invest in digital technology and training, government support may be low, and the utilization may be too infrequent to justify the investment. The purchasing power to outsource may also present challenges, particularly if it is too low. Digital technology would be more

widely adopted if it demonstrated enhanced patient care and outcomes and lowered overheads of the facility, provided the infrastructure of the country can support the technology.

5.3.5 Limitations and Conclusions

Our online survey was developed to understand digitalization in the P&O industry abroad and provide context for the use of DT in the prosthesis design process method. The length of the survey may have been the reason why 30 of the 113 respondents answered less than 10%. Furthermore, as this was an online survey, only respondents with an internet connection would be able to respond. This may have particularly affected the number of LLA responses; 12 of the 13 LLA respondents were from Singapore, contacted through the amputee support chat group, where internet connection is not a barrier. The P&O respondents may have been less affected as they could have used internet connections at work. Another reason for the low LLA response might be that they were contacted indirectly via their P&O or that multiple survey languages were unavailable.

The responses for Singapore are considered an accurate reflection of the P&Os' use of digitalization, with over 65% of all P&Os in Singapore participating. Although the other respondents came from many countries, their numbers were limited. The study is, therefore, not representative of current practices outside of Singapore, even though the results are informative.

The utilization of digitalization, scanning, and virtual care provides avenues for the continuum of care for the patient. However, essential characteristics of P&O assessments, such as palpation and sensory feedback, have yet to be overcome. Right citing the patient with the appropriate technology and answering what needs the technology is addressing is essential and may encourage adoption in the industry. Education and training should be provided to centers and individuals to enhance confidence levels and awareness of digital care benefits. Ensuring the staff has a high technology readiness level is critical. The delivery care model should be evaluated to provide sufficient outreach and an optimal level of digital technology that provides adequate care.

Technology advancements, such as virtual platforms, digitalization methods, and improved connectivity, will change the future of healthcare. Digital technology is transforming healthcare into a new normal and is being accelerated due to recent pandemics. This transformation is expected to continue in the years to come. The prosthetic and orthotic industry should keep an open mind and move towards creating the required infrastructure to support this digital transformation or risk being left behind.

5.4 Summary

This chapter provided further understanding the role quantification plays in assess and designing for comfort. Importantly, the digitalization survey identified several advantages and potential barriers to its use which could affect comfort levels in a prosthesis. The importance to use DT such as sensors to indicate levels of comfort helped to address the second objective in this thesis "identification and evaluation of digital technology potential."

The research to date has address the literature, user perspective, quantification to compliment qualitative knowledge and the role digitalization may play. As a result, of this new knowledge, several solutions were evaluated to contextualize comfort in Asia. This would help to provide insights to RQ2 and RQ3.

6 DESIGNING COMFORT – PRODUCT IMPROVEMENT

6.1 Introduction

The previous chapter discussed potential application of a pressure sensor to compliment qualitative user information and the opportunities to explore the role of DT to further understand comfort. This chapter will focus on combining the findings from chapters 2,4, & 5, into three potential solutions to improve comfort. Comfort solutions are lacking in the prosthetics industry with most research on functional outcomes and the componentry that seeks to achieve this. Therefore, it was important to find solutions to address pain points of the users identified in Chapter 4.

The first solution involves the design and development of a method to determine the Lines of Non-Extension (LoNE) of transtibial amputations. The LoNE are explained in detail (Section 6.2). The second solution involves the design and development of a sweat reducing prosthesis liner to address the physiological comfort factor of thermal regulation, expressed as one of the main problem issues with prosthesis in South-East Asia (Section 6.3). Following this, a case study is presented utilizing digital technology to create a comfort-driven design process and product of a forequarter prosthesis for a user (Section 6.4). The case study assists to provide information related to RQ2.

The following articles are referenced throughout this chapter and the full texts can be found online for further reference.

Binedell, Trevor, Karupppasamy Subburaj, Yoko Wong, and Lucienne TM Blessing. "Leveraging digital technology to overcome barriers in the prosthetic and orthotic industry: Evaluation of its applicability and use during the COVID-19 pandemic." *JMIR Rehabilitation and Assistive Technologies* 7, no. 2 (2020).

Binedell T, Gupta U, Sithanathan B, Subburaj K, Blessing L.T.M. “Mapping Lines of Non-Extension in persons with lower limb amputation to aid comfort-driven prosthetic socket design”. *Medical Engineering and Physics*. (Submitted 23rd August 2022)

T. Binedell, E. Meng, K. Subburaj, Design and Development of a Novel 3D-printed Non-Metallic Self-Locking Prosthetic Arm for a Forequarter Amputation,” *Prosthetics and Orthotics International*, (**2020**), 45 (1), 94-99. [PMID: 33834751]

6.2 Lines of Non-Extension

Current prosthetic socket designs for people with transtibial amputation are categorized into four main groups: 1 - patellar tendon bearing, 2 - total surface bearing, 3 - hydrostatic, and 4 - vacuum-assisted

suction sockets (Safari & Meier, 2015). Each design is based on either gait biomechanics, soft tissue tolerant or intolerant areas, volume matching, or elevated negative pressure, which reduces the pistoning effect and improves the mechanical coupling between the residual limb and prosthesis (Ghoseiri et al., 2018). “As the prosthetic socket provides the necessary attachment between the residual limb following amputation and the prosthetic device, each socket is made bespoke to the user and is designed in a manual and iterative process by a prosthetist” (Steer, Worsley, Browne, & Dickinson, 2020). Thus, for persons with lower limb amputation, where the soft tissues must bear large loads, great care is taken in the prosthetic socket design to minimize discomfort and possible tissue trauma (Silver-Thorn et al., 1996).

The prosthetic socket must provide an intimate fit around the residual limb producing minimal movement (Safari & Meier, 2015). Relative movement between prosthesis and stump increases shear frictional forces that lead to tissue breakdown and wounds. A poorly fitting prosthetic socket could also influence the use of a prosthesis. The comfort of the prosthesis is necessary for the user's overall quality of life and satisfaction and prevents prosthesis abandonment (see Section 2.1). Physical comfort depends on several factors, including socket type and shape, interface materials, and suspension approaches (Stevens, Depalma, & Wurdeman, 2019). Usability, stability, and safety are other essential requirements in developing prostheses (Barrios-Muriel, Sanchez, Alonso, & Salgado, 2019). In designing devices that interact with the human body, the mechanical properties of the soft tissues should be known. If not well understood, any relative motion and tangential strains between the device and skin could lead to complications such as wounds (Barrios-Muriel, Rodriguez Jiménez, Romero Sánchez, Alonso Sánchez, & Rodriguez Salgado, 2018; Kwiatkowska, Franklin, Hendriks, & Kwiatkowski, 2009) as identified in Chapter 5.

There is an extensive understanding of human skin properties based on active tensile testing, both in in-vitro and in-vivo settings. (Iberall, 1970), demonstrated areas of the skin where during body motion, no deformation occurred as the skin rotated during the movement, known today as Lines of Non-Extension (LoNE) (Figure 6-1). However, there remains little current knowledge of the strains experienced by the skin during natural movements (Wessendorf & Newman, 2012). Given its heterogeneous mechanical properties, measuring skin strain is a challenge that needs to be addressed (Lin, Moerman, McMahan, Pasch, & Herr, 2017).

Figure 6-1. Lines of Non-Extension for the human lower limb, Adapted from (Iberall, 1970). (A) Anterior view of Lines of Non-Extension, (B) Posterior view of Lines of Non-Extension.

Several researchers have studied LoNE using different methods, including full-motion capture analysis (Wessendorf & Newman, 2012) and inexpensive methods (Lin et al., 2017). These LoNE have previously been incorporated as a design criterion for products in areas with low movement and minimum strain to support the structure of wearable devices (Forner-Cordero et al., 2008; Mitchell, Medland, & Salo, 2007). The use of LoNE in products reduce repetitive friction in the skin during daily motion and, in turn, prevent skin damage (Barrios-Muriel, Romero Sánchez, Alonso Sánchez, & Rodríguez Salgado, 2019). This concept has been attempted to optimize comfort in several works, such as spacesuits (Wessendorf & Newman, 2012), clothing (Seo, Kim, Cordier, Choi, & Hong, 2013), and prostheses or orthoses (Barrios-Muriel, Sanchez, et al., 2019; Lin et al., 2017; P. C. Silva, Silva, & Martins, 2010), but further research is needed to verify and validate the results.

Despite the large applications in the rehabilitation field, the number of studies related to this subject is low (Barrios-Muriel, Sanchez, et al., 2019), and there has been very little work on transferring results of the skin strain field and LoNEs to the design of a product (Barrios-Muriel et al., 2018). To optimize the comfort of a prosthesis, its properties at the interface with the skin could be modified to accommodate the natural skin deformation pattern (Lin et al., 2017). Therefore, the skin strain field may represent a design opportunity for optimizing the interface between skin and product, much like a second skin (Barrios-Muriel, Sanchez, et al., 2019; H. Herr, 2009).

In this study, we aimed to obtain the skin strain field map of the residual limb following a transtibial amputation by calculating the minimum and maximum strains and finding the directions of the non-extension lines. Also, we placed a constraint on designing and developing this method using simple, low-cost video equipment and 2D skin marker application to highlight a cost-effective and clinically applicable process.

6.2.1 Methods

Participants

Five volunteers were recruited using purposive sampling from an amputee support group in Singapore. During the study briefing, all participants were given informed consent. The institutional review board (IRB) of the Singapore University of Technology and Design approved the study protocol. The included participants met the following criteria: unilateral amputees at the transtibial level due to either diabetes, trauma, infection, or skin disease; using a prosthesis for longer than six months.

Methodology

The methodology has 3 main sections: data acquisition, model reconstruction, and generation and localization of Lines of Non-Extension (Figure 6-2). A DSLR camera (FUJIFILM, X-A5/XC15-45MM, resolution full HD 1080/59.9P, FUJIFILM, Tokyo, Japan) was used to acquire the position of markers on a subject's leg to measure the skin's strain at multiple points (a strain field) during flexion and extension. We then compared the residual limb of multiple subjects to determine whether a similar strain field is observed among people with an amputation. 3-D skin measurements recorded during the entire motion allowed us to confirm and quantify calculated LoNE and identify skin contours exhibiting minimum extension or minimum compression (Wessendorf & Newman, 2012).

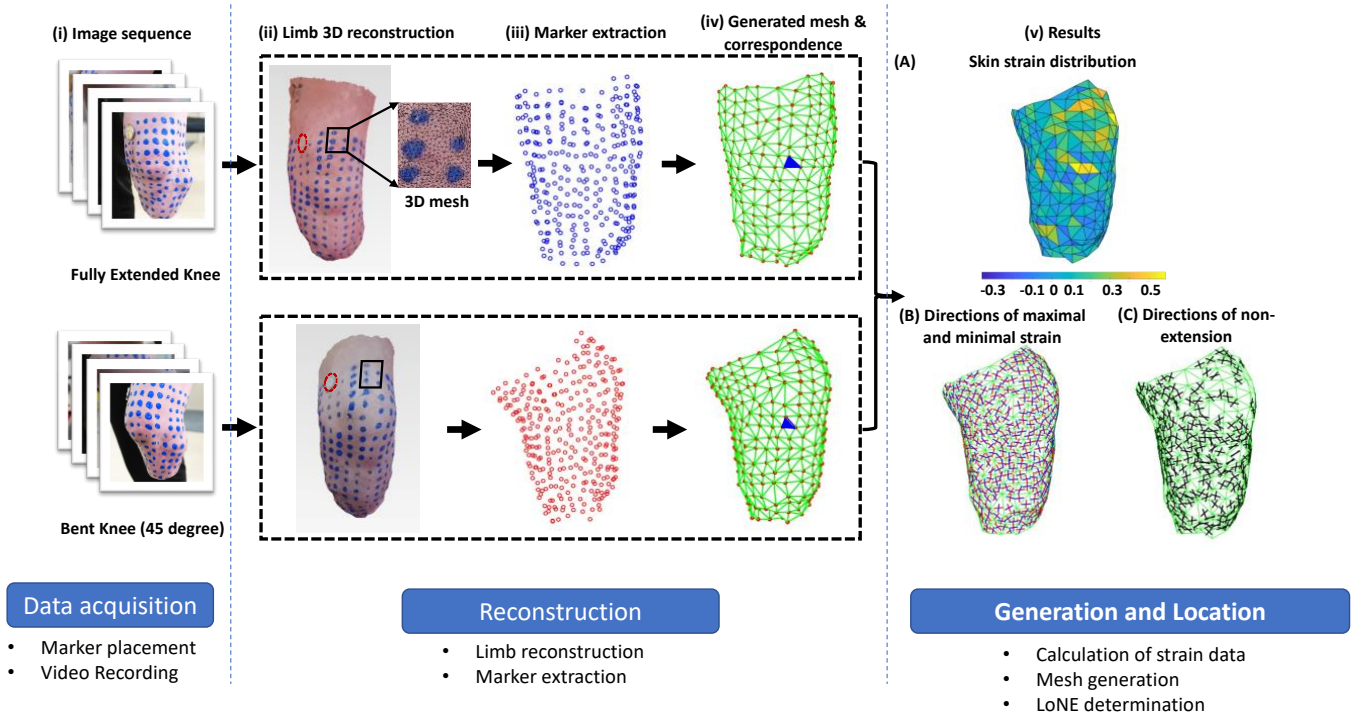

Figure 6-2. Overview of the Methodology and Workflow for skin strain measurement procedure. (i) Image sequence generated for both fully extended (0o) and bent state (45o) from the videos captured in respective poses. (ii) 3D textured meshed generated from the sequence of images using photogrammetry technique in Meshroom. (iii) Marker locations extracted for both the poses following the same order to ensure correspondence between markers. (iv) Reconstructed mesh of marker locations in the two poses. Triangular face in blue shows the corresponding triangle that deformed from the fully extended state to the bent state. (v) The triangular faces in the two states are compared to measure the skin strain between the two poses as shown in (A), the directions of maximal extension (red) and minimal extension (blue) as shown in (B), and non-extension (black) as shown in (C).

Step (1): Skin Marker Placement

A 3D printed stamp was made using polylactic acid (PLA) on an Ultimaker S3 (Utrecht, Netherlands) and skin-safe black ink (Pop Artz finger paint, Popular Book Company Pte Ltd, Singapore) (Figure 6-3A) was used to manually apply a dotted marker pattern on the residual limb (Figure 6-3B). Markers were 0.5cm in radius and 1 cm apart. The marker pattern was applied in such a manner that emulates the vertices of an equilateral triangular pattern. This pattern allows for accurate model construction and strain computation through point correspondence (Lin et al., 2017). While the space between markers and location on the limb or the size of each marker needs to be precise, the number of markers per cm^2 on the skin surface is the key parameter as it denotes the resolution of the resulting skin strain field. The 3D stamp provides an easy solution to applying this marker pattern quickly and efficiently, without manual measurements. Additionally, a 50cent Singapore coin was added to the antero proximal thigh region for scaling during the model reconstruction. This study considered an average of 300 static knee joint postures.

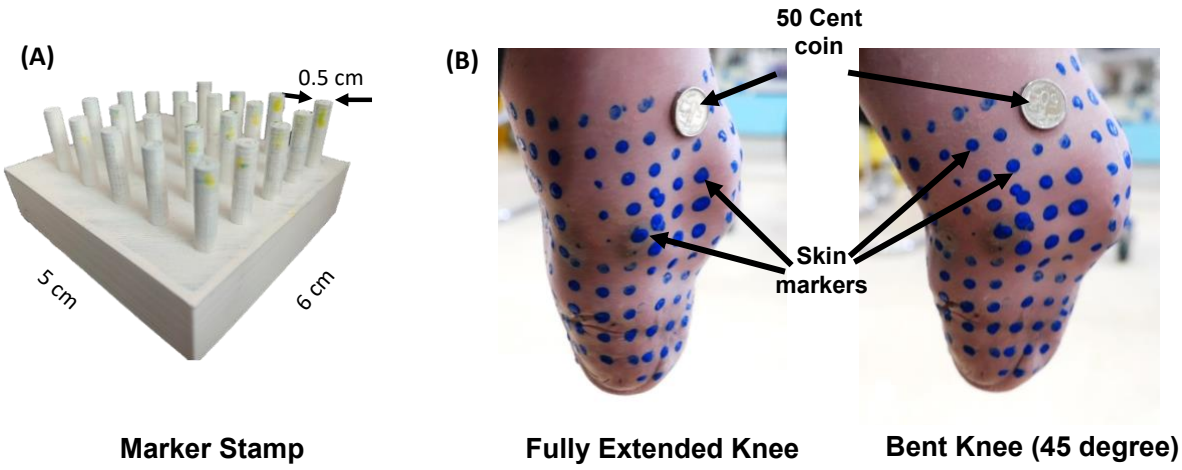

Figure 6-3. Skin markers placement (A) 3-D printed stamp, (B) Placement of markers and 50 cents coin

Step (2): Image Acquisition

An overview of the process steps is listed below:

1. Apply maker pattern and coin
2. The participant is positioned between parallel bars for image acquisition. After positioning, we used a video capturing system comprising a standard DSLR camera in automatic shooting mode without flash, in single-point focus (X-A5/XC15-45MM, resolution full HD 1080/59.9P, FUJIFILM, Tokyo, Japan).
3. The participant fully extends their knee for the first video
4. Circumferential video of the limb is taken using the handheld camera from the anterior surface, moving right or left for approx. 90 seconds (length of time is reflected on screen of camera during recording).
5. Participant flexes knee to 60 degrees, check with a goniometer
6. Circumferential video of the limb is taken as per Step 4.

Step (3): 3D surface model reconstruction

Figure 6-2 shows the workflow for strain and directionality computation from the recorded videos of the limb. Individual videos are spliced into around 300 frames each for both the fully extended and bent knee state, as shown in Figure 6-2(i). A 3D surface model is reconstructed from the images using an open-source software Meshroom, (Ver. 2021.1.0, AliceVision) (Carsten Griwodz, Simone Gasparini, Lilian Calvet, Pierre Gurdjos, Fabien Castan, Benoit Maujean, Gregoire De Lillo, 2021), as shown in Figure 6-2(ii).

The marker locations on the reconstructed limb were extracted for both the fully extended and bent knee state using MeshLab (Ver.2021.20) (Cignoni et al., 2008), as shown in Figure 6-2(iii). They were extracted in the same order they were placed to maintain correspondence between these two positions. The centroid point cloud was then exported in text files to process in MATLAB further (Version R2021a. Natick, Massachusetts: The MathWorks Inc.). The reconstructed poses were scaled manually according to the reference dimensions of the 50-cent coin. A new triangular mesh of the extracted marker locations was then reconstructed for both the fully extended and flexed knee states, as shown in Figure 6-2(iv). The blue triangles in the figure show the corresponding faces between the fully extended and bent knee states.

Step 4: Strain and directionality computation

The processed mesh of markers in the two states was used for strain and directionality computation. It was assumed that the deformation of the marker mesh from a fully extended state to a bent state is caused purely due to flexion of the knee. Therefore, the strain and directionality were computed for individual triangular faces without considering the effect of other faces. Figure 4A shows a schematic representation of the corresponding triangular faces in the fully extended and bent states. The affine transformation relating the triangle in the fully extended to the bent state was then obtained. The in-plane maximal and minimal principal stretches and their directions were identified using singular value decomposition of the transformation matrix ("Skin strain analysis software for the study of human skin deformation," n.d.). The algorithm for computing the strain and directionality is listed in Figure 6-5. Figure 4B shows an illustration of the distribution of principal strains. Three exhaustive strain scenarios exist with the triangular face experiencing 1) both extension and compression (Figure 4B(i)), 2) only extension (Figure 4B(ii)), and 3) only compression (Figure 4B(iii)). The principal strains ε_1 and ε_2 are used to compute the von Mises or equivalent strain for the triangular face, and given by the equation referenced below (Liu, 2005).

$$\varepsilon_{eq} = \sqrt{\frac{1}{2}[(\varepsilon_1 - \varepsilon_2)^2 + \varepsilon_1^2 + \varepsilon_2^2} \quad [1]$$

The directions of maximal and minimal strains exist for all three cases. In contrast, the direction of non-extension exists only for the case when the triangular face experiences both extension and compression. The directions of non-extension θ_1 and θ_2 are obtained from the intersection between the circle of unit diameter and the deformed ellipse, as shown in Figure 4B(i).

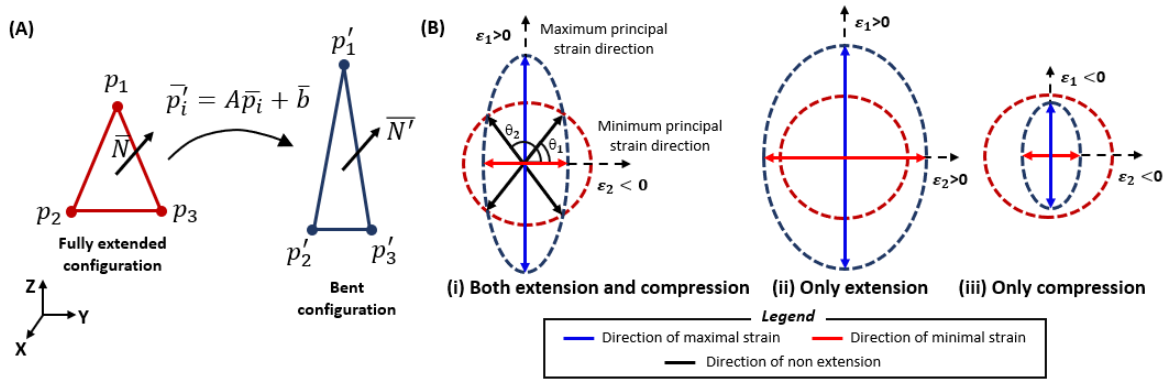

Figure 6-4. Strain and directionality computation (A) Corresponding triangles in the fully extended and bent configuration, (B). Possible strain relationships between the corresponding triangles.

Algorithm: *Strain and directionality computation*

Input: *Mesh of marker locations, $M_1$of fully extended state and M_2 of bent state*
Output: *skin strain, direction of maximal/minimal extension, direction of non-extension*

begin
  for *every triangular face in mesh M* ***do***
    $\boldsymbol{f_k}$ ← *store* $\boldsymbol{i^{th}}$ *triangular face from mesh* $\boldsymbol{M_k}$, *where* **k** *(k=1,2) represents the mesh state.*
    $\boldsymbol{N_k}$ ← *compute normal vectors of the triangular faces.*
    $\boldsymbol{Rot3D_k}$ ← *calculate transformation matrix that transforms vector* $\boldsymbol{N_k}$ *parallel to z axis.*
    $\boldsymbol{f_k^t}$ ← *transform* $\boldsymbol{f_k}$ *parallel to the xy plane, using matrix* $\boldsymbol{Rot3D_k}$.
    A ← *compute affine transformation that maps face* $\boldsymbol{f_1^t}$ *to* $\boldsymbol{f_2^t}$, *through rigid body transformation.* **A** *is the transformation matrix governing rotation and scaling parameters of the transformation.*
    [U, S, V] ← *compute singular value decomposition (SVD) 0f transformation matrix* **A**, *giving singular values in* **S** *and singular vectors as* **U** *and* **V.**
    $\boldsymbol{X_j}$ ← *store principal stretches from diagonal elements of singular value matrix* **S,** *where* **j** *(j=1,2) represents principal stretch direction.*
    equivalent strain ← *compute von Mises strain from the principal stretches* $\boldsymbol{X_j}$, *given by equation [1].*
    $\boldsymbol{\theta_j^{princ}}$ ← *compute principal stretch directions using the transformation matrix* **A**
    if $X_1 > 1$ *and* $X_2 < 1$ ***then***
      $\boldsymbol{\theta_j^{nonExt}}$ ← *compute non-extension directions*
    end if
  end
end

Figure 6-5. Algorithm for strain and directionality computation.

In addition, we designed an experiment to verify the accuracy of the 3D reconstruction process by conducting tests on a sample fabric with markers stamped on it at the reference state. The markers were placed 2cm apart in a 7x7 matrix on the material. The fabric was clamped on all four sides using a

custom-built setup with mechanical clamps, as shown in Figure 6-6A. A video of the fabric was captured at the reference state and was 3D reconstructed using the workflow discussed in Figure 6-2. Figure 6-6B shows the original image of the fabric captured using the camera and the image of the top view of the 3D reconstructed object. We compared the marker locations across the two images to compute the error in the 3D reconstruction process. Figure 6-6C shows the error in estimating the position of the markers in the reconstructed object. As can be seen, the markers on the 3D reconstructed object lie near the original marker locations. The mean error and standard deviation in reconstruction were found to be 2.36% ± 1.73%, with a maximum error of 9.57% at the corner.

Next, we also verified the sensitivity of the directionality computation algorithm to detect maximal and minimal stretch directions accurately. This step was carried out by stretching the fabric uniaxially along the X axis by 50%, as shown in Figure 6-6D. The markers on the 3D reconstructed object of the stretched state and the reference state were compared to compute the maximum/minimum directions, following the workflow discussed in Figure 6-2. Figure 6E shows the directions of maximal strains (red) and minimal strains (blue). As can be seen, the directions of maximal strains are predominantly oriented along the X-axis because of the uniaxial stretch in that direction. Similarly, the directions of minimal strains are oriented along the Y-axis as the fabric has small strains in that direction.

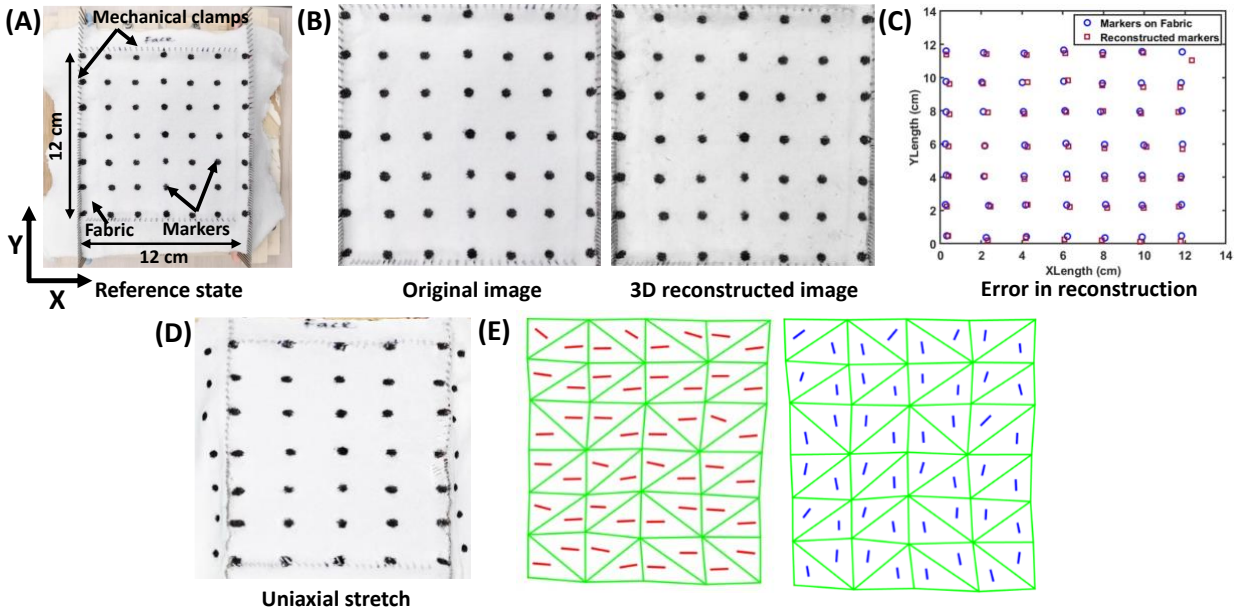

Figure 6-6. Algorithm verification experiment. (A) Reference state, (B) Original image of the reference state and top view of the 3D reconstructed object of the reference state, (C) Error in marker estimation during reconstruction, (D) Fabric under uniaxial stretch, (E) Directions of maximal (red) and minimal (blue) strain.

6.2.2 Results

A total number of 5 participants were recruited and analyzed. Table 6-1 provides a summary of the demographic characteristics of the participants. The participants were four males and one female, ages

38-67 years (mean 50 ± 10.91 years). There were four left side amputations and one right side amputation. All participants used a silicone liner within a laminated fiberglass socket in combination with suction or pin-locking suspension. The residual limb lengths were similar and ranged between 12-15cm from the knee center to the distal end of the residual limb.

Strain Characteristics

The DSLR camera accurately captured the 2D pattern of markers with a video recording for an average of 90 seconds. Three hundred images were used per participant to develop the strain characteristics, including maximum, minimum, and non-extension for each participant (Figure 6-7).

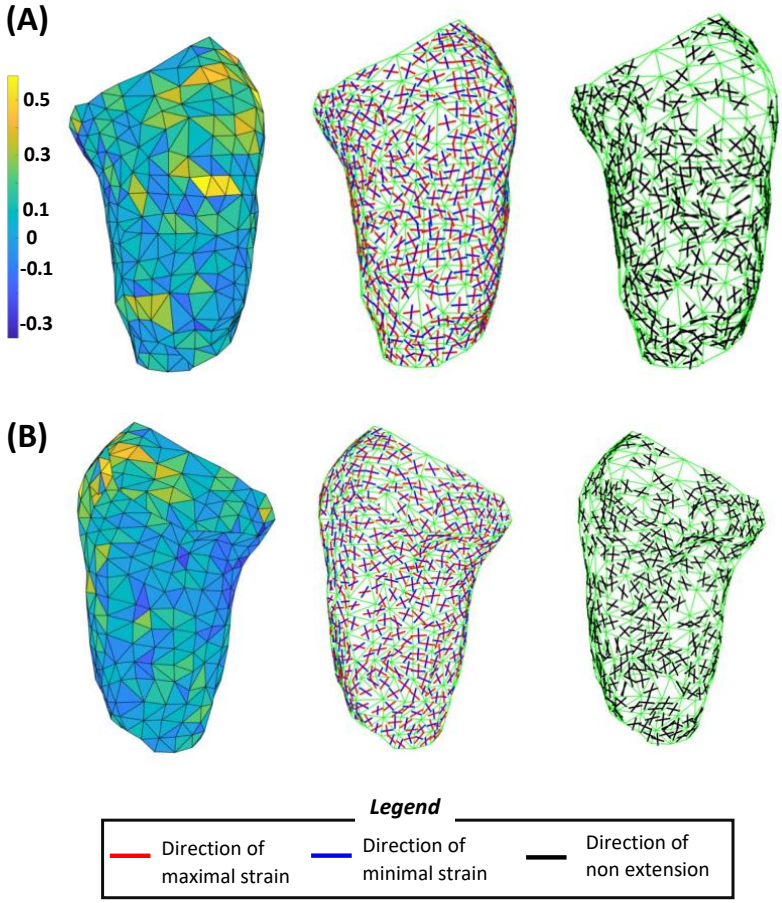

Figure 6-7. Strain and directionality computation example of one participant. (A) indicates the anterior medial direction of the limb and (B) indicates the posterior lateral direction of the residual limb.

Table 6-2 shows the principal strain data for all participants. The maximum mean principal strain was 67.91% ± 0.14% and was observed on or around the patella. In comparison, the minimum compressive mean principal strain was -31.10% ± 0.04% and was observed posteriorly in the popliteal region of the knee.

Table 6-1. Demographic Characteristics of Participants

	Sex F/M	Age	Weight kg	Amputation	Cause	Suture type	Hours of daily use (Hrs.)	Evidence of poor socket fit	Socket design and suspension
1	F	38	90	Left	Diabetes	Posterior flap	10	Nil	Lamination, Iceross synergy liner 3mm, pin lock
2	M	47	80	Left	Trauma	Posterior flap	18	Fibula head, medial condyle	Lamination, Iceross synergy liner 3mm, pin lock
3	M	53	81	Left	Skin infection	Posterior flap	16	Distal tibia	Lamination, Iceross synergy liner 3mm, knee sleeve
4	M	67	96	Right	Trauma	Posterior flap	8	Distal tibia, medial epicondyle	Lamination, Iceross seal-in V3 liner 3mm, knee sleeve, suction valve
5	M	45	100	Left	Osteomyelitis	Posterior flap	12	Distal tibia, lateral epicondyle	Lamination, Iceross Activa cushion liner 3mm, knee sleeve, suction valve

Table 6-2. Principal Strain Data showing maximum and minimum strain data and their locations

Subject No.	Maximum Strain (%)	Location	Minimum Strain (%)	Location
1	77.77%	On patella	-31%	Posterior Side of the Knee
2	58.88%	Around patella	-36.23%	Posterior Side of the Knee
3	78.15%	On patella	-30.30%	Posterior Side of the Knee
4	77.28%	On patella	-25.39%	Posterior Side of the Knee
5	47.47%	Around patella	-32.58%	Posterior Side of the Knee
Mean ± SD	**67.91% ± 14.05%**		**-31.10% ± 3.93%**	
Range	**[47.47 - 78.15]**		**[-36.23 - -25.39]**	

Preliminary analysis identified that maximum strains were less than 78.15%, within the physical limitations of skin, in an appropriate distribution (Figure. 6-8A). The algorithm for calculating LoNEs from the strain field data found a pattern of LoNEs (Figure. 6-8B).

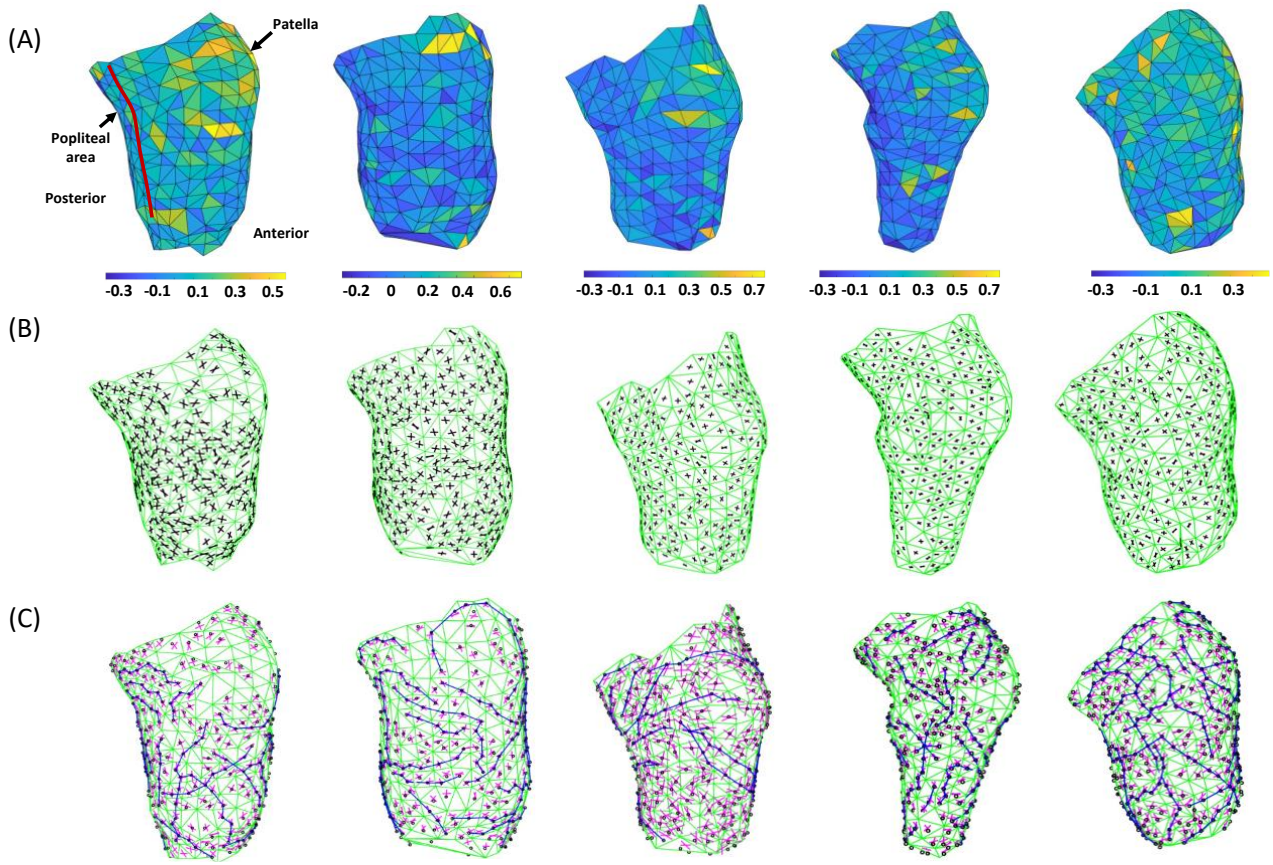

Figure 6-8. Comparison of residual limbs generation of strain data into LoNE. (A) Strain calculation data. (B) The pattern of Lines of Non-Extension. (C) Lines of Non-Extension

Lines of Non-Extension

The LoNEs were observed to be individual for each participant (Figure 6-8C). However, commonality was seen in several locations across all participants. They also tend to follow the lines of minimal extension closely. The LoNE strain data can be located around the edges of the patella, circumferentially around the thigh and proximal to the patella, diagonally from the lateral condyle towards the medial muscle belly of the gastrocnemius, diagonally from the medial condyle towards the distal edge of the fibula head, vertically on medial and lateral sides from the distal end of stump to the knee center, and in a crisscross pattern when viewed posteriorly. Participants, in general, had a vertical LoNE along the lateral border of the amputation; however, participant 5 did not, although they did have one along the medial border. Participants 2 and 5 had well-formed circle patterns around the patella, whereas participants 1, 3, and 4 had approximately two-thirds of a LoNE but minimal strain data in the remaining areas. All participants had LoNE running perpendicular to the ground in the popliteal region.

Our results also indicate that the LoNE appears to be discontinuous. Anatomically, the LoNE does not appear to cross over the distal end of the tibia in all subjects. Similarly, they do not run over the fibula head nor extend all the way from the bottom of the residual limb and across the knee joint.

Based on the information provided in the results, we attempted to generalize the LoNE for prosthetic socket designs of the future (Figure 6-9). Circumferential support can be provided proximal to the patella. Support around the patella, diagonally from the medial/lateral borders to the tibial crest (without crossing), along the medial and lateral edges, below the knee center, and in a criss-cross formation over the posterior muscle belly and below the knee crease.

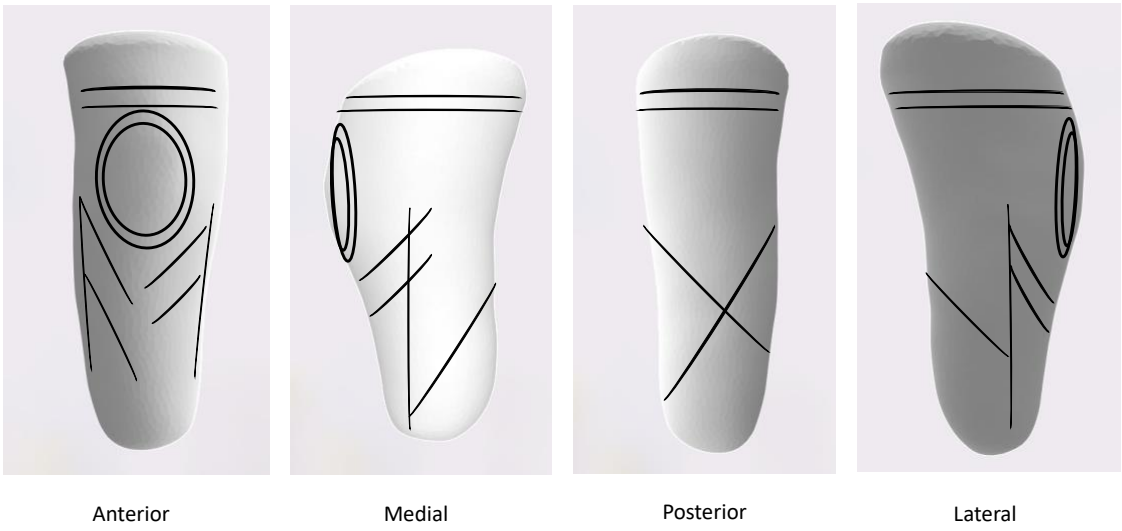

Figure 6-9. Generalized Lines of Non-Extension for design purposes

6.2.3 Discussion

Mapping the strain field of skin in residual limbs for persons with lower-limb amputations could be helpful in designing prosthetic sockets to enhance comfort. We designed and developed a simple, low-cost experimental method for determining strain field data and Lines of Non-Extension for lower limb amputations that could be utilized in a clinical setting. We evaluated this skin strain measurement methodology for five transtibial residual limbs in a flexed and extended knee posture. Patterns of LONEs largely follow photographs from Iberall's original qualitative methods with abled-bodied participants (Iberall, 1970), further confirming the technique. The results of our study could be used to help design prosthetic sockets or prosthetic socket interfaces along these LoNE.

Using a consumer-grade DSLR camera with skin markers appears to be an acceptable and easily accessible method to determine the LoNE. Video capture enabled dynamic skin strain analysis while retaining still-frame data (Lin et al., 2017). Maintaining focal length during image capture has been a challenge in previous research. To overcome these, we added an object of known size as a reference, in this case, a 50cent coin, to reduce the error calculations. An evaluation of the code produced mean error of <3% across the tested sample, confirming the accuracy of the reconstructed data. This result demonstrates that a consumer-grade camera with a video recording function could significantly reduce cost compared to motion capture or DIC-based strain imaging. DIC has also been used to investigate local skin strains (Evans & Holt, 2009). Although DIC offers superior resolution, applications have been limited to measurements near a loading site and approximately planar geometries (Lin et al., 2017). DIC and motion capture are still limited to lab settings, however the proposed solution in this thesis provides the opportunity for a mobile application inside a clinic. This may be useful in poor resource areas such as developing countries. We recorded the video at 60fps to ensure enough images could be captured to generate the model. Considering many smartphones are also capable of recording at this framerate and image resolution and storing raw image data, they could be regarded as alternatives in resource-constrained settings.

Furthermore, we had endeavored only to use freely available software programs and consumer-grade cameras so the data capture system setup and the results could be replicated in other research institutes, clinical practice, and developing countries where appropriate skillsets can be found or trained. However, we did use MATLAB ver. R2018b (USA), which requires a subscription, as the authors were familiar with this system and prevented delays in our results from learning another free software program.

The minimum and maximum strain values obtained in our experiments were within the skin's physiological properties. The maximum strain values were found over the patella region and are consistent with other research studies reported in the literature (Iberall, 1970; Lin et al., 2017; Wessendorf & Newman, 2012). The minimum strain values largely followed the LoNE, with the largest compression data recorded posteriorly near the knee crease. The maximum and minimum strain values are expected when considering the natural motion of the human knee. Skin must stretch over the patella region and compress posteriorly during knee flexion (Choi & Hong, 2015). The current socket designs have attempted to accommodate such conditions. A common patella-tendon bearing (PTB) socket design has an approximate Trimline to the mid-line of the patella, potentially causing friction issues (Foort, 1965). The posterior wall needs to be high enough to minimize movement in the anterior and posterior directions. However, a wall that is too high could also impact where the skin needs to compress, leading to cause abrasions, particularly in the sitting position. So, care must be taken to optimize the fit. Materials that offer flexibility and stiffness could be considered when designing a prosthetic socket along the LONE to reduce the abovementioned issues.

In our study participants, we found subtle differences in the length and position of the LoNE across the five residual limbs. While the literature on LONE in the able-bodied subjects is illustrated as continuous lines throughout entire body sections, our results are discontinuous across the residual limbs and support previous findings in the amputee population (Lin et al., 2017). Furthermore, these locations of LoNE were not found in anatomical regions where the participants had previously experienced socket fit issues such as distal tibial, medial condyle, and head of fibula regions. In these regions where skin strain occurs, there is evidence to suggest that the presence of pressure can lead to the development of wounds (Binedell et al., 2022; Salawu et al., 2006). Researchers have shown that most pressure-related damage begins in deep tissues at the bone-muscle interface and progresses towards superficial layers in a bottom-up pathogenesis (Aoi et al., 2009; Berlowitz & Brienza, 2007). LoNE do not appear in locations where wounds often occur. In a study by Salawu et al. (Salawu et al., 2006), they found a high prevalence of wounds along the surgical scar line, with other common locations along the anterior surface and distal end of the residual limb. However, we cannot state that there will be wounds solely because there were no LoNE. Posteriorly we found no location of a LoNE at the distal end, along with no evidence of wounds. Biomechanically, that region experiences tensile load posteriorly during knee flexion and extension, but not shear loads; hence wounds are not commonly found in this area, despite a lack of LoNE. LoNE do not appear to follow any underlying structure or geometry, e.g., the position of muscles, blood vessels, nerves, tendons, or ligaments. Still, care should be taken by the surgeon in selecting the length of amputation and type of suture to allow for prosthetic sockets to be designed along the LoNE. We propose that variations in a position identified in our research may be attributed to the individual or cause of surgery. Therefore, using generalized patterns should be considered cautiously, and individual designs along the LoNE should be the preferred option. The low-cost and easily accessible process described in this research would suffice in capturing these LoNE.

The natural deformation of the skin tissue throughout movement at this anatomical location could be utilized to maximize the comfort of wearable devices such as prosthetic sockets or prosthetic interfaces. Interface material can be reinforced along the Lines of Non-Extension or minimum strain to enable maximum motility of the skin while providing targeted support (Lin et al., 2017). Support along the LoNE could offer design freedoms. Current prosthetic designs focus on adding pressure in the tolerant areas such as muscle bellies and relieving pressure from intolerant regions such as bony prominences. Recent advances in technology such as 3D printing have introduced multi-material prints that incorporate flexibility and stiffness in various locations. However, these are not optimized for the individual with commonly held constructs as to pressure tolerant and intolerant areas guiding the use of such material properties. Elastomer liners have been introduced to overcome inconsistencies in manufacturing or clinical technique. These liners remain homogeneous and provide generalized protection to the residual limb. With the introduction of LoNE, there is the possibility of introducing

heterogeneous designs that continue to protect the residual limb while enhancing the user's comfort. Designs could provide stiffness and support along the LoNE while allowing greater flexibility over areas of maximum strain, such as the patella region. These designs become truly user-centric, optimizing the geometry of the individual's limb.

Future work will investigate the use of LoNE in developing a prosthetic socket and liner, comparing both user-specific patterns of LoNE to a generalized way. Future work will also explore how such prosthetic designs may affect developing a deep tissue injury or wound. The authors also plan on creating a fully operational low-cost methodology for the clinical application of our approach to allow for customized designs for all levels of amputation and other orthotic rehabilitation wearables.

6.2.4 Conclusion

The use of a consumer-grade DSLR camera with freely available software programs was suitable for determining the LoNE and could be used in a clinical setting as a cost-affordable option. Skin movement and directional skin strain in persons with amputation largely follow similar patterns to those of the able-bodied. However, they appear discontinuous in areas, particularly across the tibial crest. Our results provide helpful information for developing enhancements to the physical comfort through new interfaces to assist with mobility and improve the quality of life for the user. Heterogeneous designs that provide stiffness or compression along the LoNE while allowing greater flexibility along the maximum skin strain locations could be more comfortable.

6.3 Thermal Comfort

To address the physiological comfort, this study investigated the design and development of a sweat reducing prosthesis liner. Sweat within the liner and socket was commented on heavily in Chapters 2 & 4, thus it was necessary to find a solution to this need. Section 6.3 resulted in the patent in Appendix 4.

The socket is the primary component of a prosthesis and provides structural coupling, control, and proper transfer of forces at its interface with the residual limb (Klute et al., 2009). To enhance physiological and physical comfort, the use of prosthetic liners, typically made from silicone, TPE, or gel, aids to improve the comfort by reducing impact forces and serves as a form of suspension (Baars et al., 2018; Gholizadeh et al., 2014). However, liners and the sockets can prevent thermal regulation mechanisms (Klute et al., 2007). Without thermal regulation, the elevated residuum skin temperatures may reduce the prosthesis user's quality of life, particularly in hot or humid surroundings such as Singapore (Klute et al., 2007).The low permeability and insulative nature of the liner and socket causes discomfort, skin irritation, skin maceration, infection, unpleasant odour, and an environment for

bacterial invasion to hair follicles of the residual limb (Hachisuka et al., 2001; Huff et al., 2008; Klute et al., 2007; Köhler, Lindh, & Bjorklind, 1989; Visscher et al., 2011), eventually impacting the prosthesis use and comfort. (Ghoseiri & Safari, 2014) found that more than 53% of prosthetic users feel discomfort due to excessive heat or sweating while using the prosthesis, with an increment of 1-2°C sufficient to trigger these kinds of problems (Williams, Washington, Miodownik, & Holloway, 2018).

There have been attempts developed to address the heat and sweat discomfort in lower-limb prostheses, however their efficacy requires improvement (Ghoseiri, Zheng, Hing, Safari, & Leung, 2016; Ghoseiri et al., 2018; Han, Liu, Dowd, & Zhe, 2015; Wernke, Schroeder, Kelley, Denune, & Colvin, 2015). Commercially available liners attempt to assist thermal regulation and prevent sweat build up using methods such as: phase change materials (PCM) (Alpha SmartTemp Liner with Outlast Willowwood, USA) which proactively absorb heat, store it, and release it for optimal thermal comfort; and the use of laser cut pin holes to allow breathability (Silicare Breathe, Blatchfords, UK). However, PCM has a ceiling effect, while the breathing holes in the Silicare Breathe liner create hygiene issues as some of the sweat that is expelled through the holes is left behind causing a potential area for bacterial growth.

Therefore, a new solution was needed to address the issue of thermal comfort. The dynamic capillary effect was chosen as the main principle behind the design of the liner and is explained below. This decision was influenced by the need to not only remove sweat from inside the liner but to move it to a location that would allow natural evaporation. Using the dynamic capillary effect, we aimed to move the sweat towards the proximal trimline of the liner where natural evaporation could take place.

Capillary action occurs when the adhesion to the walls is stronger than the cohesive forces between the liquid molecules. The height to which capillary action will take the sweat is limited by surface tension and gravity. Based on these principles, this study was designed to identify the correct dimensions for the capillary effect to work within a liner, then to evaluate these findings in an actual developed liner.

6.3.1 Methods

To develop the correct microchannel diameter for the liner, we first evaluated the theory of capillary action.

Theory of capillary action

Capillary action is defined as the spontaneous flow of liquid into narrow tube or porous material and the height of travel is determined by the following equation:

$$h = \frac{2T\cos(\theta)}{\rho g r}$$

Where

h= elevation of the liquid [m]

T= liquid surface tension [Nm^{-1}]

Θ = angle of contact between liquid and capillary tube [radians]

p = density of liquid [kgm^{-3}]

g = standard of acceleration due to gravity [ms^{-2}]

r = radius of capillary tube [m]

This movement does not require gravity force to occur and can act opposite to gravity. Capillary action happens due to both cohesion force and adhesion force. Cohesion force is the attraction force between the fluid molecules and adhesion force is the attraction force between fluid molecules and contact surface. A good meniscus is favourable for capillary action to take place but it requires a low contact angle and capillary radius (Figure 6-10).

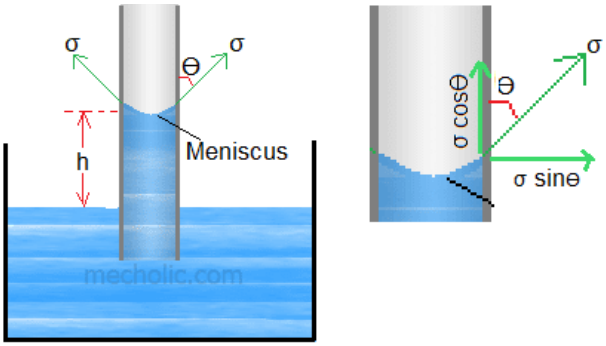

Figure 6-10. Capillary tubes showing meniscus contact angles. (photo credit mecholic.com)

The calculation for the height of capillary rise was considered against the safety factor to determine the suitable radius as per the equation mentioned and can be seen in Table 6-3.

Table 6-3. Comparison table of the effects of various factors and their influence

Safety Factor	Capillary Height (cm)	Diameter of channel (mm)	Time Taken to Travel 20 cm distance (s)
1	22.6	0.2	0.378
2	45.1	0.1	0.285
5	112.8	0.04	0.224
10	225.6	0.02	0.221

The capillary effect of the liner is governed by two main factors, diameter of the channels and material of the liner. To determine the size and shape of the capillary tubes simulation software Comsol

Multiphysics (Burlington, MA, USA, Ver 5.0) and Ansys (Canonsburg, PA, USA) were used to study behaviour of liquid in the tubes (Figure 6-11).

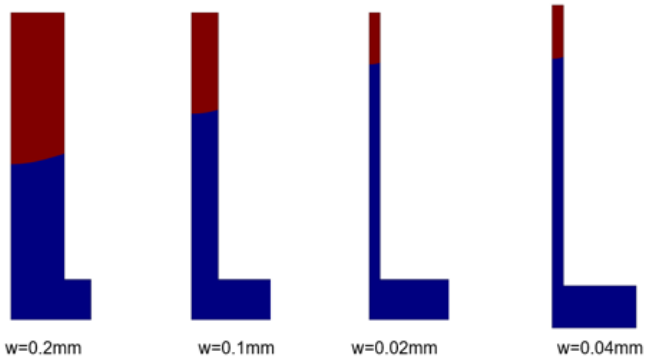

Figure 6-11. Simulation of liquid to determine capillary tube diameter.

Microchannels of 200 microns (0.2mm) was deemed the most suitable for the liner. The travelled height is 22.6 cm which is above the standard length of most liners. Subsequently, a master mould with different channel dimensions was made to confirm the simulation (Figure 6-12A). Casting was done with different substrates (e.g. TMPEOTA 3, TMPEOTA 9, Tecoflex) to find the best material, i.e., material that provides a cushioning effect similar to commercially available liners and does not compromise channel features. If the material is too soft the channels may close when donning the liner rendering the channels useless. Using a hydrophilic mixture of TIMPEOTA 3 + 9 we then demonstrated efficacy of channels (Figure 6-12B).

In-situ test of capillary effect

To allow an in-situ test, a 3D printed mould with 0.2mm channels was printed using a Polyjet J750 (Stratasys Eden Prairie, MN, USA) for casting of a full scale liner (Figure 6-12C). Injection moulding with Ecoflex 00-30 (Smooth-on, Macungie, PA, USA) was done inside a custom made bivalved cast (Figure 6-12D), before being fitted to a user for testing (Figure 6-12E).

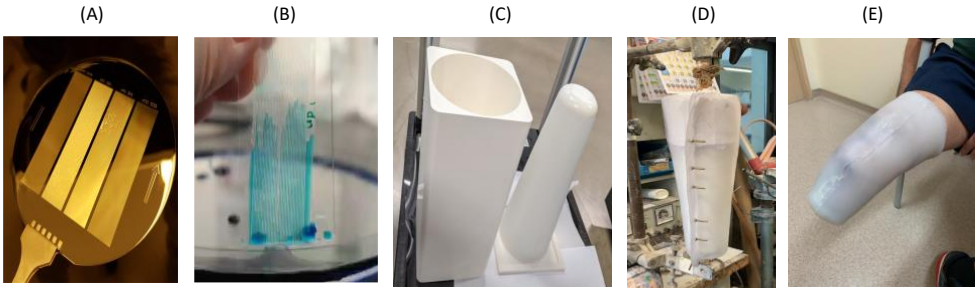

Figure 6-12. Development of microchannel liner. (A) Master mould of various channel dimensions, (B) Demonstration of capillary action, (C) 3D printed mould, (D) Injection moulding process, (E) Final liner on user.

After receiving ethical approval from Singapore University of Technology and Design Ethical board a single participant was recruited through Singapore Amputee Support Group. All methods were carried out in accordance with relevant guidelines and regulations, and informed consent was obtained from the participant. The following inclusion criteria were applied:

- Single Lower limb amputee
- Be willing and able to complete the tasks outlined
- Are at least 6 months on a definitive prosthesis
- Fits within the experimental liners
- Can understand English to be properly consented and provide their feedback to the study personnel
- At least 21 years of age
- Physical ability to walk continuously for 15 minutes

Exclusion criteria were

- Bilaterally lower limb amputees or upper limb amputees
- Below 21 years of age
- Cognitive impairments
- Not using a prosthesis
- Those with existing known chronic medical problems

The participant completed a survey with questions on demographics and the usage of their prosthesis. The weight of the participants liner (control liner) and the experimental liner were taken. The centre muscle mass of the calf belly was marked with a pen to indicate the position to record the temperatures. The location was chosen because muscle cells are the primary cells to generate and store heat during exercise (Silbernagl & Despopoulos, 2015), and therefore, measuring skin over the muscle is likely to give a good indicator of the temperature changes that occur during exercise. However, other sites were marked for measurement to ensure thoroughness. These included the medial and lateral para tibial areas. The study followed the following protocol (Figure 6-13).

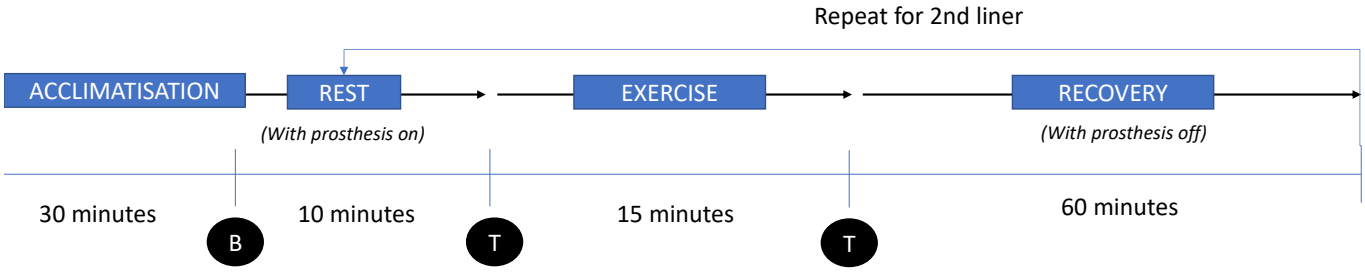

Figure 6-13. Protocol for testing of each liner in Experiment 1. B – indicates baseline temperature recording, T – indicates points in time where temperature measurements were recorded.

Our hypothesis from the initial findings was

H1: The experimental liner would result in less sweat on the residuum and cool the residuum, keeping it dry and comfortable.

6.3.1.1 Experiment 1

The detailed steps of the experiment are listed below.

- Participant rested in a seated position without the prosthesis for 30 minutes after arriving. Due to the short distance needed to travel between his car and the testing cite, 30 minutes was deemed suitable.
- An absorbent towel was weighed using a high precision scale (Sartorius Secura225D1S Semi-Micro Balance 120 g x 0.01 mg and 220 g x 0.1 mg, Gottingen, Germany) to record the pre-weight of the towel. This would then be compared to the weight of the towel used to wipe any sweat from the liner and residuum following the trial.
- After 30 minutes, surface temperatures were recorded in three locations (Figure 6-14) using the Guide IR T120 thermal imaging camera 120x90 (Sensmart Tech Co, Wuhan, China) with a 0.060°C resolution.
- The control liner is then donned.
- Control liner is removed after 10-minutes and temperatures are recorded in the same locations. This was done within 20 seconds to avoid excessive change in temperature. After the readings were recorded,
- The control liner is worn and the prosthesis is attached over the liner.
- The participant walks on a Landice L7 rehabilitation treadmill (Randolph, New Jersey, USA) at a self-selected pace of 3.0km/hr continuously for 15 minutes
- Participant removes liner and temperatures are recorded by study team member.
- Second study team member wipes the liner and residuum (after temperature recording is finished) to collect sweat generated.
- Towel is weighed on high precision scale and results recorded.
- Participant rests for 60 minutes to allow sufficient stabilisation of the thermal regulation within the subject's body.
- Evaluation statements and questionnaire information (including SCS) are obtained.

The same procedure was followed for the experimental liner following the 60-minute rest.

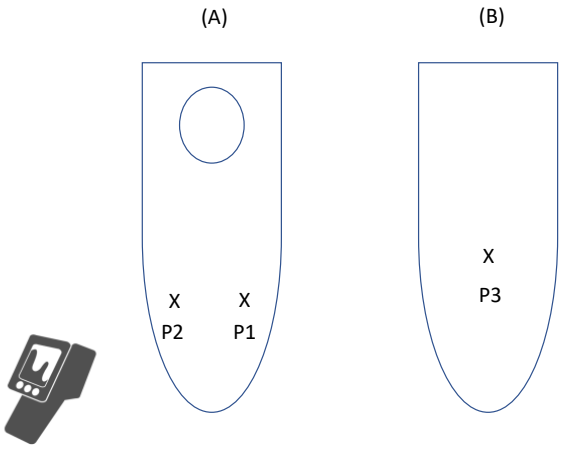

Figure 6-14. Position of temperature recordings. "X" marks the location. (A) Anterior view, (B) Posterior view

Unfortunately, during the testing of the control liner and experimental liner, the absorbent towel did not display any measured difference of sweat (0mg) despite perspiration observed on the user himself and the participant verbally stating he felt sweat inside his liner after the 15 minutes of exercise. Possible reasons for the result include: the testing of the user in an air-conditioned environment, the self-selected speed was too low leading to low exertion efforts, the testing period was too short, or the sweat generated was too small and evaporated from the towel before measuring.

As a result of this outcome only temperature readings, evaluation statements, and questionnaire results were considered in the analysis and an additional experiment (Experiment 2) was planned to specifically test the microchannels on a separate day two weeks later.

6.3.1.2 Experiment 2.

This experiment was designed to simulate sweat accumulation using coloured water droplets to determine if the microchannels would be successful in their capillary action.
The process is shown in Figure 6-15. The steps are explained below.

- 30-minute acclimatization of residuum after arriving at clinic, as per Experiment 1.
- Drops of water (approximately 20mm) are applied to lower half of residuum
- A piece of qualitative filter paper (Jiao Jie, Liao Jing, China) is weighed using same high precision scale as Experiment 1.
- Filter paper is backed on one side with baking paper to prevent any direct sweat absorption from the skin of the residuum.
- Filter paper is applied to the internal surface of the proximal edge of the liner on the lateral wall.
- The participant wears the liner and prosthesis over the filter paper.

- Participant walks a predetermined pathway for 10 minutes to simulate real life environment.
- Participant removes prosthesis and liner.
- Filter paper is weighed for water and sweat absorption.
- Qualitative feedback obtained.

After a rest period of 60 minutes, the same procedure was followed for the experimental liner.

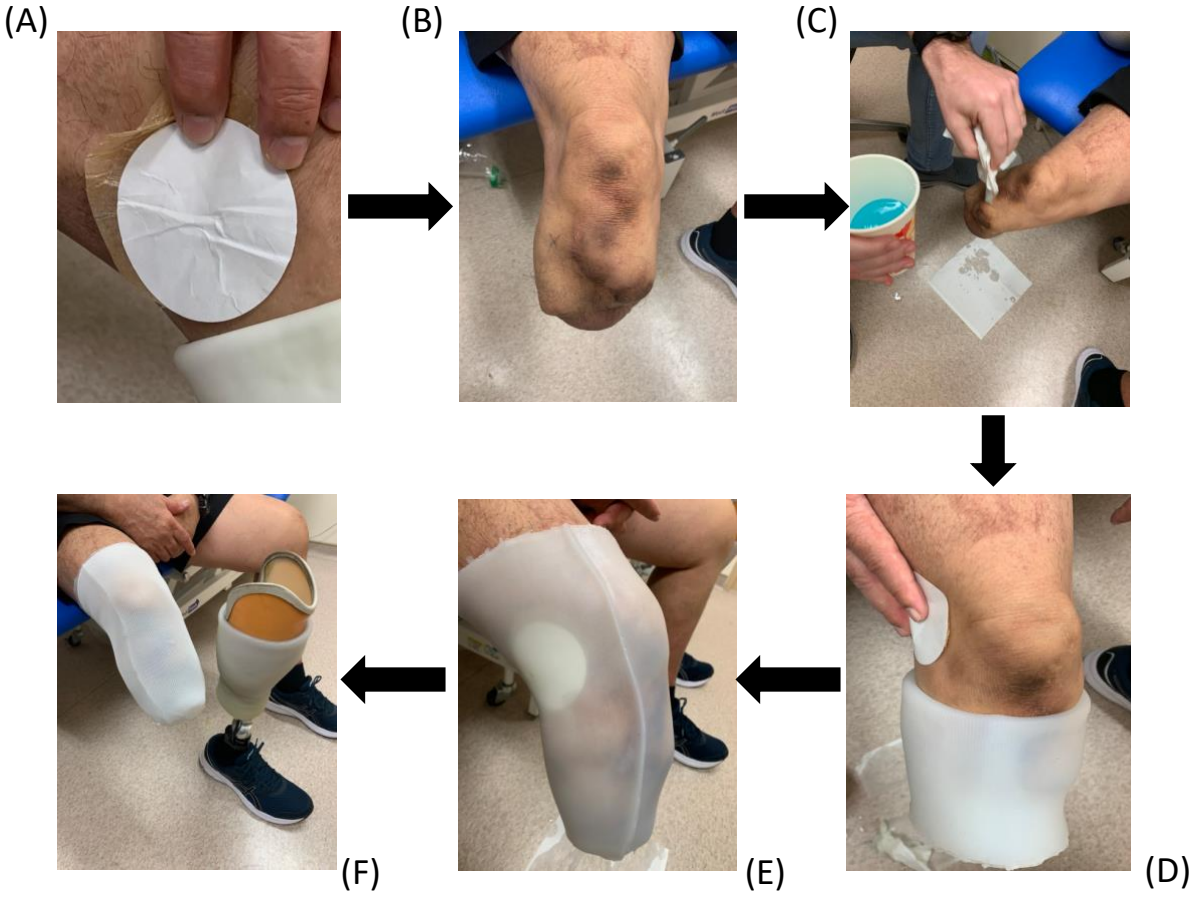

Figure 6-15. Process for assessing capillary effectiveness. (A) Baking paper behind qualitative paper, (B) Residuum, (C) Water being applied, (D) Placement of filter paper, (E) liner rolled over limb, (F) Stocking added over liner to aid in wearing prosthesis

6.3.2 Data Analysis

All data was analyzed using Microsoft Excel for Mac (Version 16.63.1, Redmond, Washington, USA). Temperature results and filter paper absorption were reported with mean and SD. Sweat (Water) volume is reported in absolute numbers. Evaluation statements have pertinent statements reported. The questionnaire data was compared using one-tailed t-test and significant when $p<0.05$. Qualitative feedback was obtained using unstructured interview that focused on three areas suspension, temperature, and overall comfort. This was recorded and transcribed.

6.3.3 Results

Experiment 1

A single male participant, 68 years old with a right transtibial amputation was recruited for this study. He has a BMI of >30 putting him at risk of diseases associated with obesity. The participant uses his prosthesis for 18 hours per day on average. Other demographic details can be found in Table 6-4.

Table 6-4. Demographics of participant.

Subject	Weight (Kg)	Height (cm)	Age	Time since amputation (years)	Cause	Socket	Interface	Suspension
1	95	173	68	14	Trauma	Laminate	Silicone liner	Vacuum

The participant walked 740m with each liner, each time burning 42 calories. His heart rate (HR) with the control liner was slightly higher at 103bpm, than compared to the test liner of 101 bpm. During each test 0g of sweat was collect. The room temperature was centrally controlled at 23°C. The weight of the user's prosthesis was 2.36kg but variances were found in the weight of the liners. The control liner was 521g, and the experimental liner was 653g, i.e., the experimental liner is 114g or 25.33% heavier, resulting in a 1.04% higher weight for the prosthesis (socket and liner). The temperature changes between both liners (Table 6-5) are similar, although the experimental liner has slightly higher standard deviations given the drop in temperature of P3 from baseline to end temperature of -1.5 degrees. The experimental liner produced lower start and end temperatures and appeared to lower the residuum surface temperatures after application as indicated by the lowering of all start temperatures.

Table 6-5. Temperature results recorded throughout experiment 1.

Liner	**Location**	**Baseline**	**Start**	**End**	**Change**
Control liner	P1	30.1	30.3	31.3	1.2
	P2	29.8	29.8	30.4	0.6
	P3	28.0	28.0	28.4	0.4
Mean (SD)		**29.3 ± 1.14**	**29.4 ± 1.21**	**30.0 ± 1.48**	**0.73 ± 0.42**
Experimental liner	P1	28.5	28.1	28.7	0.6
	P2	28.1	28.0	29.6	1.5
	P3	29.8	27.3	27.3	-1.5
Mean (SD)		**28.8 ± 0.89**	**27.8 ± 0.44**	**28.5 ± 1.16**	**0.6 ± 1.5**

The participant scored the Experimental liner significantly higher than the control liner ($p=0.05$), (Table 6-6). However, the actual temperature recorded did not indicate significant change suggesting the possibility of a placebo effect. The reported SCS of the control liner was 7/10, whereas the Experimental liner was higher at 8.5/10.

Table 6-6. Comparison of liners across various factors

Factor	Control	Experimental
Temperature	1	4
Weight	2	3
Suspension	3	4
Overall Comfort	3	4

Following the test liner trial, the participant completed a series of evaluation statements (Table 6-7). The user felt more comfortable, cooler and would prefer to use the test liner in the future should it become commercially available. However, the use of the fabric backing on the control liner appears to influence how easily the liner is to wear. As the test liner did not have a fabric backing, it was more difficult to roll over itself. It is possible to add this into the future design of the experimental liner to improve this aspect of comfort.

Table 6-7. Response to Evaluation statements.

Evaluation Statement	VAS score (100)
Use of the new silicon liner helped me feel more comfortable when compared to my existing prosthesis	80
When using the new silicone liner, my stump felt cooler	81
When using the new silicone liner I felt I could walk for longer without the need to remove it.	70
The new silicone liner was comfortable against my skin	73
I would prefer use the new silicone liner as my choice of liner in the future	86
My leg felt dry when using the new silicone liner	84
It was easy to wear the new silicone liner	38

Experiment 2

The results of the water absorption are reported in Table 8. When analyzing the effects of the microchannels in the experimental liner, it was clear they were more effective in removing any water than the control liner. The filter paper in the experimental liner absorbed 177.66mg, while the control liner showed zero absorption of water. The amount of water collected from each liner on the filter paper can be seen in Table 6-8 and Figure 6-16.

Table 6-8. Comparison of liners and filter paper absorption of water.

Liner	**Pre paper-weight (mg)**	**Post paper-weight (mg)**	**Change (mg)**
Control	324.70	324.70	0.00
Test	324.70	502.36	177.66

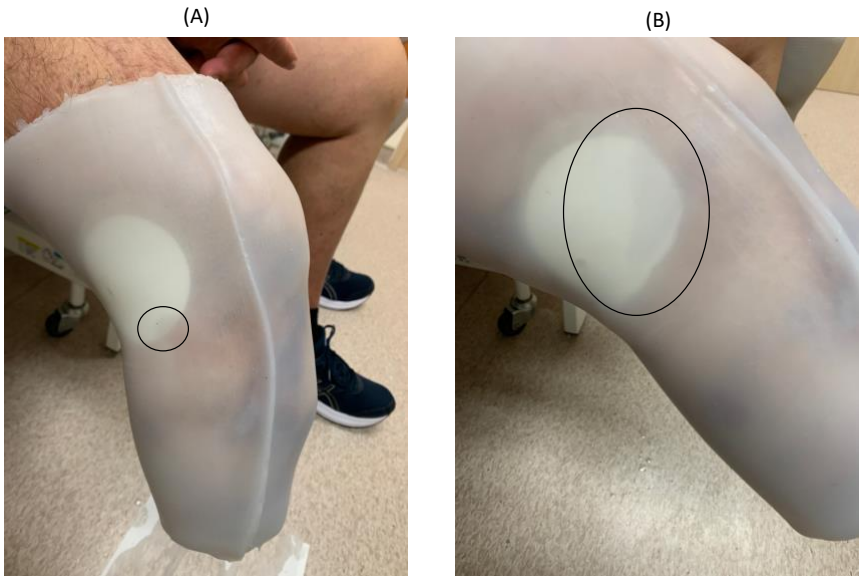

Figure 6-16. Picture showing water absorption amount with filter paper. (A) Pre-test walking, (B) Post-test walking

As can be seen in Figure 6-16A. Water absorption was occurring as soon as the liner was rolled on and before the user donned his prosthesis, highlighting its effectiveness. Figure 6-16B indicates further absorption of the water following the walking period.

The user provided the following feedback about the two liners (Table 6-9) during the interview. Generally, the user was more in favour of the experimental liner. He felt improved suspension, however commented on the lack of a longer trial which may affect the long-term thermal comfort. Still, he felt the experimental liner had higher overall comfort.

Table 6-9. Qualitative feedback of the microchannel liner

	Strengths	**Weaknesses**
Suspension	"it feels like it has a better grip." "it doesn't feel loose even after adding the water, my leg feels dry."	Nil
Temperature	"my leg feels so cool when using the new liner." "I didn't sweat as much when trialling the second liner."	"I wonder if the temperature would be different to my own liner, I didn't walk for long enough, perhaps 30 minutes would have been better."
Comfort	"it's very soft and comfortable, the bones are well protected" "I'd much rather use the new liner."	"it's a little tight on the inside just near my knee, could be that I'm not used to it."

6.3.4 Discussion

This study aimed to determine the correct dimensions of a microchannel to remove sweat from within a prosthesis liner and to evaluate these findings by developing a prosthesis liner with microchannels.

Microchannels of 0.2mm were identified as the most appropriate for the removal of sweat from within the liner. While the size may appear small, the initial size of sweat droplets is below this (<100microns), allowing for the molecules to easily enter the microchannel. The use of hydrophilic or super hydrophilic materials may help to improve the efficacy of the microchannels (Ahmad, van den Boogaert, Miller, Presswell, & Jouhara, 2018) by attracting the droplets towards the microchannels. This could improve the rate of sweat removal leading to improved comfort levels.

An interesting result was the differences in recorded temperatures. Our hypothesis was correct, with the experimental liner keeping the residuum cooler than the control liner. There was a decrease in temperature of 1 degree after using the experimental liner for 10 mins and levels rose back to starting temperatures after the exercise. The use of a textured surface could explain the results. Given both liners were made from a silicon substrate, the application of microchannels to the experimental liner may have created channels for the hotter air to be trapped, leaving the residuum cooler. The use of surface texturing has shown improvement to physiological comfort levels (Raccuglia, Sales, Heyde, Havenith, & Hodder, 2018) by reducing saturation in high contact areas and improving the perception of comfort. The use of surface texturing could be valuable in creating a comfortable physiological performance of liners.

The participant perceived significant higher levels of comfort with the experimental liner. Despite temperature readings showing no significant changes, the user's feedback was interesting and further shows how attempts to improve comfort levels through design changes can lead to differences in perceived levels of comfort. Feeling comfortable within the prosthesis liner may aid in building confidence in the new design, encouraging use, and improving health outcomes. The user's willingness to wear the experimental liner may also highlight the need for improved designs over current technologies. Utilizing design concepts such as the theory of capillary action seemed to address this need.

Water was absorbed along the channels to the filter paper providing evidence that the channels were successful. The contrast between the control liner and experimental liner was evident with zero water or sweat absorbed in the control liner and 177mg absorbed in the experimental liner. Furthermore, water could be observed on the filter paper directly after rolling on the liner suggesting this process is very effective. Commonly, prosthesis users remove their prosthesis to dry their residuum, which

improves suspension. Sweat accumulation can lead to issues such as wounds, hair folliculitis and bacteria growth. The high humidity and temperatures in South-East Asia exacerbate these problems. By removing sweat from the liner as the users walk, residuum's can stay dry, which has shown some benefits to improving the perceived level of comfort (Davies et al., 2020). A context sensitive solution such as a liner with microchannels could aid in improving the physiological and physical comfort levels of prosthesis users.

The overall feedback from the user was positive towards the experimental liner. Of particular importance was the improvement in suspension. Although this was not directly measured, suspension comfort could be perceived and efforts to validate this finding with objective measures is encouraged. The microchannels which appear to keep the limb dry could play a role in the increased feeling of suspension. The microchannels altered the smooth surface texture of the interface with thin longitudinal lines, potentially improving suspension and explaining the user's feedback on better control when using the test liner. (Quinlan, Yohay, Subramanian, Poziembo, & Fatone, 2020; Wernke et al., 2017) showed that by increasing friction properties of the socket/liner/residual limb socket suspension may be improved. However, the results of (Quinlan et al., 2020) suggest texturing should occur in the horizontal direction rather than the vertical, which does not support our results, although they were looking only at the socket and not liner structures. Furthermore, surface texturing may impact levels of comfort by increasing or decreasing water droplet contact angles (Mohammadi, Tembely, & Dolatabadi, 2017). This could impact the efficacy of the microchannels and their relationship to friction or shear forces and require further exploration.

The temperatures between the two liners have already been explained, however an important point to note is that the testing was conducted for only 15 minutes. A longer duration may influence the results and should be considered. However, caution must be taken when testing new technology worn against the skin for an extended time. In Experiment 1, it was decided that 15 minutes would suffice in developing sweat and temperature changes. However, only after the completion of the 15 minutes was it obvious that a longer period or a change in environment may have helped. The researchers were guided by feedback from the user when he felt sweat was accumulating. It may be useful to explore the perceived level of comfort further through quantitative methods as indicated in Chapter 2.

Overall, the user was comfortable with the experimental liner and felt confident he would be able to use it long-term. However, initial tightness with the experimental liner suggests, as with any new technology there may be a period of adjustment and regular reviews should be conducted to ensure user comfort.

6.3.5 Conclusion

This section describes the use of microchannels inside a prosthesis liner as a potential solution in addressing the physiological and physical comfort factors with a prosthesis. Microchannels of 0.2mm were the preferred diameter to optimize sweat transfer and the addition of a hydrophilic coating may improve the microchannel's effectiveness.

Prosthesis users have real pain points with thermal regulation and sweat and appear ready to try new solutions to improve comfort levels. While these technologies immediately impact the perceived level of comfort, quantitative methods to validate temperature changes, sweat accumulation are necessary to support its effectiveness.

6.4 Digitalization process to improve comfort – A case study

This section describes the use of digitalization in the design and development of a novel 3D printed forequarter prosthesis. We further address the objective "identification and evaluation of digital technology potential", and provide input to affirm "Hypothesis 2. Using existing product design methods provides sufficient structure to improve comfort in the current prosthetic design process". Information presented can be found in published research (Binedell, Meng, et al., 2020; Binedell & Subburaj, 2022).

6.4.1 Introduction (Forequarter prosthesis)

A forequarter amputation is a radical surgical procedure that includes the entire upper extremity with its shoulder girdle (Levine, Warso, McCoy, & Das Gupta, 1994). This procedure was originally described in the early 19th century to manage severe, traumatic injuries of the upper extremity (Bhagia, Elek, Grimer, Carter, & Tillman, 1997; Clark & Thomas, 2003). Currently, the most frequent indications are the presence of malignant tumours of the arm, axilla, shoulder, and scapula (Levine et al., 1994). Fortunately, forequarter amputation is rarely performed today.

While exoskeleton prostheses can sufficiently compensate for amputations of the lower extremity, the psychological and physiological impact of a forequarter amputation (FQA) on the patient is significant (Elsner et al., 2016). However, using a prosthesis to regain the functions of the lost arm is not very common among patients. Typically, only a cosmetic prosthesis is applied to restore the shoulder contour, although other options exist, such as myoelectric and body-powered. Up to 22% of high-level amputations refuse to use any prosthesis (Heger, Millstein, & Hunter, 1985).

6.4.2 Background

The loss of one hand significantly affects the level of autonomy and the capability of performing activities of daily living, working, and social activities. It is estimated that 4-5/10,000 have a UL deficiency (Bethge, Von Groote, Giustini, & Gutenbrunner, 2014). Shoulder disarticulation and forequarter amputations are lower in number, 5% and 3%, respectively (NHSScotland, 2005). Tan Tock Seng Hospital, the largest provider of prosthetic services in Singapore, sees 5% of all its patients for upper limb prostheses. These cases resulted from increased numbers of Group-A Streptococcus infections and traumatic events.

Worldwide, there is a gap in the market for affordable and comfortable prosthetic solutions. Due to the lack of trained prosthetists and the rising number of amputees, there has been an increase in user wait times. Prosthetics require a highly individualized and flexible approach and, if possible, low maintenance demands and cost (Wyss, Lindsay, Cleghorn, & Andrysek, 2015)(Andrysek, 2010). Substantial percentages of people with UL loss choose not to use a device, despite having access to one (Resnik et al., 2013; Watve, Dodd, MacDonald, & Stoppard, 2011; Wright, Hagen, & Wood, 1995). Rates of rejection for both body-powered (26%) and electric (23%) devices were observed in adult populations due mostly to cost, maintenance, and weight-associated issues. (Biddiss & Chau, 2007; Fitzgibbons & Medvedev, 2015; Saunders et al., 1989). Evidence suggests that cosmetic prostheses have a higher rate of continuous use in both adult and pediatric populations than other UL options (Crandall & Tomhave, 2002)(Dudkiewicz, Gabrielov, Seiv-Ner, Zelig, & Heim, 2004). The rise of additive manufacturing (AM) capabilities has helped revolutionize design and manufacturing sectors, including healthcare products. AM technologies expand design and manufacturing capabilities significantly in developing products with lighter, multi-material, complex geometrical, and multifunctional design features. They offer an alternative avenue for designing patient-specific prosthetic solutions (Fitzgibbons & Medvedev, 2015). Still, quality assurance, standardization, and durability remain with products designed with AM technologies and materials. A significant development in using AM for designing customized UL prostheses has occurred over the past five years since they can fabricate parts of almost any geometrical complexity in less time and without significant requirements in technical expertise (Giannatsis & Dedoussis, 2009; ten Kate, Smit, & Breedveld, 2017; Zuniga et al., 2017).

This study aimed to design a 3D-printed forequarter prosthesis for a pre-selected user to replace his current device by enhancing the comfort factors of appearance and functionality. The new design aimed to be comfortable, lightweight, capable of dissipating heat, locking at 90 degrees of flexion, and void of metal components that would be detectable by airport scanners since the user was a frequent traveller.

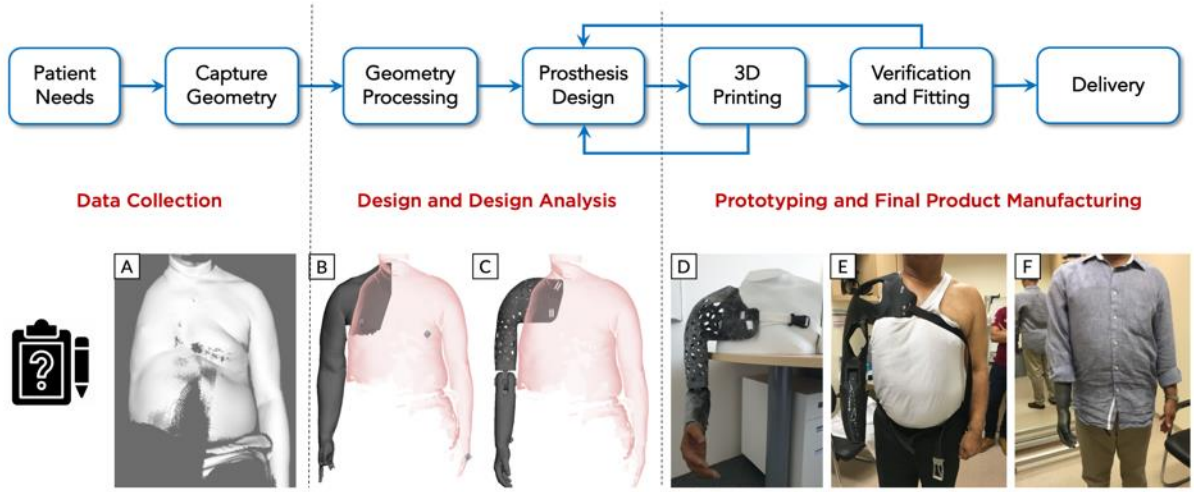

Figure 6-17. Schematic representation of the stages of the user-centered and iterative process of the prosthesis design. (A) 3D reconstruction of the patient's upper body with residual limb and sound contra-lateral arm from the cloud points captured via digital scan; (B) Basic shape of the prosthesis was obtained using the shape of the residual limb and the contralateral limb; (C) Fully-designed prosthesis in the extended position to test whether the device would hit the hip and impede the walking; (D) 3D-printed prosthesis in 90 degree flexed position to assess the angle and position of the hand with respect to the contralateral limb in a 3D-printed mannequin of the user; (E) Use-testing and verification of the prototype of the socket and interface design for design feedback; (F) Final fitting of the prosthesis to the patient and validation of the user requirement, administration of QUEST survey.

6.4.3 Design Overview

This study follows a user-centred design approach to reduce time to delivery while optimizing the fit and function of the design (Figure 6-17). User-centred design (UCD) is an approach that involves end-users throughout the development process, so the designs are easy to operate, and are of value to users [16]. The end-user was a 60-year-old male (weight 86kg, height 1.75cm) with a left traumatic forequarter amputation that occurred >40 years ago. His current cosmetic prosthesis was made from materials including pelite, laminate, silicone, and leather coverings, with the fishing line passing through the elbow joint to allow a free range of motion. Initial consultations with the user, clinical prosthetist, and user shadowing activity yielded the following major design parameters (Table 6-10). The study was approved by both local healthcare and educational institutional review boards.

Table 6-10. Description of user-defined requirements

Item No	Criteria	Rationale
1	Self-suspending	When the arm can self-suspend on the residuum, it will allow the user to hold and fix the strap around the body with the other hand.
2	Smooth surface texture	To prevent friction between device and shirt as patient wears the shirt or as the arm swings freely beneath the shirt when walking. The smooth surface will prevent the shirt from bunching in areas.
3	Heat dissipation	As Singapore is a hot climate, the user required a cooler interface between his residuum and the socket. This reduces sweat and improves overall comfort.
4	Aesthetic	User requested for the arm to match sound side in overall size, shape, and contour. The current arm doesn't match his sound side and user feels this can be improved.
5	Lightweight	Due to the difficulty of suspension for this level of amputation, the user requires the device to be as light as possible, preferably <600g. He would also be using the arm for long periods of time. Current device weighs 590 grams.
6	Non-metallic	As the user was a frequent traveller, he required no metal parts to pass through airport security easily.
7	Locking elbow	During business meetings, his current arm would slip off the armrest, drawing attention to his arm. Also, while driving, it would slide between the driver's seat and the car door, sometimes getting stuck. A locking elbow would eliminate these problems.

The iterative UCD and development methodology (Figure 6-17) followed in this project involves:

1) capturing residuum as well as contra-lateral arm geometry,
2) designing of different prosthetic elements from the captured geometry,
3) manufacturing the prosthetic elements and verifying fit, patient comfort, technical requirements,
4) capturing and documenting the design and development methodology of the process to apply to other device design applications
5) administration of the QUEST survey to determine patient satisfaction

Part I: Shape Capturing and Prosthesis Design

The portable 3D scanner (Artec EVA, Artec 3D Europe, Luxembourg) was used to scan and digitize the residuum. The device uses laser-free structured light scanning, is quick to use, and accommodates some minor movement while capturing geometry and texture information, eliminating the need for

reference markers. After a point cloud was created, we repaired the 3D triangular meshes through MeshLab Opensource software (Visual Computing Lab, CNR-ISTI, Italy) before converting them into parametric data to edit and design prosthesis components in the AutoDesk Fusion 360 CAD modelling software (Autodesk Inc., San Rafael, California, U.S.). Design and technical requirements were derived from the users' and prosthetists' needs and revised based on their feedback during the process.

Part II: Manufacturing and Delivery:

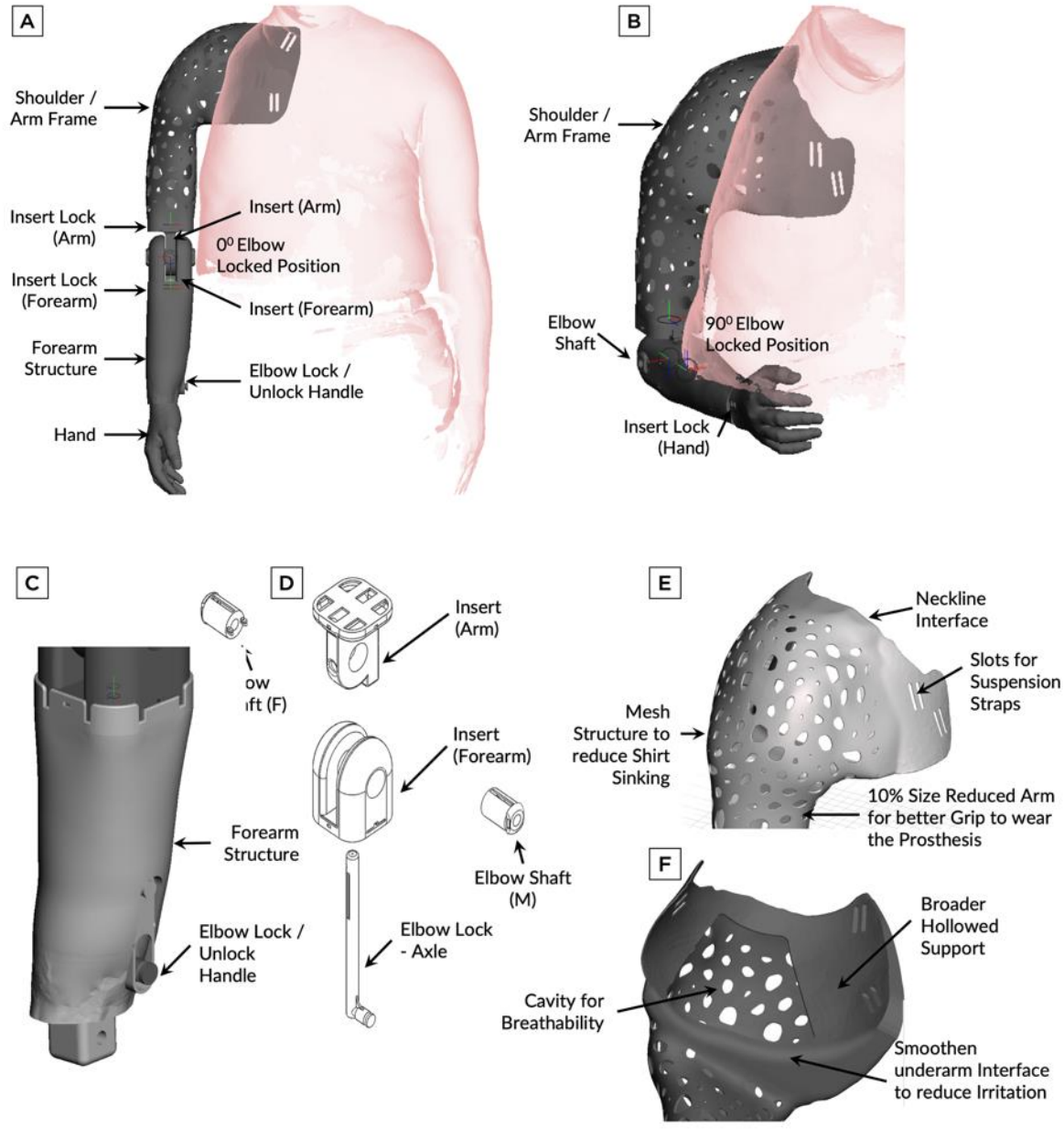

Figure 6-18. CAD model of the prosthesis (A) with forearm structure (B) incorporating the elbow lock mechanism (C) and the mesh structure of the shoulder frame (D). The elbow joint was designed to automatically lock in the required position (90 degrees) using an elastic spring at the wrist that holds and pre-loads the mechanism via an integrated shaft, which extends to the elbow and features a 90-degree bend to facilitate the elastic spring attachment and unlocking of the elbow joint. [E] A cavity was designed to improve the breathability of the prosthesis along the amputation site.

SOCKET: An early-stage design prototype (Figure 6-18E) was designed to provide a symmetrical, lightweight, and cool structure. The hollows of the socket, while providing heat dissipation, allowed the shirt to sink into them, making the arm more obvious. Based on the user's feedback, the design was revised (Figure 6-18F) by adding mesh structures over the hollows and shrinking the overall size by 10% of the captured shape to allow the shirt to fit over the arm better. The mesh structures provided a grip to help don the prosthesis with one hand. Additionally, the neckline height was lowered for improved comfort, which led to a small loss of shape symmetry to the user's sound side. The suspension was attached with webbing straps sewn through appropriately located slots created to remove the need for the user to feed the strap through the slot before tightening.

ELBOW: The user identified that a more distal location near the wrist for a control switch to lock/unlock the elbow would be advantageous as it required less sound side shoulder adduction. The elbow joint was designed to swing freely in full extension and automatically lock in the required position (90 degrees) using an elastic spring at the wrist that holds and pre-loads the mechanism via an integrated shaft. Connecting to the elbow, it features a 90-degree bend to facilitate the elastic spring attachment, unlocking the elbow joint. The carrying angles of the elbow were matched to the user's sound limb [Figure 6-18A].

The locking mechanism was incorporated in the arm structure of the CAD model itself to 3D-print the integrated assembly altogether. This design decision ensured a smooth functioning lock mechanism in the internal geometry of the arm structure, reducing interference with other structures.

HAND: The final hand structure was created 10% smaller from the scan data and was printed on an HP multi-jet fusion printer with HP-3D-HR-CB-PA-12 (Nylon) material and an Ottobock silicone glove applied to provide cosmesis. Originally the hand was printed on a J750 3D printer (Stratasys Ltd., Eden Prairie, Minnesota, United States) but was rejected by the user for being too sticky when trying to wear his shirt.

Finally, the Multi Jet Fusion (MJF) 3D printing process was used. It produces high-quality strong parts by fusing plastic powder with detailed agent and heat instead of lasers as in the Selective Laser Sintering (SLS) process (commercial PA12 powder, 60 μm particle size, 1.01 g/cm2 print density, 0.08mm layer thickness, pre-heated by the infrared lamp, and 10sec /layer speed). Experimental studies [18–20] have shown that parts made with nylon via MJF have excellent mechanical and thermal properties, are less porous, and have smoother surfaces than SLS Polyamide. This makes it more suitable for end-use products, allowing the user's shirt, in this study, to slide over the material more naturally (Figure 6-

19B). The decision to use MJF printers was based on the time required to pre-process, print, and post-process the 3D model, cost, and accessibility for feasibility in the prosthetic field.

Figure 6-19. Delivery of the prosthesis to the patient and validation of the user requirements (A) Users current arm; (B) 3D-printed final design of the prosthesis; (C-D) photographs of the user in AP and ML views showing the near-perfect aesthetic fitting of the prosthesis.

The cost for the final design was calculated after finalizing all the design parameters (Table 6-11). The user's current prosthesis costs $2000 GDP; a similar device in Singapore would cost $2800SGD, making this 3D printed device approximately 20% cheaper.

Table 6-11. Final manufacturing cost of the individual parts of the prosthesis using a commercial 3D printer (Industrial multi-jet fusion (MJF) Printer with Polyamide material)

Item Description	**Dimensions (mm)**	**Unit price (SGD)**
Elbow Shaft – Male Connector	52.66 x 29.99 x 27.50	33.00
Elbow Joint – Forearm – Insert Lock	75 x 17.75 x 76	20.00
Holder Pin (11 Numbers)	16.24 x 48.21 x 13.33	5.00
Elbow Shaft – Female Connector	45.5L x 48.21 x 13.33	33.00
Forearm (Hollowed)	77.92 x 80.62 x 228.26	238.00
Shoulder Frame	252.29 x 272.07 x 340.97	708.00
Hand - No Glove	106.3 x 68.22 x 164.56	325.00
Elbow Lock – Axle (90-degree bend)	34.35 x 175 x 12.7	38.00
Elbow Joint – Arm –Insert	71 x 87.75 x 72	250.00
Elbow Joint – Forearm –Insert	71 x 92.45 x 72	168.00
Elbow Joint – Arm – Insert Lock	75 x 17.75 x 76	20.00
Scanning and rent of scanner	1hour + $8/hr	33.00
Labour Cost and assembly	$25/hr x 12	300.00
	Total Cost (SGD)	$2171.00

Using the QUEST satisfaction survey, the designed prosthesis was compared to the user's traditionally made prosthesis (Table 6-12). Results indicated that the 3D printed arm was preferred due to its overall effectiveness, weight (670g), accurate size, ease of use, and suspension, most likely contributing to the feel of a lighter arm. It was, however, deemed less durable than traditional methods, perhaps due to the unfamiliarity of 3D printing.

Table 6-12. QUEST survey results comparing the 3D printed arm to a traditionally fabricated cosmetic prosthesis.

ITEM	Traditional (0-5 scale)	3D printed (0-5 scale)
Dimension	4	5
Weight	4	5
Ease of adjustment	4	5
Safe and Secure	4	5
Durability	5	4
Easy to use	4	5
Comfortable	4	4
Effective	4	5
Total Average	4.13	**4.75**

6.4.4 Discussion

The prosthetic options for a forequarter amputee are limited and expensive (Zuniga et al., 2017). Despite cosmetic arms being worn more frequently than electric or body-powered prostheses, they are still limited in their use (Crandall & Tomhave, 2002)(Dudkiewicz et al., 2004). In this case study, the user required a completely non-metal prosthesis that incorporated the functionality of a metal locking elbow currently used in most cosmetic arms. The use of additive manufacturing, being metal-free, and the capabilities of the scanner, software, and 3D printers to replicate the user's arm with high precision and geometric complexity was deemed the most suitable for this prosthesis.

The benefits of AM, in this case, were threefold. Firstly, this was a large and highly complex device design that would take much time to produce and at a high cost if done traditionally. There was a need to balance the time required to pre-process, print, and post-process the device. The time taken to fabricate the prosthesis with AM would be considerably less than traditional methods. For traditional methods, the labor would have been over 10 hours to cast, rectify, manufacture, fit, and deliver the prosthesis. Digital methods allowed for data capturing, geometry modifications, design, print, and post-processing to be done faster, while the accuracy of scanning and digital analysis helped to reduce the number of repeat visits during the fitting. This resulted in an overall saving of approximately 5 hours. AM provided augmentation and optimization for the customized upper-limb prosthesis while reducing human resource costs and time. The cost to produce this prosthesis was $1830, which is approximately 20% cheaper than traditional methods (Binedell, Meng, et al., 2020).

Secondly, the design freedom offered by AM accelerated the reconstruction process of the 3D anatomical limb, allowed for subtle variations in design between iterations, and contributed to a very

symmetrical look of the arm when worn under business shirts. The structural integrity of the locking mechanism and the mesh structures of the socket were tested using FE analysis. AM was then used to rapid prototype these parts for user feedback and reiteration. The final design of the prosthesis is a departure from the user's original design as it incorporates strategically placed mesh structures, resulting in a device that is cooler and more comfortable to wear. The added functions of a locking elbow provided freedom for the user to lock when driving or in business meetings, addressing a key requirement.

Thirdly, the material choice available for AM resolved the issue of being detected while passing through airport security, lowering his psychological stress. In deciding to use AM, specifically the Multi Jet Fusion (MJF), the arm could be made completely metal free without sacrificing strength and shape. MJF printed parts have excellent mechanical and thermal properties and are less porous with smoother surfaces. Therefore, apart from the security clearance benefit, this smoother surface would allow the user to easily slide his business shirt over the prosthesis when getting dressed, improving his usability experience.

AM technologies have been around in the P&O industry since the 1980s, but the adoption rate has been slow due to its limitations. However, following the wide availability of desktop printers at affordable prices, many designs can now be found on social media. The success of AM in replicating many common objects, including prostheses and orthoses, is regularly showcased on the internet. As media outlets report these stories, patients worldwide are inspired and often encouraged to try these "new" technologies. Their expectations from these reports are that they will fit better, be more comfortable, and be more useable.

The user had not considered 3D printing his new arm in our case study. Instead, he was looking to make a new arm the traditional way, with a few upgrades. After a detailed discussion about the user requirements, it was clear that AM provided the best chance of a successful outcome. By providing the user with our rationale, he became aware that AM would be the preferred method of manufacture to address all his requirements. Throughout the prototyping and iterations, the user had his expectations of the device easily surpassed, leading the user to request new options like the location of the release lock mechanism near the wrist. It may be common for users to alter their expectations based on the prototype design, hence trialing with the user is critical to ensuring optimal outcomes.

We also found that having the right team members with the right skills aided a successful outcome. With the CAD systems still very engineered focused, we needed an expert in CAD to assist with the design and printing and time to practice with the scanner and software. The clinician and engineer communication also needed to be clear to ensure the correct changes were made between iterations.

Communicating the clinical need into a design problem that could be mitigated was challenging as there was a difference in the language terms used. Having clear definitions and a good working relationship will help to overcome such challenges in the future.

Finally, apart from the user's expectations about the process and product, there were issues regarding the durability of the device. Due to the moveable locking elbow section and its controlling mechanism, the user was apprehensive about the long-term durability of the device. Again, this may have been due to his limited knowledge of the strength of materials or capabilities of AM, but it still needed to be addressed. Over time, the user became confident in the strength of the arm, and his satisfaction increased. The final satisfaction with the device was determined through the validated Quebec User Evaluation of Satisfaction with Assistive Technology questionnaire (Quest). Scores were higher or the same in all categories except durability, for reasons previously mentioned. Recording the outcomes of AM with validated instruments can help verify whether AM has met the expectations of the user.

6.4.5 Limitations and Conclusions

Studies clearly show that clinical, technological (in both design and manufacturing), and financial barriers must be overcome before AM technology can be adopted for full-scale implementation in a service system for the P&O industry (Chen, Jin, Wensman, & Shih, 2016). While the industry does not use only one manufacturing method, AM offers design opportunities to break down barriers and provide alternatives to traditional approaches. With barriers lowered, opportunities increase for users to receive optimally fitted and functional devices will lead to greater outcomes.

AM has shown the potential to outperform traditional manufacturing for complex and small specific tasks in design and cost-effectiveness. Greater technology adoption depends on material advancement, digital expertise, the development of easy-to-use software, and increased communication and collaboration with industry experts. By addressing the requirements of the user, the clinician, and the system, AM may prove to be valuable in creating sustainable and feasible solutions. AM will transform the industry eventually, but integration of AM with traditional practice may be the most appropriate method to take currently as the P&O industry transitions into digital design and workflows.

Concurrently, working with the user at each stage of the design process was an important step in verifying and validating the needs of the user. User feedback is critical to successful optimization and uses. However, users may not be fully aware of the capabilities of the technology when establishing their expectations and opportunities, and a thorough discussion is warranted.

6.5 Summary

This chapter provided evidence for possible product improvements that could enhance comfort levels. The solutions involved the design and development of a process to capture and record LoNE that may be useful for design of prostheses to manage physical comfort factors. LoNE could allow for greater ROM that would improve functional activities such as climb stairs and cycling. It would also aid in sitting comfort. Consideration should be given to the stabilisation of the residuum within the prosthesis for stability and safety during functional mobility tasks and this requires further investigation.

The thermal comfort was addressed through the design and development of a sweat reducing liner based on the dynamic capillary effect. Such an effect was demonstrated to provide enhanced comfort to the user by reducing residuum temperatures and maintaining a dry residuum during activity. This is important as it could reduce the possibility of wounds developing and allows the user the psychological comfort by reducing the need to remove the prosthesis throughout the day. Further investigation is required into the application of surface texturing and whether the microchannels can be optimized to locations known to cause sweat e.g., over the muscle belly.

Finally, the case study highlighted the usability and usefulness of digital technology (DT) in the prosthesis design process. The participant in that study was open to DT as a process but remained unfamiliar with its potential. Therefore, the use of DT with users should involve an aspect of education to build awareness and trust with the technology. DT should be developed with the prosthetist to identify real pain points that impact their everyday roles and responsibilities. When technology aids in decision-making quickly and easily, there will be significant impact and value added to the design process. It is clear from the case study that when implemented correctly, the outcomes benefit the user, the prosthetist, and the other stakeholders, e.g., the hospital. The following two chapters combine these results with previous chapters to develop the comfort-driven prosthetic design methodology

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7 DESIGNING COMFORT – PCAM

7.1 Introduction

This chapter describes the development and verification of a Prosthetic Comfort Assessment Metric (PCAM). This chapter intends to address the following objective of the thesis identified previously in Chapter 3, "Design and Verification of a comfort assessment tool." The PCAM is intended to provide insight into the comfort status of the prosthesis user to determine appropriate adjustments for improving the comfort and to provide insights into the design for subsequent prostheses. As comfort needs to be experience, PCAM is not developed to be used for the initial prosthesis of the user following their amputation, however, it can be used at the first review of the prosthesis user. Alternative solutions to address initial comfort are described in the design methodology of Chapter 8.

7.2 Background

Comfort is an essential issue and is subjective by nature (Section 2.1). Comfort can be assessed qualitatively and quantitatively. Qualitative assessment usually involves asking specific questions about the levels of comfort experienced (Richards, 1980). Quantitative assessment is usually objective by nature. The metrics for qualitative and quantitative assessment of comfort have been described in detail (Section 2.3). Quantitative methods present an aspect of a user's comfort by measuring a surrogate parameter (e.g., pressure, temperature) (See Chapter 5.2). These methods are less time-consuming and can be applied at earlier stages of the development process to determine baseline comfort levels and improvement to comfort levels. However, it is valuable for holistic assessment of the prosthesis user comfort to combine both methods.

Each prosthesis user has a different way of assessing their perception of comfort (Harms Ringdahl, Brodin, Eklund, & Borg, 1983), which may vary over time (Neumann, 2001b; Zidarov, Swaine, & Gauthier-Gagnon, 2009), increasing the difficulty in developing a standardized scale (Ramirez Patiño et al., 2015). Identifying and weighing the factors contributing to the user's comfort could lead to timely and practical improvements to their comfort levels, improving prosthetic use. Attempts have been made to measure comfort (Section 2.3). However, the interpretation of comfort remains ambiguous; a measure or a score to describe a pleasant or unpleasant experience should indicate and provide weightage to the contributing factors, enabling the designer to effectively modify the prosthesis.

The interpretation and standardization of terms expressed by the user and prosthetist with the currently used comfort scales were seen as significant barriers to overcome (Gailey et al., 2019; Ramirez Patiño et al., 2015) and did not cover other meaningful user situations such as time of day or use environment (Morgan, Askew, & Hafner, 2022). While these methods have accumulated various factors that contribute to comfort favorably or unfavorably (discomfort), they fail to demonstrate the importance of

the individual factors for the end-user. Without identifying these factors, the challenge remains in isolating their importance and impact on prosthesis design. Therefore, this study aimed to develop a Prosthetic Comfort Assessment Metric (PCAM) that reflected a holistic assessment of prosthesis comfort and provided insights into timely adjustments and design of future prostheses for the individual user.

7.3 PCAM Overview

The PCAM was developed to provide insights into the factors of comfort that matter most to the individual user and into the areas to be addressed in the prosthesis design to enhance comfort. Factors were established based on literature (Chapter 2) and a qualitative study (Chapter 4). PCAM uses six main determinants for assessing comfort: 1) Physical, 2) Physiological, 3) Psychological, 4) Expectations, 5) Context, and 6) Communication. Table 7-1 shows the six determinants and their assigned factors of comfort.

Each of the factors within a determinant are assessed individually with the prosthesis user on a three-point Likert scale, unsatisfactory [0], fair [1], and satisfactory [2] (see Appendix 5 for details). Measurement scales such as these are employed to offer a simple evaluation of each factor. These scores are also color coded using a traffic light system to focus the prosthetists attention on the factors that are not comfortable. These should be addressed where possible during the consultation. Each determinant is arranged to facilitate the conversation with the user, addressing their expectations first and finishing with communication.

To determine the level of comfort for each determinant, the Likert scale results of the factors of a determinant are added up and scaled to obtain a final score within the range of 1 to 10 (1: low level of comfort and 10: excellent level of comfort). A total combined score of the determinants is also calculated and scaled to a score of 1-10 as this was deemed easier to interpret by the prosthetists given their experience using the single-item SCS, which also uses a scale of 1-10. However, this total score is considered not relevant for the actual use of PCAM, as the aim of PCAM is to identify the comfort level of each determinant and factor in order to understand which factors contribute to discomfort. This is the main, and most significant difference with the one-item SCS.

In the following section (Section 7.4) the development and verification are described in detail.

Table 7-1. The Determinants and Factors of the Prosthetic Comfort Assessment Metric (PCAM)

Determinants	**Factors**
Expectations *The way in which the prosthesis meets the needs of the user, often expressed as an experience or goal*	Early Rehabilitation Success
	Suitable for activity needs
	Freedom from design limitations
	Ease of wearing
	Experience
Psychological *The perception of the prosthesis and its impact on the user's life*	Aesthetics (size, colour, shape)
	Reliability
	Satisfaction and QOL
Physical *The way the prosthesis design characteristics support the participation in functional activities in the user's life.*	Type of activity (walking, running, sitting etc)
	Suspension
	Componentry and Materials
	Socket contour
	Trimlines and ROM
	Shape Capture method
	Weight
	Safety and Stability (Alignment)
Physiological *The interaction between the residuum and the prosthetic socket across time*	Volume changes
	Pressure Distribution
	Thermal regulation
	Time of Exposure
Context *The way the user with the prosthesis interacts in the use and user environment.*	Environment
	Duration of activity
	Specific requirements (travel, movies, extended periods of sitting)
	Cultural/Religious activities *(Enter score 2 if not applicable)*
	Financial position
Communication *The effectiveness of the communication between the user and support networks.*	Relationship with service provider (professionalism, service delivery)
	Trust in process, product and technology
	Access to care
	Social support network

7.4 Verification questions

To address the objective listed in 7.1, several verification questions were derived.

- VQ.1 Does the use of the PCAM improve understanding of prosthesis user comfort?
- VQ.2 Does PCAM provide high internal consistency in measuring comfort factors?

- VQ.3 Does the use of PCAM provide an effective way to describe comfort related issues with the prosthesis?
- VQ.4 When is it most appropriate to administer the PCAM?
- VQ.5 Does PCAM provide correlation with the SCS?

7.5 Research Methods

7.5.1 PCAM Development

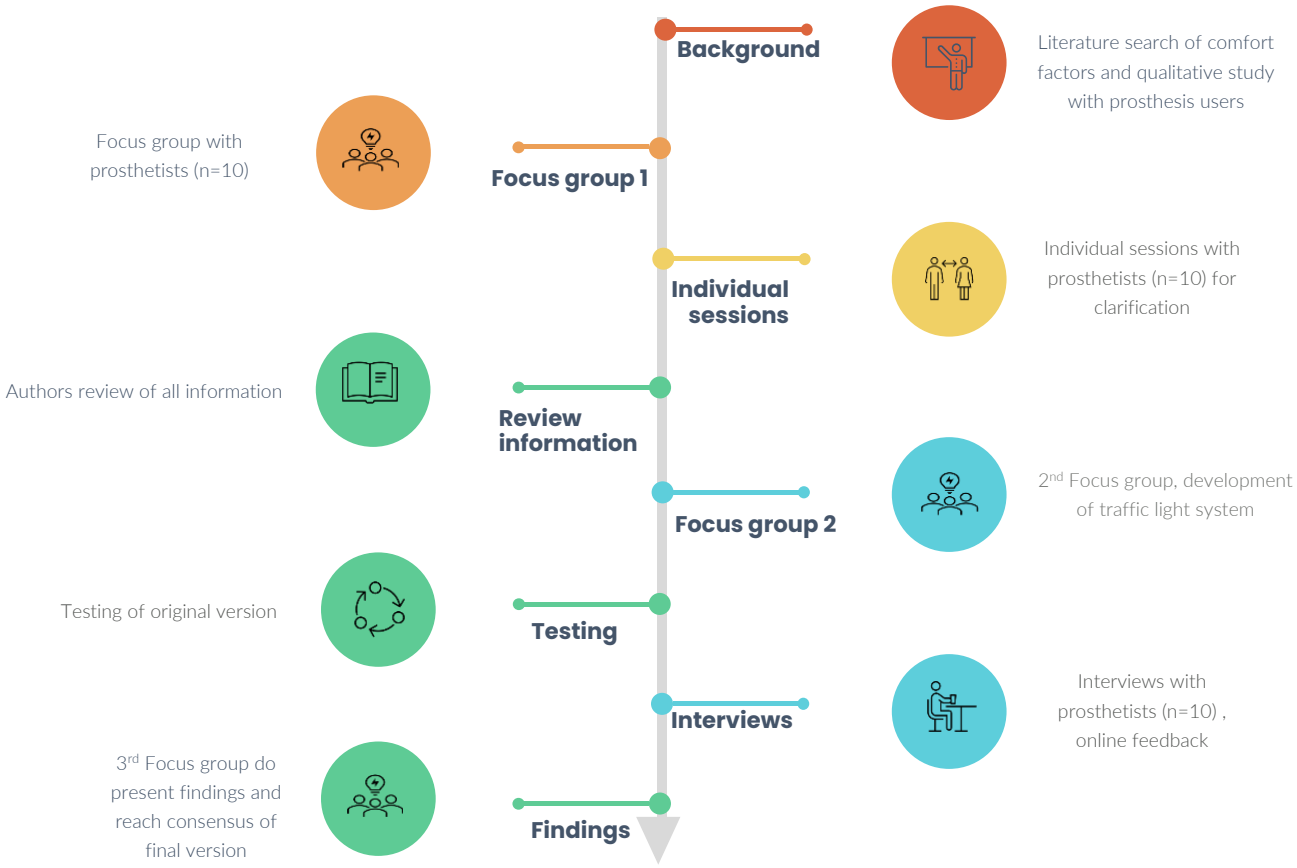

Figure 7-1. Schematic representation of the development process of the PCAM

The timeline for the development of PCAM can be seen in Figure 7-1. Following a previous literature search (Chapter 2) and qualitative research investigation with prosthetic users (Chapter 4), the information provided the background details for the metric. The factors that most affected comfort were presented to a focus group of 10 prosthetists from Singapore for discussion on their importance to design and subsequent need to include into a metric. The prosthetists had various Asian backgrounds and experience. Individual sessions with each prosthetist followed to ensure understanding and for any clarification. The authors then reviewed the factors and created a draft of the PCAM for discussion

during a second focus group. Delivery methods and barriers to implementation were discussed, and a consensus was reached. PCAM was created in a digital version using Microsoft Excel for Mac (Ver.16.62), with a traffic light system (TLS) to identify more easily the comfort factors that required more urgent attention. The TLS was adopted to present the factors of comfort in which the red and green colors indicate unacceptable and acceptable comfort levels, respectively. The yellow color in the TLS is also used to indicate marginal comfort issues. Following the administration of PCAM, feedback was recorded through individual interviews and surveys as it related to the six determinants. Finally, we reviewed the internal consistency results and prosthetists' comments to determine the most meaningful items for inclusion in the final PCAM.

Ten prosthetists completed the testing of the original version of PCAM. Each prosthetist was instructed to test on at least two prosthesis users. The prosthetists were required to complete a pre-survey on their content knowledge of comfort and familiarity with PCAM before administering the metric to the prosthesis users. Immediately following the user's visit, a second survey was filled in to gather feedback on the usefulness and usability of PCAM. Questions were open-ended and closed where relevant. For every subsequent user, the same procedure was followed.

Following the testing phase, each prosthetist was interviewed again about the usefulness and usability of PCAM. Results were collated by the authors and analyzed. A final focus group was conducted to present the findings, clarify the results, and seek consensus on the changes required for the final version of PCAM. All revisions of the PCAM after data collection are discussed in the "Results" section.

7.5.2 Participants

A cross-sectional convenience sample of category 1 ISPO-trained working prosthetists in Singapore was recruited to test and provide feedback to the final version of the PCAM. Inclusion criteria were: [1] Category 1 trained in accordance with ISPO standards (Lemaire, Supan, & Ortiz, 2018), [2] currently working as a prosthetist in Singapore. This study was approved by the Singapore University of Technology and Design Ethical Board. All participants received an explanation of the study and signed an informed consent

7.5.3 Procedure

The prosthetists were required to complete a pre-survey on their content knowledge of comfort and familiarity with PCAM before administering the metric to the prosthesis users. The prosthetists were instructed to administered PCAM with at least two prosthesis users during their regular appointment to the hospital. The PCAM was uploaded to the prosthetists computers as a digital file to test the

effectiveness of the TLS. The prosthetists were instructed to also ask for the SCS. Following the user's visit, a second survey was completed to gather feedback on the usefulness and usability of PCAM. Questions in this survey were open-ended and closed, where relevant. For every subsequent user to whom the PCAM was administered, the same procedure was followed. A copy of the survey is provided in Appendix 6.

Once the survey's had all been completed by all prosthetists, they were analyzed, and clarifications were sought during follow up interviews with each prosthetist. Results were collated and analyzed for common findings. A final focus group was conducted to present the findings, clarify the results, and seek consensus on the changes required for the final version of PCAM. All revisions of the PCAM after data collection are discussed in section 7.7.

7.5.4 Data Analysis

Descriptive statistics were computed using mean and standard deviation for continuous data and frequencies for categorical variable items. Item analysis was performed using Cronbach's alpha to determine the internal consistency of each determinant overall. Two tailed T-tests were conducted for correlation between metric determinants and SCS. Data analysis was performed with Microsoft Excel for Mac (16.62). Interview and survey responses were analyzed and grouped into common themes. The potential themes were compared across all the prosthetists.

7.6 Verification

Demographics

Ten prosthetists were recruited to participate in the study, assessing 17 prosthetic users with PCAM. The prosthetists' mean number of years of experience was 11.3 ± 7.69 (Table 7-2).

Table 7-2. Descriptive Analysis of participants understanding of comfort and PCAM.

Prosthetist	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**MEAN + SD**
Experience (years)	2	3	4	8	10	13	13	13	22	25	**11.3 ± 7.69**

Of the 17 LLA prosthesis users that were assessed with PCAM, 100% were male and were amputated at a transtibial level (Table 7-3). All but one user came to the clinic to review the prosthesis, one was there to fit their prosthesis.

Table 7-3. Descriptive analysis of prosthetic users

Amputation Level	Age (mean ± SD)	Male	Female	Reason for appointment
Transtibial (n=17) Transfemoral (n=0) Other (n=0)	54.29 ± 13.51	N=17	N=0	Review of prosthesis (n=16) Fitting of prosthesis (n=1)

VQ. 1. Does the use of the PCAM improve understanding of prosthesis user comfort?

Even though the prosthetists had all attended the focus groups and were interviewed individually to clarify any concerns they had, the prosthetists' self-rated understanding of comfort as a concept varied. The pre-and post-implementation survey suggested that using the PCAM more than once increased the prosthetists' understanding of the comfort concept. The changes to understanding are reported in (Figure 7-2). Prosthetists with lesser experience had lower scores for understanding of comfort than those with more experience, although there is some overlap.

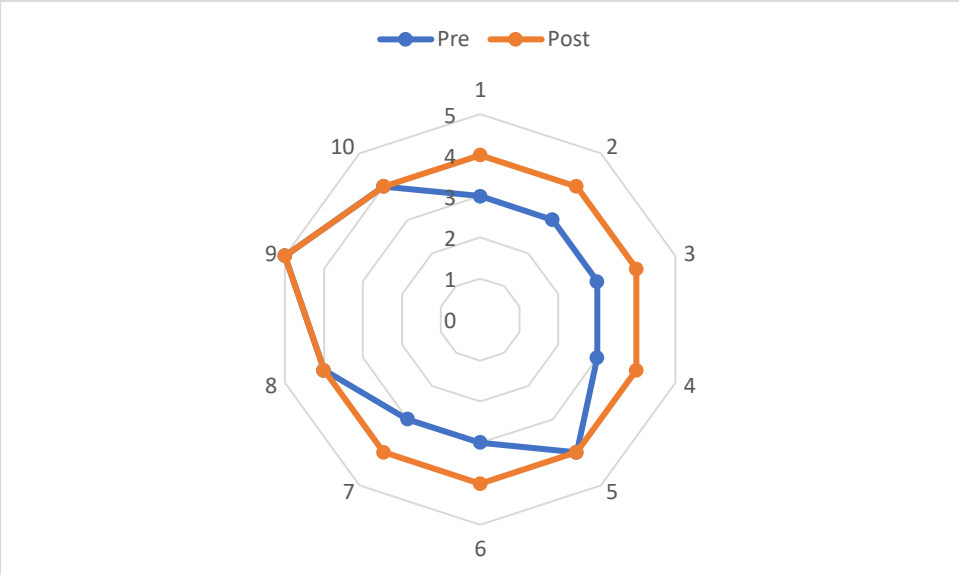

Figure 7-2. Understanding of user comfort, Numbers 1-10 reflect the participating prosthetists that correlates to Table 1; Improvement in understanding is indicated on a scale from 0-5.

VQ.2. Does PCAM provide high internal consistency in measuring comfort factors?

Analysis of determinants was conducted with Cronbach's alpha to identify a high internal consistency of PCAM [0.873]. Results above 0.80 are generally accepted to be of high internal consistency (Table 7-4). For intra-item consistency, only the context determinant showed high consistency (0.807). Calculations were conducted when individual factors were removed, however the overall Cronbach

alpha result did not change beyond the range of 0.1 suggesting each of the individual factors within the determinants are important.

Table 7-4. Correlation with Cronbach's alpha and PCAM determinants.

Metric determinants	**Intra-item consistency** *(Cronbach's alpha)*	**Overall correlation** *(Cronbach's alpha)*
Physical	(0.591)	0.873
Physiological	(0.464)	
Psychological	(0.414)	
Expectations	(0.600)	
Context	(0.807)	
Communication	(0.714)	

VQ.3. Does the use of PCAM provide an effective way to describe comfort related issues with the prosthesis?

When the prosthetists were asked *"How valuable is this way of assessing comfort to your designs?"* All 10 prosthetists stated that they thought that all relevant comfort factors were included. On a 5-point Likert scale with range (Extremely valuable – Not at all Valuable), one prosthetist found the PCAM extremely valuable, and three prosthetists very valuable in determining areas of comfort that need addressing.

When the prosthetists answered the question "*Were there any difficult questions or areas that you had trouble with?" in an open-ended question on the survey,* difficulties were noted in explaining the concepts within three determinants: Psychological, Expectations, and Context (Figure 7-3). These were investigated during the final focus group. The prosthetists felt the factors within these determinants provide some overlap or descriptions were not clear, making it seem as if questions were being repeated to the user. In the Psychological determinate, perception, satisfaction and QOL were deemed to be assessing similar factors of comfort and it was decided to combine into one, reducing the total number of factors in Psychological to three. In Expectations, the factor "freedom with prosthesis" was felt to ambiguous and was changed to "freedom from design limitations", to better reflect this comfort factor. The difficulty with Context arose when users were not religious. The prosthetists did not know how to answer this question and leaving it blank would affect the aggregate scores. Therefore, it was decided to indicate a score of 2 if this field was not applicable to the user.

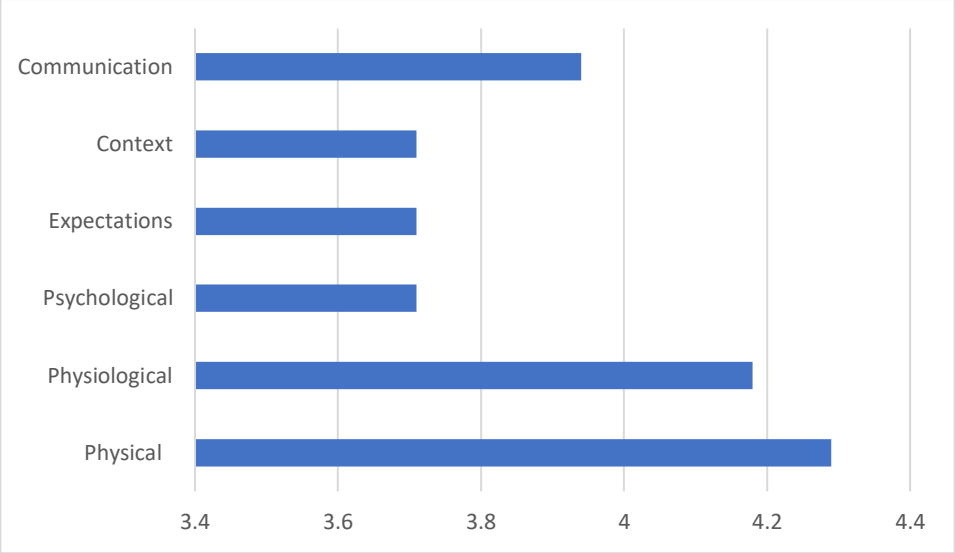

Figure 7-3. Weighted average for ease of PCAM use

The common comments when answering the question "*What were 3 things you liked when using the assessment*?" were

- Helped with communication, building rapport with patient
- Comprehensive and showed areas that need addressing
- Auto Score calculation with traffic light system

The prosthetists comments in answering the question "*What were 3 things you would have liked when using the assessment*?" the improvements needed were

- Converting the English version to regional languages for easier administration
- Adding prompts for action or decisions to take
- Improving the flow of questions to facilitate the conversation.

As a result of these suggestions, a summary of the changes incorporated into the final version is below.

1. A change in the order in which the determinants were asked to improve the flow for a more organic conversation with the user.
2. The Psychological determinant was shortened to three factors to prevent overlap.
3. Perception, satisfaction and QOL were merged, and perception was removed, and the factor is listed as Satisfaction and QOL.
4. In Expectations, the factor "freedom with prosthesis" was changed to "freedom from design limitations", to better reflect this comfort factor.
5. In Context, it was decided to indicate a score of 2 if this field if it was not applicable to the user.

The focus group of prosthetists reached a consensus on all changes.

VQ.4. When is it most important to administer the PCAM?

The prosthetists estimated that between 5-10 minutes was required to administer PCAM, with many suggesting closer to 5 minutes would be ideal. Limited clinical time was reported to be the main reason behind this. One prosthetist when answering the open-ended survey question "Would you be willing to use this assessment in your regular consultations at the appropriate appointment?", replied with maybe, explaining the feeling that it felt like another outcome measure.

Nine prosthetists believe the appropriate phase to administer the PCAM is during a review appointment after the prosthesis has been fitted. One prosthetist stated it would be useful following discharge from physiotherapy sessions. All agreeing that the prosthesis would need to be delivered and used, for PCAM to be of any benefit.

The prosthetists were asked "*Is there a particular group of patients whom this assessment would be suited to*?" as an open-ended question. Three prosthetists mentioned English speaking as the form was designed in English. Three prosthetists mentioned a base mobility level of a community ambulator. One prosthetist felt it was not useful for congenital users.

VQ.5. Does PCAM provide significant difference with the SCS?

The multi-item PCAM scores were compared to the single item SCS described in section 2.3. A scatterplot comparing the results of the PCAM and SCS can be seen in Figure 7-4. There was no significant difference between the SCS score and each of the PCAM determinants (Table 7-5).

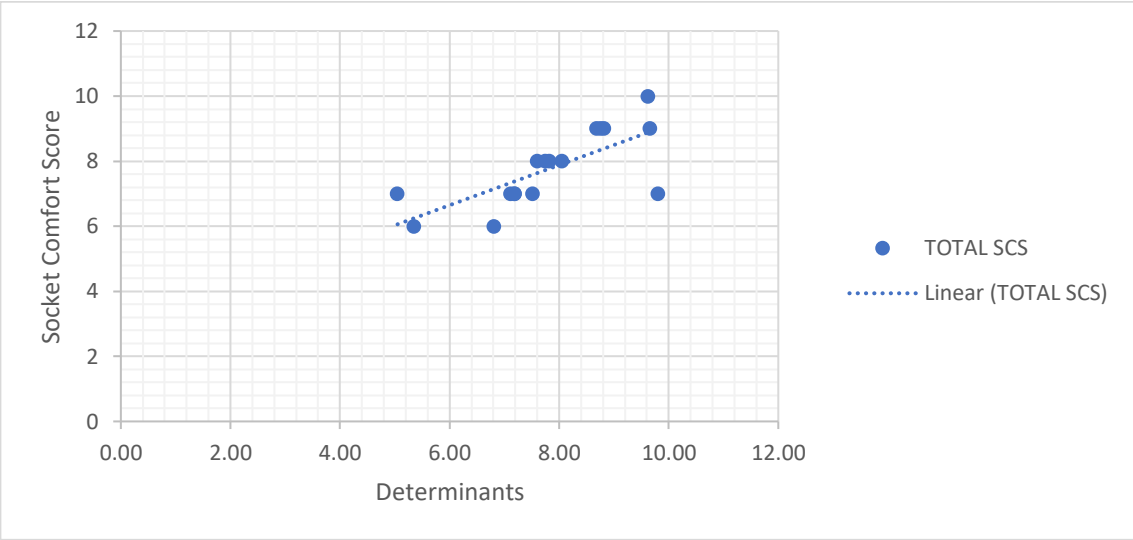

Figure 7-4. Scatterplot comparison of PCAM and SCS

Table 7-5. Significant difference of PCAM and Socket comfort scores within determinants

Metric determinants	**p-value**
Physical	0.56
Physiological	0.31
Psychological	0.16
Expectations	0.88
Context	0.15
Communication	0.065

7.7 Discussion

This study aimed to design and verify the PCAM assessment tool. The following discussion is based around the verification questions earlier identified. They are repeated here for ease of comparison. While other studies have tested their tools with users, this study sought to test the usefulness of PCAM primarily with prosthetists to improve the design of the prosthesis. Typically, it is the prosthetist as part of a multi-disciplinary team that decides on the prescription of the prosthesis for the user. However, users and prosthetists encounter each other in rehabilitation with different expectations and concerns (Messinger, 2010). Understanding these expectations are necessary to improve outcomes. The PCAM aims to support this collaborative approach: the PCAM is designed to be administered by the prosthetist to help build rapport and trust between the prosthetist and the user.

VQ.1 Does the use of the PCAM improve understanding of prosthesis user comfort?

Using PCAM increased prosthetists' knowledge and understanding of comfort. PCAM was particularly useful for less-experienced prosthetists. It is likely that the experienced users have encountered more comfort related factors over the years, leading to an established understanding of comfort. Repeated use of PCAM increased familiarity with comfort and the PCAM assessment tool, which may lead to improved decision-making for the adjustment or new design of the prosthesis. While the PCAM cannot replace experience of user comfort, it may help create greater understanding earlier for the lesser experienced prosthetists improving the comfort of their designs.

VQ.2 Does PCAM provide high internal consistency in measuring comfort factors?

As previously described, the internal consistency for PCAM was high. Each factor within the determinants was relevant. Despite these findings the prosthetists felt the need to consolidate the

psychological determinant to 3 questions and combine perception with satisfaction and QOL to facilitate easier administration. While perception, satisfaction and QOL are different this may not be apparent to the prosthetists. Clearer definition of these factors is required if they are to be considered individual factors of comfort. The small sample size in this study limited its findings and generalization.

VQ.3 Does the use of PCAM provide an effective way to describe comfort related issues with the prosthesis?

The six main determinants covered all factors of comfort. Previous comfort measurement tools have expanded on the SCS due to its limitations in applicability to include items such as aesthetics, stability, suspension, functionality, and psychological factors (Gailey et al., 2019; Ramirez Patiño et al., 2015). The PCAM contains these factors and expands to incorporate factors identified in the literature (Chapter 2) and the user study (Chapter 4). Furthermore, the use of the focus groups with the prosthetists helped to confirm no additional factors to be included that represent the local populations of prosthesis users.

Many of the prosthetists in this study were surprised because they had not considered many of these factors in the design of the prosthesis explicitly, such as trust, religious and cultural contexts, and financial situation. This suggests there may be bias over years of practice that interfere with fully optimized designs (Kurichi et al., 2007). The prosthetist may end up designing the prosthesis based on previous experiences or availability of componentry. Efforts should be made to encourage design innovation which limits the prosthetists preferences in the design process. Acknowledging these exist is a good starting point. By using the PCAM in their decision the users feel they are being listened to rather than prescribed to, leading to their needs being optimized in the prosthesis design.

In identifying the comfort factors to optimize in the design, the prosthetists were supportive of the TLS to categorize the factors and support decision making. They noted its usefulness to zoom into factors that need urgent attention. The usefulness of a TLS has been demonstrated in the early detection of problems and in the ongoing assessment (Hindley, 2012; Vizcaychipi et al., 2020) confirming its value to the PCAM. Scores with the TLS could be used as a reference check for improved comfort with the prosthesis over time, particularly for challenging cases.

VQ.4 When is it most appropriate to administer the PCAM?

PCAM is best utilized after the prosthesis has been delivered. Our study indicated that there was a need for the prosthesis to be experienced so that all factors of comfort could be assessed. This supports the earlier statements from the literature (Chapter 2) that suggests comfort should be experienced.

Therefore, they may need to be a second PCAM to address issues prior to the first prosthesis, however these would remain as expectations for the design and may change once the prosthesis is delivered.

The larger consideration with administering PCAM is the amount of time required and available. Insufficient time has been a critical barrier to adopting assessment tools as clinicians struggled with the consultations in their usual clinical routines (Gaunaurd et al., 2015; Hafner et al., 2017; Young, Rowley, & Lalor, 2018). PCAM was ideally administered within 5 minutes as the clinical time per patient is limited to 45 minutes. However, it is important to consider the depth of the PCAM and its findings into the overall prosthesis design process. Adding additional factors that directly influence the design can save clinical time in making the adjustments while positively impacting the communication between the prosthetist and the user (Ramirez Patiño et al., 2015).

The concern over time to administer PCAM is usually compounded by lack of confidence and knowledge of the tool. Increasing the use of PCAM, may naturally allow the prosthetist to familiarize themselves with the questions and facilitate faster delivery. The small sample sized supports this, however, a larger cohort is required to confirm this finding. Using language that the users understand could facilitate faster responses and avoid potential misinterpretations, and hence improve insights obtained from the use of PCAM. Using the user's language was found to improve communication between prosthetists and users (Gailey et al., 2019). This is supported by the feedback of the survey to create additional PCAM versions in multiple languages.

VQ.5 Does PCAM provide significant difference with the SCS?

The PCAM results were not significantly different to the SCS overall or within the six determinants. This comparison in the context of this thesis is relevant because the SCS score is widely used to determine overall comfort, i.e., both prosthetists and users are familiar with the scale, and both are subjective measures. However, the aim is not to obtain an absolute value, but how to increase the value. As the introduction to this thesis shows, designing a comfortable prosthesis is very difficult and multiple visits to the clinic are necessary to adjust the prosthesis. SCS as a single-item scale is easy to administer taking less than a minute to complete (Hanspal et al., 2003) but does not provide any indication of the factors that could be addressed to increase comfort. PCAM provides a detailed understanding by obtaining comfort scores for all factors that affect comfort, which the prosthetist can use to focus improvement on those factors that matter. The overall scores in PCAM therefore only play a minor role as an overall indicator similar to the familiar SCS. The prosthetists suggested during the follow-up focus group that the SCS is still a quick measure to determine overall comfort, while the PCAM could be used to determine areas for improvement should the SCS be low.

Despite PCAM's expected value to the design process and the introduction of the TLS, PCM does require more time at the beginning of the process which could lead to under-utilization.

7.8 Limitations

There are limitations associated with the study that may have impacted the findings and our ability to draw conclusions.

The PCAM was designed in English, but some participating prosthesis users were non-native speakers. If there is a language barrier this remains a problem in the current traditional way of determining user comfort and needs. The PCAM can be translated and is thus an improvement over the current practice. The PCAM is not designed to specifically ask a question within a factor, rather to allow greater communication and understanding of each factor with the user's experience with the prosthesis. Thus, the prosthetists' may vary the wording used to ask the questions which may influence the user's interpretations and therefore their answers.

PCAM was tested only with male prosthesis users with a transtibial amputation expanding to include females and other levels of amputation may help inform the tool's reliability. As mentioned in Section 2.2, gender differences exist in physiological comfort.

7.9 Conclusions

The decision support of PCAM provides deeper understanding of comfort related factors in the design of a prosthesis. New factors were identified with users previously not considered in the design. PCAM can effectively determine the factors of comfort for prosthesis users, enabling the prosthetists to address them and is a suitable tool to understand comfort as part of the Comfort-driven Prosthesis Design Methodology (CPDM). Prosthesis users felt better understood and their concerns addressed through the sharing of their needs created by the PCAM.

The PCAM is a reliable assessment tool which is best administered after the user has had some experience with the prosthesis i.e., after delivery. Experience with the prosthesis enables the user to better convey the factors and their impact on their lives. This will lead to better decision making of the prosthetists in the design. The next chapter discusses the development of the CPDM followed by the evaluation in Chapter 9. The final version of the PCAM was used in the evaluation of CPDM.

8 COMFORT-DRIVEN PROSTHESIS DESIGN METHODOLOGY (CPDM) – DEVELOPMENT

8.1 Introduction

This chapter describes and evaluates a methodology which aims to assist prosthetists in designing lower limb prostheses for optimal comfort, called Comfort-driven Prosthetic Design Methodology (CPDM). This chapter addresses the following objective of this thesis identified earlier in Chapter 3, "Development and evaluation a methodology to assist comfort-driven prosthesis design."

The backbone for CPDM are the factors that influence comfort as well as traditional and state-of-the-art methods for capturing and measuring these factors that were identified through the research described in Section 2.2.2 and 4-6. Figure 8-1 displays all the identified factors of prosthesis comfort. Some factors are known and are explicitly addressed by prosthetists using a variety of methods. However, we are not aware of any approach that brings all factors and methods together into a methodology that supports prosthetists in addressing these factors in a systematic manner to enable them to design a comfortable prosthesis.

Figure 8-1. Factors of comfort identified through a literature review (Section 2.2.2), user interviews (Section 4.4), and focus groups with prosthetists

8.2 Design Guide and Importance

Lower limb prosthesis design has evolved from creating devices that provide weight-bearing support to devices that perform specific behaviors to aid locomotion (Price et al., 2019). The design process for a prosthesis has been summarized in Section 2.4, with several factors influencing the decision-making of

the prosthetist. Factors specific to the prosthesis user are often associated with the various components of a prosthesis, e.g., socket, interface, knee, and foot. The decision to use certain components is influenced by available resources, the environment or are psychological in nature (Anderson, 2022). Specifically, a prosthesis user may place different weightage on certain factors and have preferences for some factors over others (Elwyn et al., 2012). Additionally, every individual with a new lower limb amputation (LLA) will progress through the various stages of rehabilitation at their own pace, further complicating the prosthesis design decision-making process (Meier & Heckman, 2014; Stineman et al., 2010). Although multiple prosthesis designs exist, many remain uncomfortable or disused, and no solid evidence exists for matching any specific design to an individual user (Balk et al., 2018; A. Donaghy et al., 2020; Van Twillert et al., 2013).

Despite the need for designing a prosthesis that maximizes clinical and functional outcomes, only a few design changes have been proposed to improve the design process which have centered on the initial prosthetic prescription process through user-centred design approaches (Anderson, 2022; A. Donaghy et al., 2020; Price et al., 2019), rather than being prepared to change the entire design process through methodologies, such as the human-machine-design centered framework for the development of a powered prosthetic knee by (Beckerle et al., 2017). CPDM covers entire design process including the refinement phase which helps to ensure comfort levels are maintained and the prosthesis is usable and useful in the user's life, where as the model of Beckerle is focus on an end-product only as is modelled off design methods from mechanical engineering. Beckerle does however, use the Quality Function Deployment (QFD) to rank the technical requirements based on interrelations between technical and human needs. Such methods are also incorporated into the CPDM and are explained in detail in Section 8.6.

8.3 Pahl and Beitz engineering design methodology (Pahl et al., 2007)

As shown in Section 2.4.1, mechanical engineering and product development offer various methodologies describing a stepwise, iterative approach to designing a product that ensures quality and safety and avoids missing any critical steps. These methodologies appear to be useful for designing prostheses as they capture the technical aspects of the design. One of the most well-known methodologies in mechanical engineering design is that of Pahl and Beitz (Pahl et al., 2007). It is the basis for many design methodologies and has been translated into multiple languages indicating its usefulness in design. Pahl and Beitz's (Pahl et al., 2007) systematic design approach (Figure 8-2) involves a sequence of four (iterative) phases: (1) Task Clarification, (2) Conceptual Design, (3) Embodiment Design, and (4) Detail Design. This design approach was adopted and adapted to develop CPDM. An obvious gap in the approach of (Pahl et al., 2007) specifically for prosthesis design is the needs gathering, due to the focus on engineering industry. The needs are of vital importance to

determine the requirements of the prosthesis (Anderson, 2022; Beckerle et al., 2013; Price et al., 2019; Walker et al., 2020) and are critical for creating a comfortable prosthesis and positive user experience. Product development methodologies such as Ulrich and Eppinger (Ulrich & Eppinger, 2012) fulfil that need but are less detailed as compared to Pahl and Beitz (Pahl et al., 2007).

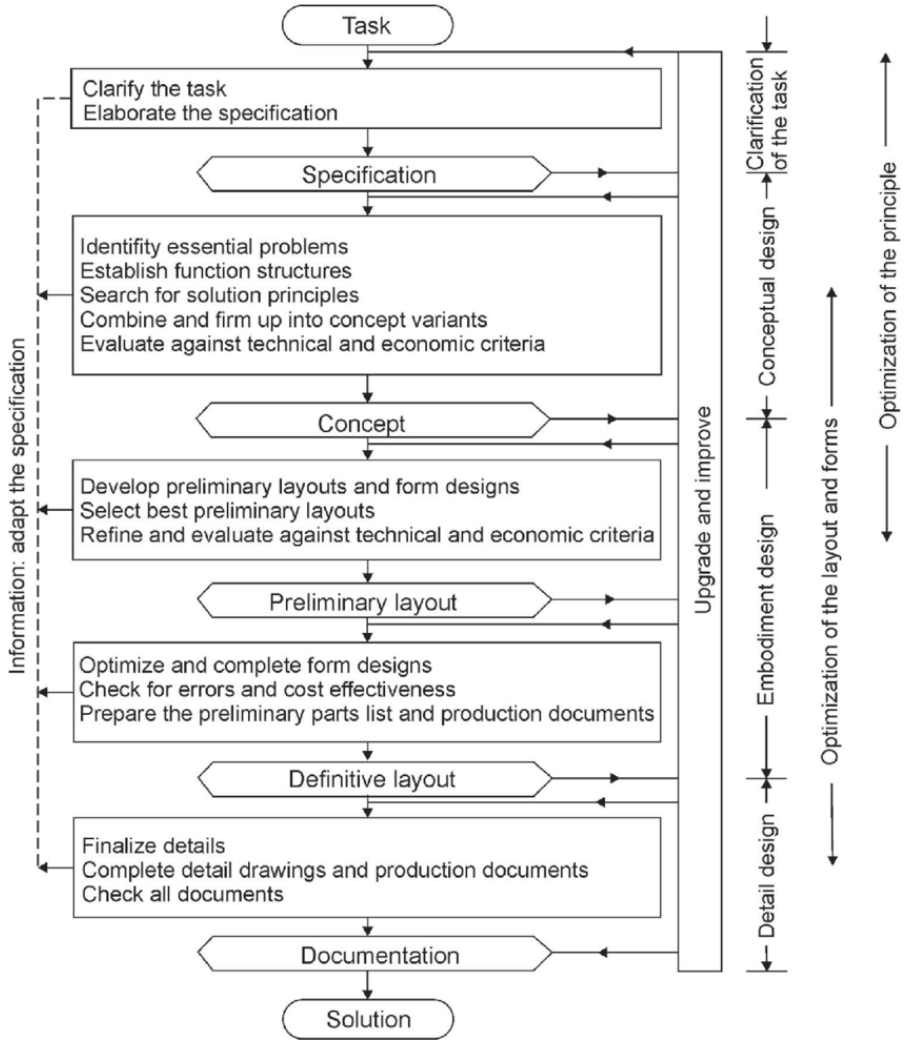

Figure 8-2. The general engineering design process proposed by Pahl and Beitz (Pahl et al., 2007)

The design phases in the methodology of Pahl and Beitz (Pahl et al., 2007) shown in Figure 2 are explained below.

Task Clarification involves collecting, formulating, and documenting the product's requirements to be designed and any constraints. ***Conceptual Design*** aims to identify the basic principles and outline of a design solution (or concept) in an abstract, solution-neutral functional structure. This makes the solution space as wide as possible, removing prejudices that may tempt the designer to decide on a specific solution before other alternatives have been considered (Malmqvist, Axelsson, & Johansson, 1996).

Embodiment Design then elaborates the concept into a layout that satisfies various technical, manufacturing, and economic criteria. The design will, in this phase, be developed to the point that an explicit check of function, durability, production, assembly, and other requirements can be carried out (Malmqvist et al., 1996). ***Detail Design*** finalizes the design and prepares production documents.

Each of the four phases comprises a sequence of activities that are usually executed iteratively. After every phase, a gate review is performed to assess the results and decide whether the subsequent phase can be started or whether it needs iteration (Kannengiesser & Gero, 2017).

Despite the detailed approach to design, some of the critical factors of prosthesis design are not addressed in sufficient detail, such as the expectations and experience of the end-user concerning changes over time, user testing, and review of the end product on multiple occasions. In particular, the expectations and experiences of the users are essential in prescribing and designing lower limb prostheses but are rarely examined in practice. According to (Price et al., 2019) involving the user at the early stage of the design process to ascertain their expectations would aid in making better design decisions, resulting in innovative prosthesis designs. To address changes that occur over time, a User Experience Lifestyle Model ContinUE has been developed in the field of product development (Pohlmeyer, Hecht, & Blessing, 2009). This model provides sequential phases of a user experience and expands the temporal space of the system-user (or prosthesis-user) relationship. It considers five experience types of experiences: Anticipated, Use, Reflective, Repetitive, and Retrospective Experiences. The ContinUE model helps to understand the evolving expectations and the inherent experience-based feelings of comfort with the prostheses.

8.4 The Kano Model

To further improve the understanding of the human factors in design between the prosthesis and user, the Kano model of Customer Satisfaction can be used. This model has been developed in 1984 by a Japanese researcher and consultant, Noriaki Kano (Kano, Seraku, Takahashi, & Tsuji, 1984) to identify requirements that satisfy customer needs, (Figure 8-3). The Kano model identifies customer understanding with the attributes of a product, such as aesthetics or weight. It classifies the attributes into different categories depending on their impact on customer satisfaction. The basic features are the expected results or must-haves, the performance features are generally one-dimensional, and the excitement features bring a “wow” factor to the customer. Over time, the unexpected excitement features become expected features of which the performance drives satisfaction. Eventually, many will become basic features.

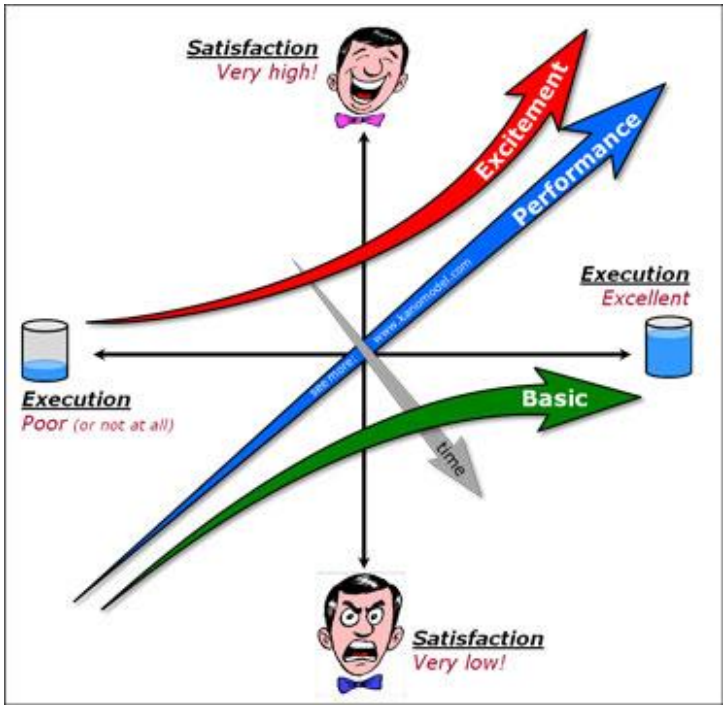

Figure 8-3. Kano Model of customer satisfaction (Kano et al., 1984)

In adapting this model to represent prosthesis comfort (Figure 8-4), the basic arrow can be adapted to represent a basic level of comfort – based on the user's expectations – that must be included in the design, e.g., the ability to walk, balance, and safety. Basic features are usually not expressed by the user but expected. Therefore, even if they are fulfilled fully, this will not improve satisfaction. If they are not well fulfilled, satisfaction will drop quickly. The performance arrow reflects a "*higher order"* level of comfort that the user wishes for in their prosthesis, e.g., lightweight, or more functional components. The performance features are those normally expressed and expected by the users and the better these features are fulfilled, the more satisfied the user. The highest level is the excitement level of comfort and is the "wow" of a comfortable prosthesis, e.g., aesthetic features, sweat reducing liners, new design freedoms from incorporating the Lines of Non-Extension. The Wow factors (or novelty factors) are not expected and therefore not expressed by the user, and even if they are only marginally fulfilled, the fact that the product has these features leads to high satisfaction. Figure 8-4 also indicates the relationship between discomfort and comfort experiences and how expectations and experiences evolve and change over time with the use of and growing experience with the prosthesis. While comfort and discomfort are not a linear continuum, there is a relationship, in that the discomfort factors need to be addressed for comfort to be experienced. Satisfaction levels can drop over time, either because of higher expectations or worsening experiences. (Anderson, 2022) suggests that the prosthesis design process should be adaptable to accommodate changes in the user's life. The assumption behind the development of CPDM is that with a suitable prosthesis design methodology, the prosthetist could preempt the potential challenges, by capturing these requirements as early as possible in the design process and

design the prosthesis to accommodate these. The time arrow indicates these changes in user needs and expectations on the level of comfort.

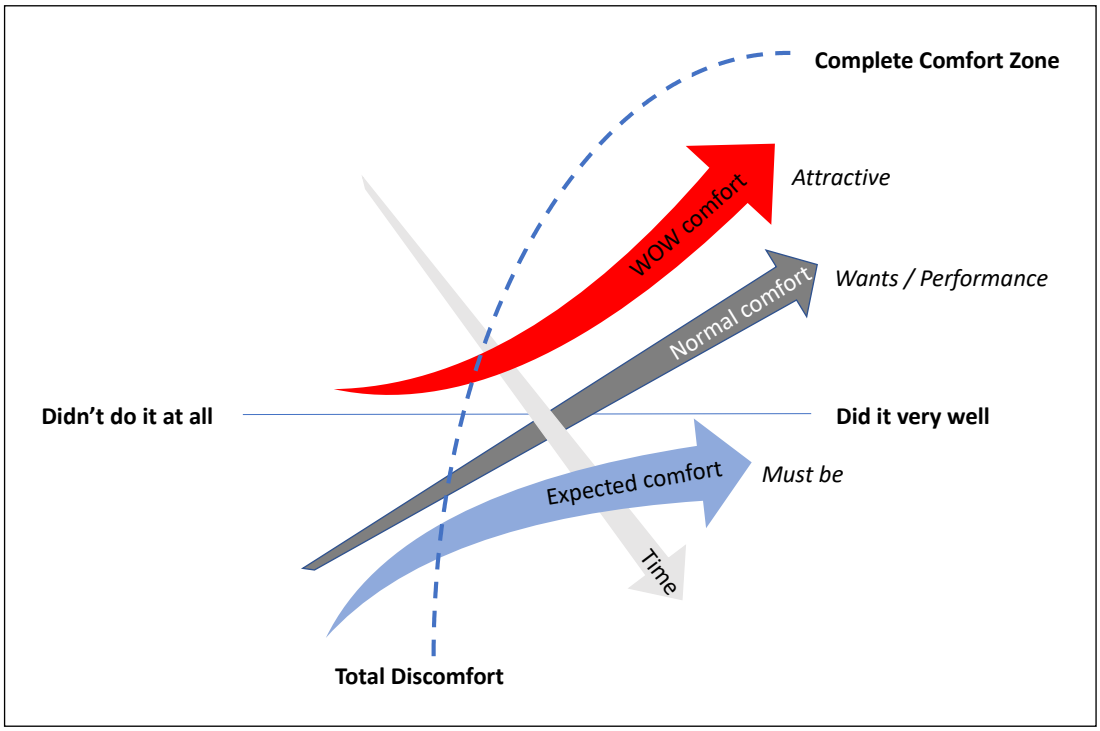

Figure 8-4. Prostheses model of comfort (Adapted from Kano Model)

8.5 Influences of Pahl and Beitz methodology and Kano model on CPDM

In most cases, the primary design goal of current lower limb prostheses is to restore gait symmetry and effort to able-bodied levels (Price et al., 2019). The prosthetist typically assesses the need for the prosthesis, the fit of the current prosthesis (if any), intended or actual use and function, and takes an inventory of the prosthesis user's problems and (dis)satisfaction with the prosthesis (Sansam et al., 2014). "In practice, this assessment is often not standardized. Standardization of the process may improve the efficiency and quality of the consultation, provided it includes the systematic collection of prosthesis users' information and experiences. It includes any problems with the residual limb" (Baars, Geertzen, & Dijkstra, 2021). One problem is that experienced users tend to provide negative feedback, indicating what needs to be altered but not how best to do so (Walker et al., 2020) – an acknowledged problem in assistive device design for many years (Batavia & Hammer, 1990). Where positive feedback is elicited, there is a tendency among prosthetists to focus on the quantitative, functional aspects of a design (e.g., device performance), leaving the qualitative and contextual aspects of user experience (e.g., how users feel about their prosthesis) underexplored (Walker et al., 2020).

Meeting user requirements is necessary for product success in general (Pahl et al., 2007). This is a key step in overcoming some of the barriers with current prosthesis design processes. The requirements generation task in CPDM aids to establish and improve the communication between the prosthetist and the prosthesis user, as it helps form the beginning of understanding, user motivation, expectations, experience, and trust (Figure 8-1). Furthermore, addressing changes in expectations and socket fit over time could enhance the current static socket systems that lack the ability to provide end-users a comfortable prosthesis.

To address this, we use The Pahl and Beitz engineering design methodology (Pahl et al., 2007) (Figure 8-2) and the Prosthesis Model of Comfort (Figure 8-4) as the basis for the CPDM, representing the technical and human aspects of the prosthesis design process, respectively.

Considerable attention in CPDM is given to understanding the user's needs and expectations of the prosthesis. Prosthesis users often have individual expectations expressed as either demands or wishes. They express what the user expects as a must have or good to have and help to shape the user experience. This necessitates the need for prosthetists and prosthesis users to work together in deciding on a prosthesis design (Van Der Linde et al., 2004). These demands and wishes should be captured during the Task Clarification phase, such as recommended in Pahl and Beitz (Pahl et al., 2007), to derive requirements. The Task Clarification phase results in a list of requirements that guide the design process. It also "acts as a mantle or cloak that envelops all subsequent stages in the design" (O'Connor, 1991).

Generation of requirements for a prosthesis requires a thorough understanding of the user, the use environment, the support network, and the system-level influences. These requirements should be derived from the factors of comfort. (Anderson, 2022) describes shared decision-making (SDM) as a method to capture these elements by involving the user in the decision-making process. However, as discussed in Chapter 4, users may not feel comfortable or able to express all their needs and expectations. The user also may not know what is important or possible. The prosthetists should ask about all relevant factors from Figure 1 and determine if the information is accurate, otherwise requirements may be overstated or missed in the design.

The literature identifies requirements of appropriate prosthetic technologies, including function, cost, reliability, and others (Andrysek, 2010; Day, 1996). These requirements, coupled with the user, the use environment, the support network, and the system-level influences should be prioritized given it may not be possible to achieve all the requirements, but it is often unclear how to achieve this (Wyss et al., 2015).

The combination of factors presented in Figure 1 can be achieved with various technical and human approaches which is critical to the success of comfort-driven prosthesis design. The user's preferences for the prosthesis, and its impact, rely not just on product related factors but various contextual factors and the user's perception of the prosthesis in their life (Chapters 2 and 4). As the requirements are referred to throughout the design phases, they must be correct, precise, and comprehensive (Ward, Shefelbine, & Clarkson, 2003). Writing the requirements may take 30% of the total design time (Lowery, Strojny, & Puleo, 1996); however, it reduces work and redesign and increases the overall quality of the design (Ward et al., 2003).

In this section, we have combined the findings of our clinical and experimental studies reported in previous chapters (Chapters 2,4-6) and elements of (Figure 8-2) and (Figure 8-4) for the development of the CPDM. The process used to develop the CPDM is described in detail in Section 8.6, the CPDM and its phases is described in Section 8.7. For the results of the validation of the CPDM, we refer to Chapter 9.

8.6 Development Process

To develop the CPDM process, a team of prosthetists, design researchers, and prosthesis users worked together. Figure 8-5 shows the development steps: 1) Define scope, 2) Engage Stakeholders, 3) Capture Comfort, 4) Develop and Evaluate Tools/Measures, 5) Frame Methodology, and 6) Evaluation of Methods and Measures.

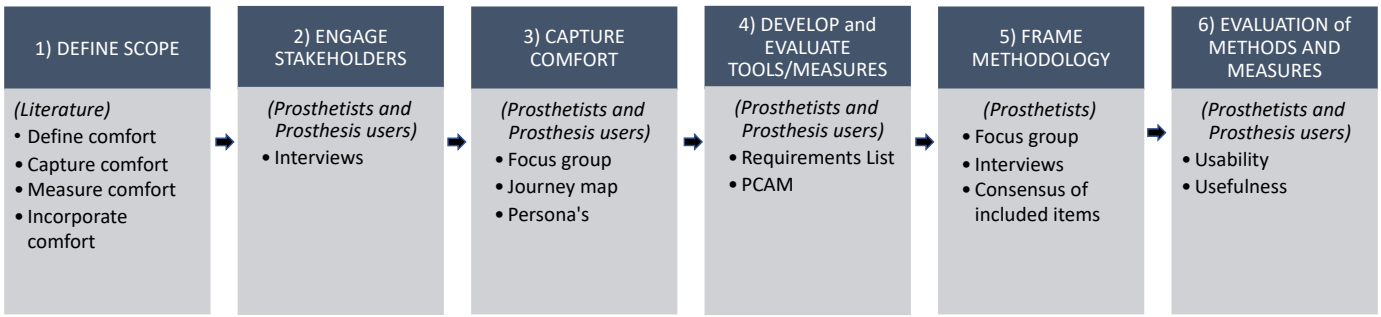

Figure 8-5. Overview of the development process of the CPDM.

Step 1) Define scope

The objective in this step is to define the scope of CPDM. This was obtained from the insights of the literature review (Chapter 2) and from the insights obtained from the interviews with prosthesis users who shared their perspectives on comfort (Chapter 4) and from insights obtained through the experiments in Chapters 5 and 6. The outcomes of this first step are important to ensure all relevant information on comfort is incorporated into the prosthesis design. The factors identified that contribute to comfort along with existing attempts and ideas to capture and measure comfort help to provide background to the CPDM. There was also clear evidence for the CPDM methodology to capture and incorporate the context-based needs of the user and build transparent, concise communication and trust.

Step 2) Engage Stakeholders

Engagement with prosthetists and prosthesis users was a critical step to obtain their perspectives on factors that contribute to comfort, their experiences, and expectations. This involved interviews with prosthesis users (Chapter 4) and with prosthetists from various hospitals in Singapore (Chapter 7). There was clear evidence after the interviews with the prosthesis users for the CPDM methodology to capture and incorporate the context-based needs of the user and build transparent, concise communication and trust. The findings of the interviews with the prosthetists helped to align misconceptions of the comfort factors, to establish the importance of these factors in the design process, and to find common understanding, all of which are relevant for the CPDM. Ways to incentivize the prosthetists to adopt a new design process were also discussed. The prosthetists identified that their lack of clinical time with the users and low technology know-how should be considered in the development of CPDM and its design phases. Furthermore, they emphasized that CPDM should be presented as a tool to help add value to the prosthetists, rather than an outcome measure.

Step 3) Capture Comfort

The aim of step 3 was to determine how and where to capture comfort in the current design process to help identify the CPDM phase(s) in which this should be applied. A focus group discussion was conducted with 10 prosthetists divided into two groups. Utilizing design thinking methods, the discussion was focused on brainstorming ideas for the question, "*How might we support the process of designing comfort?".* The participants were given a diagram showing the prosthesis design process (Section 2.4) and two personas developed by the researcher, representing two types of users (Appendix 7). The AEIOU (Activities, Environment, Interactions, Objects, and Users) method (Lewrick, 2018) was used to obtain the prosthetists perspectives on the AEIOU of the two personas. The proposed set

of questions in the AEIOU was contextualized to fit the usage scenario of prosthesis comfort (Table 8-1).

Table 8-1. AEIOU method with modified questions to reflect comfort in prosthesis design. Adapted from (Lewrick, 2018)

AREAS	GUIDING QUESTIONS
Activities	What activities do you usually do? Weekends vs Weekdays Could you describe the top 5 activities they carry out in a typical day? What happens before or after that? What are the specific tasks you intend to carry out?
Environment	What does the environment look like at your work and/or home? What is the nature and function of the space at home? What problems do you have completing your activities? How does the prosthetist help or hinder you in these environments? Do you have any difficulties taking transport, going to shopping centers etc.?
Interaction	How does the user, product, and our fabrication systems production systems interact with each other to achieve the requirements? What are the potential issues with the user's residuum that could affect the interaction with their prosthesis? How does the user interact with their social network? Do you need help to interact with your social network?
Objects	What objects and devices are used in conjunction with the prosthesis? Do they use different chairs, walking aids etc. How does the user interact the objects, and in which environment?
User	Who are all the users or stakeholders? What role do the stakeholders play? Who or what influences them?

Next, the participants were instructed to list all possible processes to support the design of comfortable prosthesis, based on the ideas generated using the AEIOU questions. A layout of the current prosthesis design process was drawn, and participants were asked to put post-it notes with the ideas next to the relevant design phase. The two groups then joined to allow for the cross-sharing of ideas. Together they subsequently ranked the support processes to determine which supports should be developed first. The ranking indicated a clear need for an aid to gain user insights early in the design process, and an aid to assess the comfort level from the user's perspective addressing the comfort factors shown in Figure 8-1.

Step 4) Development and evaluation of aids

This step is aimed at the development of the two aids prioritized by the prosthetists in Step 3: 1. To gather information about the user's comfort factors and use (intended or current) of the prosthesis, and

2. To assess the comfort levels from a user's perspective to obtain critical design input information. The latter resulted in the development of the Prosthesis Comfort Assessment Metric (PCAM), which has been described in Chapter 7, along with its evaluation. The former, the aid to gather information about the user, resulted in the development of a tool to capture requirements, the development and evaluation of which is described below as it can only be evaluated in the context of the CPDM methodology.

Requirement list development and evaluation

Most design methodologies emphasize the need to capture, analyze and document the requirements as part of the task clarification phase, and many generic as well as product type specific checklists can be found in literature (e.g. the generic list in Pahl and Beitz (Pahl et al., 2007)) and the medical device checklist in (Ward et al., 2003). It is the author's own experience as prosthetist and that of the focus group of prosthetists (see previous step) that drawing up such lists have not been used in the P&O industry. Checklists help in identifying potential requirements across various areas, covering the whole product life cycle. The focus group expressed the need for such checklists to avoid having to develop requirements from scratch and to avoid overlooking certain types of requirements.

According to (Ward et al., 2003) very detailed checklists help in establishing success criteria, but they can give the designer (in this case the prosthetist) a false sense of security. Following a checklist may not necessarily result in a complete set of requirements, in particular for customized products such as prostheses that highly depend on the individual. Therefore, it is important that the items in a checklist suggest areas to guide the user but are not restricting. These areas in CPDM reflect those in the PCAM.

The requirement checklist used in CPDM was developed by referencing the checklist of Pahl and Beitz (Pahl et al., 2007), considering the categories of factors from (Figure 8-4) and (Figure 8-1), and the input of the focus group of prosthetists involved in Step 4. A draft checklist was shown to the focus group. The discussion led to consensus on the structure, the items, and the presentation.

The resulting checklist is shown in Table 8-2, with an example requirement for each area. The areas in the first column are derived from the factors in Figure 1 and grouped using the categories of factors. The checklist includes a demand and wish column (column 2) to open the solution space. Without this distinction, all requirements could be considered demands. Wishes can be negotiated and are not critical to be fulfilled. A weight column (range 1-5) was added to help identify the key requirements to be fulfilled in the design. A weight score of 5 indicates a 'must have' in the design and is thus the weight given to a demand. Weights 1-4 are reserved for the Wishes. These can be determined in accordance with the Prosthesis model of comfort. After the requirements have been documented, the "W's" are grouped in accordance with their importance (weight) to identify which wishes are more significant to

address in the design. The source column in Table 2 shows the source of the requirement. All requirements should be documented by the prosthetist as success criteria to check against the final design. The list is not exhaustive but indicates what should be included in the requirements documentation.

Table 8-2. Requirements check list with an example of requirements for each area.

PHYSICAL REQUIREMENTS				
Area	**Demand or Wish**	**Requirement (examples)**	**Source**	**Weight (0-5)**
Activities, intended use	D W	• The prosthesis shall enable the user to walk in the community at a self-selected pace • The prosthesis shall be suitable to shower with.	Prosthetist User	5 3
Alignment	D W	• The prosthesis shall provide 10 degrees of socket flexion • The prosthesis shall provide 5 degrees adduction	Prosthetist Prosthetist	5 4
Components and materials	W D	• The prosthesis shall accommodate heels of 1.5inches • The prosthesis shall be lined with PET plastic	Prosthetist Prosthetist	3 5
Safety and stability	W D	• The prosthesis shall feel safe when walking downstairs • The prosthesis shall not contribute to poor posture and balance	User Prosthetist	4 5
Weight	D D	• The prosthesis is strong enough to support body weight • The prosthesis shall not weight more than 1.5kg	User Prosthetist, Technician	5 5
Range of motion/ Trimlines	W W	• The prosthesis will not limit knee flexion during extended periods of sitting • The prosthesis shall allow more than 90 degrees of knee flexion	User Prosthetist	5 4
Shape capture	W W	• The prosthesis shape shall be captured using 3D scanning • The prosthesis shape shall be stored for future reference	Prosthetist Technician	4 5
Socket contour	D D	• The prosthesis shall be total surface bearing • The prosthesis shall allow extra relief over fibula head	Prosthetist Prosthetist	5 5
Tissue Containment	D D	• The prosthesis shall contain all loose distal tissue • The prosthesis shall accommodate tibial end callous	Prosthetist Prosthetist	5 5
Other				
PHYSIOLOGICAL REQUIREMENTS				
Area	**Demand or Wish**	**Requirement (examples)**	**Source**	**Weight (0-5)**
Temperature	D W	• The temperature within the prosthesis shall not be more than 2 degrees warmer than the sound limb • The prosthesis shall not produce sweat	Prosthetist User	5 4
Volume	W D	• The prosthesis shall accommodate daily changes in residuum volume • The prosthesis shall provide volume matching	User Prosthetist	4 5

Pressure	D D	• The prosthesis shall provide even pressure over the limb • The prosthesis pressure over the distal tibia shall not be more than 30kpa	Prosthetist Prosthetist	5 5
Pain	W W	• The prosthesis shall not cause pain over distal tibia • The prosthesis shall not cause pain when sitting for extended periods	User User	4 4
Time of exposure	D W	• The prosthesis shall be used for up to 4 continuous hours • The prosthesis shall be used over night	Prosthetist User	5 4
Other				
PSYCHOLOGICAL REQUIREMENTS				
Area	**Demand or Wish**	**Requirement (examples)**	**Source**	**Weight (0-5)**
Aesthetics	D D	• The prosthesis should be black in colour • The prosthesis shall have a silicone cosmetic cover	Prosthetist, Technician	5 5
QOL	W W	• The prosthesis shall improve the users QOL • The prosthesis shall allow return to work	User User	4 5
Reliability	W D	• The prosthesis can be worn for both long and short periods without removal • The prosthesis does not require frequent maintenance i.e., >2 times per year	User Prosthetist	4 3
Other				
EXPECTATIONS REQUIREMENTS				
Area	**Demand or Wish**	**Requirement (examples)**	**Source**	**Weight (0-5)**
Early Rehab	W W	• The prosthesis shall be ready within 1 month • The prosthesis shall allow the user to walk independently in 2 months	Prosthetist Physiotherapist	4 4
Activities	D W	• The prosthesis shall allow the user the freedom to try new activities without requiring a new prosthesis • The prosthesis shall allow the user to cycle	Prosthetist User	5 2
Design	D D	• The prosthesis shall follow the Lines of Non-Extension • The prosthesis shall have adjustable panels	Prosthetist Technician	5 5
Experience	D W	• The prosthesis shall meet at least 2 wishes • The prosthesis shall allow scuba diving	Clinician User	5 4
Ease of Wearing	W D	• The prosthesis shall be easy to wear throughout the night • The prosthesis shall have no more than 3 steps to wearing	User Prosthetist	3 5
Other				
CONTEXT REQUIREMENTS				

Area	Demand or Wish	Requirement (examples)	Source	Weight (0-5)
Environment	D W	• The prosthesis shall be waterproof • The prosthesis shall allow the user to use squat toilets	Prosthetist User	5 4
Duration of activities	D	• The prosthesis shall allow the user to travel overseas on flights of up to 12 hours	Prosthetist	5
Special Requirements	W W	• The prosthesis shall allow the user to travel • The prosthesis shall allow the user to swim	User User	4 3
Cultural, Religious	D D	• The prosthesis shall allow the user to participate in all religious ceremonies and rituals • The prosthesis shall enable the user to achieve prayer positions as per religion	Prosthetist User	5 4
Financial	D W	• The prosthesis shall not cost more than $3000 • The prosthesis shall not require costly maintenance	Prosthetist User	5 4
Other				
COMMUNICATION REQUIREMENTS				
Area	**Demand or Wish**	**Requirement (examples)**	**Source**	**Weight**
Relationships	W	• The prosthesis shall enable interaction between user and granddaughter	User	5
Social support	D	• The user requires Medical Social Worker and Amputee Support Group support	Prosthetist	5
Access to care	W W	• The user shall have the direct email of the prosthetist • The user shall have pre-booked review appointments every 6 months	User Prosthetist	4 5
Trust	D	• The user shall have confidence in the prosthesis	User	5
Other				

Step 5) Synthesis of the Methodology

The results from Steps 1-4 were synthesized into a draft CPDM. This draft combined the critical factors of comfort (Figure 8-1), the engineering design methodology (Pahl et al., 2007), the Prosthesis Comfort Model, PCAM, Requirements list, the author's own experience, and insights from Chapters 2-7.

The main requirements of the CPDM are:

- Support prosthetist and prosthesis user collaboration to deepen communication, build trust, and foster better rapport.
- Support the generation of prosthesis requirements and provide means to prioritize these requirements.

- Support the collection of qualitative and quantitative data on the comfort factors to be used in the design of the prosthesis for new or existing prosthesis users.
- Provide structure and guidance to encourage the comfort-driven prosthesis design process.

The first draft was discussed in a second focus group with the same prosthetists as the focus group in Steps 3 and 4. To provide background knowledge of the product development processes, the Pahl and Beitz (Pahl et al., 2007) process was explained, and any doubts clarified. The focus group discussed each process phase of the CPDM in detail. Based on their feedback and insights obtained from the discussion, the first draft of CPDM was refined by the author to a level of details that allowed evaluation.

Step 6) Evaluation of Methods and Measures

The final step aimed to verify the developed PCAM tool and evaluate the CPDM. The verification of PCAM has been described in Chapter 7. The evaluation of the CPDM, including the Requirements Checklist is described in Chapter 9. The evaluation includes the training of the participants (prosthetists) in the use of the methodology, the application of the CPDM by the prosthetists with prosthesis users, as well as questionnaires and individual interviews to obtain insights into the use and usefulness of the CPDM.

8.7 CPDM Overview

CPDM consists of six main design phases: 1) Planning, 2) Task Clarification, 3) Concept Generation, 4) Embodiment Design, 5) Build Design, and 6) Final Design, Testing and Review (Figure 8-6). Each phase comprises a set of required tasks. The phases are designed to address the factors of comfort previously identified in Figure 8-1.

CPDM is designed to address new as well as existing users. The same process is followed for both, apart from the Embodiment Design phase, in which the new users should receive an interim prosthesis, while existing users only need to trial a check socket since they are familiar with the prosthesis experience. The Build Design phase replaces Pahl and Beitz's 'Detail Design' phase (Pahl et al., 2007), which involves the preparation of all documents required to have the product manufactured and assembled. These documents, mainly drawings, specify dimensions, tolerances, material, components, layout, etc. are not currently required for the manufacture of the prosthesis as there is no clear separation between design and manufacture activities, and the prosthetist and technician work very closely together.

After completing each of the Task Clarification, Concept Generation, and Embodiment Design phases, it is important to verify the results with the previous phase. This ensures no steps are missed, and a higher chance of success in the final design. It must be noted that iterations between and within phases are common. After completing all six phases there is a need to validate the final design against the requirements captured in the Task Clarification phase. This will determine whether the design is likely to be successful or not. These requirements can be checked against any feedback at subsequent review appointments.

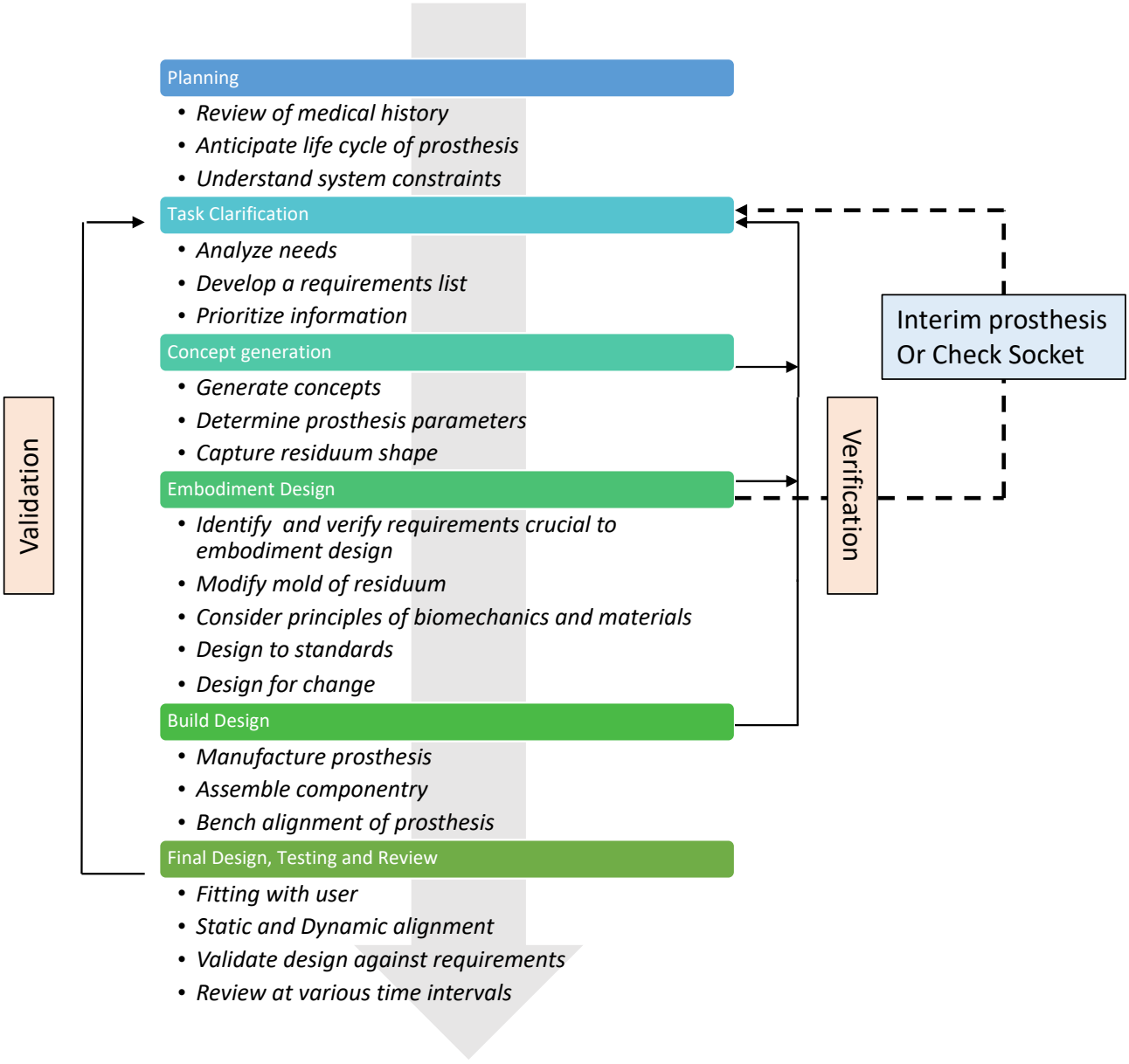

Figure 8-6. Comfort-driven Prosthesis Design Methodology (CPDM)

8.8 Phases of CPDM

In this section, each phase of CPDM is described in detail. The descriptions identify the proposed tasks in each phase and the methods selected for these tasks and digitalization opportunities. A summary can be found in Table 8-3 The methods are described where necessary, or references to available literature are provided. Given the increase growth in digital technology in prosthetics and the larger healthcare industry (see Chapters 5 & 6), digitalization processes are included as possible alternative to traditional methods. As new technologies become available that are suitable to replace traditional methods, these can be included in the CPDM.

Table 8-3. Overview of design process tasks, methods, and digital options. Red – the phases added, Blue – Phases that have been adapted from Pahl and Beitz methodology. **Bold** – the main contributions.

	Task	***Methods***	***Digital Options***
Planning	• *Review medical history* • *Anticipate life cycle of prosthesis* • *Understand system constraints*	• *Check case notes* • *Discuss with workshop manager* • *Review product catalogues*	• *Internet* • *Digital patient records*
Task Clarification	• ***Analyze needs*** • ***Develop requirements list*** • *Prioritize information*	• *Observation* • ***AIEOU*** • ***PCAM*** • ***Requirements list*** • *Assign weightage* • *QFD* • *Kansei Engineering* • *QOL surveys* • *SDM-prostheses*	• *Digital forms* • *Checklists* • *Virtual care* • *Photos / Videos of use environments*
Concept Generation	• *Generate concepts* • *Determine prosthesis parameters* • *Capture residuum shape*	• *Manual comparison of solutions* • *Amputee Mobility Predictor* • *Observation* • *Check components build heights* • *Tape Measures* • *Hand cast* • *Pressure cast (ICECAST)*	• *Scanning* • *FEA* • *Photogrammetry* • *MRI* • *CT scans* • *Xray* • ***Sensors*** • *Ultrasound* • ***LoNE***

	Task	*Methods*	*Digital Options*
Embodiment Design	• *Identify and verify requirements crucial to embodiment design* • *Modify mold of residuum* • *Consider principles of biomechanics and materials* • *Design to standards* • *Design for change*	• *Hand modification* • *Check component specifications*	• *CADCAM* • *FEA* • *Artificial intelligence*
Build Design	• *Manufacture prosthesis* • *Assemble componentry* • *Bench alignment of prosthesis*	• *Draping* • *Lamination* • *Plumb lines*	• *3D printing* • *3D knitting* • *Laser alignment*
Final Design, Testing and Review	• *Fitting with user* • *Static and dynamic alignment* • *Validate design against requirements* • *Review at various time intervals*	• *Evaluate early feedback* • *Observation* • *Schedule review appointments* • *Compare requirements list with design*	• *Activity monitors* • *Sensors* • *Gait laboratory analysis* • *Live tracking* • *Virtual care* • *Digital surveys*

8.8.1 Planning

The objectives of planning are to improve efficiency and outcomes of the initial visit.

Review of medical history

To maximize clinical time, it is necessary to review the medical history and any referral (if possible). This information can direct care and provide important clues to the health and functional status of the user. Medical histories provide insights into causes of amputation, date of surgery, any complications and current medications which may affect the volume of the residuum, functional status, and type of prosthesis used (if existing user). If the user has seen the physiotherapist, their input on muscle strength, ROM, and mobility prediction should be considered in the design of the prosthesis but the findings should be confirmed, and tests repeated with the user during consultation (see Task Clarification Phase).

Anticipate life cycle of prosthesis

When reviewing the medical history of an existing user, attention should be paid to any previous prosthesis prescribed. Although it is important not to fixate on the current prescription, identification of the socket type, suspension, and other componentry is helpful in the planning. Any issues with a

previous prosthesis mentioned in the documents should also be noted. Questions regarding this information can be formed prior to the consultation and asked explicitly with the PCAM for existing prosthesis users. During the early rehabilitation following the amputation, prosthesis users will require frequent changes to maintain good socket fitting and comfort. In anticipating the need to change the socket or other components, a review of product catalogues to ensure technical knowledge and if necessary, shape capturing tools should be arranged. The internet will provide easy access to existing and new knowledge and solutions, and digital patient records – if well-managed and centrally stored – can provide insights into the patients' health and history beyond the information about the amputation.

Understand system constraints

In this task of planning, the identification of system constraints is crucial. Information such as workshop fabrication wait times, appointment lead times, and ordering delays are important. The impact of these constraints will affect the prosthetist's ability to provide the intended prosthesis user their prosthesis in a timely manner. Given the rates of anxiety and depression following an amputation (Coffey, Gallagher, Horgan, Desmond, & MacLachlan, 2009), delays will further exacerbate these problems and have a negative effect on comfort levels. It is necessary to engage with the workshop manager to determine workloads, or reception staff to analyse appointment times. Doing this ahead of the consultation, improves the efficiencies with planning follow up care with the user.

8.8.2 Task Clarification

The objective of this phase is to identify and categorize the needs of the user into requirements for the design.

Analyze Needs

Identifying the needs of the user is the most critical component in this design process. Needs gathering should cut across the six determinants of factors previously identified (Figure 1) and consider the user, the use environment, the support network, and the system-level influences.

In understanding the user needs, careful attention must be paid by the prosthetist to limit bias and prejudice towards the user and to develop a clear understanding of the needs, expectations, and requirements (Morgenroth, 2013). Problems with the prosthesis of existing user's should also be identified and documented as these may become important requirements in the final design and impact comfort levels. The prosthetist and user must work together closely to build trust, ensure in-depth understanding of the users' needs, experiences, and expectation, and to ensure commitment of the user to create their own treatment plan.

The needs of the user can be obtained through a variety of methods, from generic (e.g., interviewing, observation) to specific (e.g., Journey Maps, Kano model). We refer to The Design Exchange (www.designsociety.org/group/49/Design+Society+Exchange), the largest database of human centered design methods, which can support many of the phases of CPDM. CPDM proposes the following methods as being particularly useful for the Task Clarification phase: AEIOU, an existing tool, and PCAM, developed in the context of this thesis.

- *The AEIOU tool* (Section 8.5, Table 1). This generic tool has been adapted for use in the context of comfort-driven prosthesis design. Areas to assess comfort are included and questions related to each area provide a starting point for understanding user needs, help to guide the conversation and provide opportunities for the user to share about their experiences and expectations in a structured manner. The AEIOU tool can be used to determine the use environment and steer towards requirements in the prosthesis design.

- *The Prosthesis Comfort Assessment Metric* (PCAM) (Chapter 7). Factors contributing to comfort are presented in an assessment scheme which can steers the prosthetist towards design changes that could significantly impact the user's comfort level. The PCAM is intended to be used for subsequent changes to the prosthesis and not at the initial visit, although it is useful after any trial period with an interim prosthesis.

It is important that all needs are documented to ensure nothing is forgotten and to be able to track changes over time. The use of digital forms of the AEIOU and PCAM can assist in faster and easier collection of data. To assess the use environments to determine the requirements, virtual care can be provided, or the users can provide photos or videos of their use environments during the consultation.

Develop requirements list

The needs identified should be translated into requirements the prosthesis must meet and documented in a requirements list. The use of the AEIOU tool can help to determine the areas that should be considered. CPDM proposes a template that can be used as a checklist (see Section 8.6,Table 2) to ensure that all comfort factors of the prosthesis (Figure 1) are addressed. The requirements are to be formulated in a solution-neutral manner where possible and may vary between new and existing users and new areas may have to be added. New users will have requirements pertaining to a perceived expected outcome, while for repeat prosthesis users the requirements will pertain to expectations determined by experiences and may include new requirements.

Prioritize information

It is not possible to develop a prosthesis that meets all requested requirements. Therefore, it is necessary to determine if a requirement is a demand or a wish (see Section 8.6, Step 4). Demands have to be met – they are essential, although the level at which they are met may be negotiated. Wishes may bring the user's experience into Kano's 'wow' level of comfort experience (see Kano model, 8.4) and should therefore be considered during the design process, even though they are not essential. However, it is more realistic to aim for Kano's performance level of comfort for the wishes, given that the 'wow' factors are usually not expressed.

To determine which requirement is more important weights are assigned to each of the requirements. Emphasis should be placed on meeting the high priority requirements, as they are likely to have the largest impact. A simple weightage scale is included in the requirements list with a range (1-5), 1 being low importance and 5 very important. (Section 8.6, Table 8-2)

Several other methods are available to rank the importance of individual factors against each other, see e.g. (Pahl et al., 2007) for some common ones, or the www.sixstigmastudyguide.com for details on the well-knows Quality Function Deployment (QFD) approach (Akao, 1990) which supports the translation of the voice of the customer into a design specification or Kansei Engineering (Nagamachi, 1995) which aims to improve the product by translating the customer's psychological feelings and needs into the domain of product design.

8.8.3 Concept Generation

The objective of this phase is to generate the initial concept of the design from the requirements list.

Generate concepts

The generation of concepts involves identifying the essential requirements in the design of the prosthesis to be combined into a new solution. In CPDM the essential requirements are those that are key to comfort for the user and should be addressed first in the design. It is important to not be fixated on previous prescriptions as these may prevent new ideas and limiting improved levels of comfort, and they may no longer be valid due to changes in a user's health, experiences, and expectations. Solutions based on traditional methods are unlikely to provide optimal answers when compared with new possible combinations of new materials, technologies, and procedures. The prescription of a prosthesis should be based on a combination of working solutions that are expected to meet as many requirements of comfort identified as possible, although trade-offs will have to be made. It is helpful to use manual comparisons of solution combinations. Several methods are available to identify the most promising

concept in an early phase of development. An easy and quick method is the Pugh-matrix or evaluation matrix (see The Design Exchange database or Pahl & Beitz).

Determine prosthesis parameters

To assist in the development of a solution it is necessary to define several key parameters, including physical, physiological, and performance factors. There is also a need to verify the findings of the physiotherapists identified in the planning phase in case changes have occurred. *Physical parameters* include length of residuum which is needed for component selection. A longer residuum will need components with lower build heights. The choice of suspension systems or interface materials is based on skin integrity, shape, and user requirements. Cost of materials and components, as well as maintenance costs should be discussed with the user to ensure affordability as these may influence the prescription. *Physiological parameters* should be measured to determine comfort of the physiological factors listed in Figure 8-1 and used for cross-referencing against future designs to detect changes. The use of sensors to detect change in comfort has been demonstrated as a successful method to use (Chapter 5). By quantifying as much data as possible during this phase, the prosthetist can validate any future qualitative data obtained from the user to assist in optimizing the design for comfort. Finally, *performance criteria* are measured to determine the correct components for the functional performance. The CPDM recommends using the Amputee Mobility Predictor (Section 2.3).

Capture residuum shape

In this task, the prosthetist creates an impression or copy of the residuum to use for the next phase. This process has been described in Section 2.4 along with new digital processes that provide quantitative data for the design such as scanning, FEA, Xrays, MRIs and sensors. The use of Lines of Non-Extension (LoNE) can be captured with a DSLR camera as per the procedure recorded in Chapter 6 (Section 6.2.1) and if used for the design should be captured during this phase. For sizing of any liners such as the sweat reducing liner in Chapter 6 (Section 6.3), measurements are taken 4cm from the distal end of residuum.

8.8.4 Embodiment Design

The objective of this phase is to develop the design based on technical data derived from The Concept Generation phase. For new users, the Embodiment Design phase results in an interim prosthesis to verify requirements and to provide the user valuable prosthesis experience. This experience will influence the requirements list, which should be checked again for consistency before proceeding to a definitive prosthesis.

Identify and verify requirements crucial to embodiment design

The initial task in Embodiment Design is to identify those requirements that have a crucial bearing on the embodiment design – these may differ from those that were crucial for the Conceptual Design. Determinants such as the user's body weight, needs for aesthetics, and safety are examples. These requirements should have identified through during the generation of the requirements list, but some may be specific to a particular concept and thus only become relevant during Embodiment Design. The identified requirements become the main drivers for the embodiment design.

Modify mold of residuum

During this task, the prosthetists must define the overall socket shape such that the pressure across the residuum will be evenly distributed. Areas of high sensitivity are relieved, and pressures on areas of high tolerance are increased. This process is described in detail in Section 2.4. For specific requirements such as extreme knee flexion it is necessary to make allowances during the modification. Both traditional and digital tools are useful methods. Digitalization improves efficiencies in the design process for subsequent prostheses and further information is found in Section 2.5. Tools such as CADCAM or FEA can help to quantify changes and remove subjectivity in the design process.

Consider principles of biomechanics and materials

Pahl and Beitz (Pahl et al., 2007) suggest the embodiment design phase be based on referenced principles pertaining to the nature of the product. In this case, the design of the prosthesis should reference principles of biomechanics and materials related, e.g., to force distribution, alignment, and strength. However, the most important principle is safe use. Pahl and Beitz (Pahl et al., 2007) are one of the authors providing an overview of safety principles, e.g., safe-life, fail-safe. Ensuring correct strength for the componentry based on the user's weight and following the manufacturers guidelines on fabrication processes can prevent failures that would severely affect the user's experience and overall comfort. Materials should be strong enough to maintain stability of the residuum during walking or other activities, resistant enough to the use environment as per user requirements. Weight of the prosthesis should be kept to a minimum to improve energy efficiencies, yet heavy enough to provide a feeling of comfort. Here too, the comfort factors will impact the decisions.

Incorrect biomechanical loading of the residuum has been shown to cause skin breakdown and wounds, leading to device disuse or abandonment (Chapter 2). Therefore, it is vital that load transfers are optimized in this Embodiment Design phase. Traditional methods using hand tools to apply correct loads remain subjective, however, the use of digital technologies (DT) such as finite element analysis (FEA) in the prosthesis design process can enhance comfort, e.g., through accurate simulation of pressures, or to identify materials to meet requirements captured in the Task Clarification phase. Literature on the advantages of the use of FEA for prosthesis design can be found in (Binedell &

Subburaj, 2022; Nayak et al., 2017; Rotariu et al., 2015; Sengeh & Herr, 2013; Steer et al., 2020). For designs that incorporate the Lines of Non-Extension (LoNE), they must not compromise the safety or biomechanical loading principles and be closely matched to the requirements.

Design to standards

The ISO 10328 Structural Testing of Lower Limb Prosthesis standard is the only standard for prosthetic design. This standard tests for structural strength during cyclic loading and static compression. While it does not specifically address socket design, it does cover the other components such as adaptors, pylon, and feet. Should new components be available and deemed suitable in the Conceptual Design phase, a key consideration should be the certification of results against this standard. Standards such as these provide reassurance to the users that the components are safe to use, which improves their psychological comfort.

Design for change

Change to the residuum of the prosthesis user, and to the use and user environments may lead to changes in experience with the prosthesis. It is necessary to elicit, identify and formulate as many of these changes early in the Task Clarification and Concept Generation phases. The Embodiment Design phase should consider include, e.g., residuum volume changes, temperature changes based on the use environment which affect comfort levels, and the need for maintenance and repair which require repeat visits to the clinic.

When designing for new prosthesis users it is recommended in CPDM that an interim prosthesis be used to provide user experience. The use of interim prosthesis provides feedback for balance and training and opportunities to test component selection, suspension techniques. It also allows for fine tuning of the socket to optimize socket contouring. The PCAM should be administered, and feedback elicited following the use of the interim prosthesis to identify issues of comfort based on real experience, in order to incorporate these insights into the definitive prosthesis. Interim prostheses also provide insights into whether a certain requirement can be met or is crucial for the design. For requirements that cannot be met, it is advisable to re-examine the Conceptual Design phase. For existing users, the testing of a check socket is sufficient as users have experience with the prosthesis. A check socket provides feedback the shape modification and socket contouring which is critical for device use and comfort.

8.8.5 Build Design

The objective of this phase is to manufacture the prosthesis and assemble the components to be ready for fitting.

Manufacture prosthesis

In this task, the prosthetist works with the technician to manufacture the socket. The process can be completed through traditional processes such as plastic draping or lamination, or through newer processes such as 3D printed or 3D knitting. The manufacturing process is described in detail in Section 2.4. Advantages of digital processes are also discussed in Section 2.5. 3D knitting is a new technology that offers the potential for socket optimization using multimaterial designs. The combination of materials can provide variable stiffness and breathability to improve thermal regulation without compromising strength and stability. More research is needed in this area. Regardless of the manufacturing process chosen careful consideration should be given to the user's preference which has been identified as a factor of comfort (Chapter 4).

Assemble componentry

In this task, the components of the prosthesis are checked, assembled to the correct length and all screws are tightened to ensure safety and stability during the user testing in the next phase. The socket is set at 5 degrees flexion and 5 degrees adduction, and the foot is adjusted to the pitch of the shoe with 5 degrees of external rotation. If during the Task Clarification phase, certain requirements dictate different angles or rotation these should be incorporated in the assembly.

Bench alignment of prosthesis

The alignment of the prosthesis is performed between the socket, pylon, and prosthetic foot through three steps: bench, static, and dynamic. Static and dynamic alignment are performed in the next phase. In this phase the bench alignment is performed by using a plumb line between two points in two orientations in the workshop without the user wearing the prosthesis. When using digital processes such as laser levels, the same positions are observed. Bench alignment is vital to ensure stability the moment the prosthesis is worn over the residuum and the user is asked to stand. By performing the bench alignment before the fitting, valuable time is saved to the prosthetist and user during their consultation as the starting position for the static and dynamic alignment steps has been established.

8.8.6 Final Design, Testing, and Review

The objective of this phase is to test and provide the finished design with the user and refine comfort through adjustments. The prosthesis will be reviewed periodically following its delivery, depending on the complexity of case but will likely range from between 1-6 months.

Fitting with user

During this task, the prosthesis is fitted to the user. Socket fit, suspension, and stability is observed and any adjustments necessary are made to optimize the fit such as through the addition of socks. The user's

first impression of the prosthesis has been identified to influence their comfort perception (Chapter 2). It is therefore necessary to ensure the prosthesis is presented well with smooth edges and is clean. The fitting process has been described in detail in Section 2.4. Any problems with comfort are addressed at this time before the user starts walking.

Static and Dynamic alignment

In static alignment the alignment of the componentry is adjusted with the user wearing the prosthesis while standing in a static position. The goal is to ensure appropriate socket height and orientation so that the user is balanced while standing. Standing balance was identified through the user study as important to comfort in situations where no seats were available (Chapter 4). Dynamic alignment is conducted with the user walking on the prosthesis. Adjustments are made to the alignment through observation of gait deviations and communication with the user about their stability and socket comfort, until the goal to maximize dynamic balance and socket comfort while walking, has been achieved.

As the user progresses in ability over time, small adjustments are usually necessary to maintain optimal performance and user experience. Therefore, there is a need to review the user periodically once the prosthesis has been delivered (see below).

The user's perception of alignment is not very reliable (Boone et al., 2012), hence it is necessary to quantify stability and walking speed. Apart from subjective observation of the prosthesis, the use of a moment logging component at the bottom of the socket is valuable as an additional device to assist with alignment (Kobayashi et al., 2014). Such tools objectively feedback to the prosthetist any alignment changes necessary.

Validate design against requirements

In this task, it is necessary to revisit the requirements list generated in the Task Clarification phase, to ensure that the finished design meets the requirements, with emphasis on the key requirements identified through the assigned weightage. Requirements will change as the user increases their prosthesis experience (and possibly expectations) and some requirements could become more important for subsequent designs. It is therefore good practice to record all requirements and their fulfillment in the user notes. This information is also important when another prosthetist sees the user, although this is not advised (Chapter 4.).

Review at various time intervals

Due to changes in needs, the residuum, use, use context, experiences and expectation, comfort levels change over time (see Chapter 2), It is therefore necessary to schedule reviews to maintain an optimally fitted and comfortable prosthesis. The PCAM should be used again during the review sessions to

determine comfort levels and use the details provided by PCAM to identify areas that require further attention. Visual inspection of the prosthesis is also necessary to determine if any repairs are required. The prosthesis will also require maintenance and repairs from time to time. The timing of these should be done in consultation with the user and based on the life of the prosthesis. Understanding the life cycle of the prosthesis helps to ensure intervals between reviews remain appropriate to avoid the user making unnecessary trips to the clinic. This will lower their user experience and affect comfort levels.

The review process is also the right time to reassess the goals and expectations of the prosthesis user. Users have been known to overstate their abilities and expectations, and these may have become requirements for the design. The use of digital activity monitors would help to provide insights into the use of the prosthesis and guide the prosthetist in any changes to improve comfort or in the design of subsequent prostheses. For users unable to return to the clinic for review, the use of digital surveys or virtual care should be explored to avoid device abandonment and to address any concerns of the user.

8.9 Novelty of CPDM

The CPDM design process is based on the processes used in established design methodologies, makes use of some well-known methods and concepts. None of these, however, were specifically developed for, and hence fully suitable for prosthesis design with its specific characteristics. This lead to adaptation of existing, as well as to the introduction of new solutions.

The general approach to mechanical product design of Pahl and Beitz was considered most suitable as a basis for CPDM. The following changes were made to align it with the prosthesis design process:

- The Planning phase incorporated in the Task Clarification phase of Pahl and Beitz, has been separated out because of to the importance of planning ahead of the user's consultation. By planning ahead considerable amount of time could be saved, allowing the prosthetist to maximize the consultation time to engage with the user and establish a high level of trust and communication.
- A Build Design phase has been introduced to replace the Detailed Design phase in which the details for the design are finalized and documentation for production are prepared, as building the prosthesis for the user is very much part of the design process. Each prosthesis is specific to an individual user, the CPDM provides a customized approach to prosthesis design and ensures an optimally comfortable design for each user.
- A Final Design, Testing, and Review phase has been included to assess the impact of the prosthesis on the user, by ascertaining the use in the actual use environment and capture the six determinants of comfort over time to continue to understand and meet the user's expectations and improve their experience.

Several existing methods and concepts not yet used in the context of prosthesis design have been adopted and adapted for CPDM.

- The Task Clarification phase of Pahl and Beitz involves the collection of information about the requirements that the products should meet, and about the constraints. This is a common method to capture success criteria in product design and is often supported by checklists, but uncommon in prosthesis design. Therefore, requirements generation was included in the CPDM as a task to explicitly reflect and document the needs of the prosthesis users and prosthetists and was structured as a checklist as requested by the prosthetists during the focus group.
- To help determine the requirements, the AEIOU questions, which originate from product design, were adapted for prosthesis design. The AEIOU tool helps to ask the appropriate questions to understand the problem, the user and the related context. Its use in CPDM guides the prosthetists through the issues relating to comfort from a variety of perspectives.
- The concept of LoNE, used to design spacesuits that improve movement and comfort for the astronauts (Wessendorf & Newman, 2012), was adopted for LLA and found to have potential for future prosthesis design as part of the CPDM.
- Pressure sensors have previously recorded physiological changes in human beings but have not been used to explore prosthesis comfort. Its use in the design of prostheses could help to track comfort levels over time and add quantification to an otherwise subjective phenomenon.

Newly developed are the PCAM and the Sweat Reducing Prosthetic Liners

The CPDM through its use of the AEIOU, requirements checklist, and PCAM incorporates both human and technical factors in the design process to holistically capture comfort. Solutions for comfort generated by these tools could be considerably affected through the use of the LoNE or the Sweat Reducing Prosthetic liners as described in Chapter 6.

Ultimately, the CPDM is geared towards the user. User involvement in the design process is of paramount importance to a comfortable outcome. By involving the user in many of the design phases, feedback given along the way can be incorporated to improve the final product (prosthesis).

The evaluation of the CPDM is described in the next Chapter.

9 COMFORT-DRIVEN PROSTHESIS DESIGN METHODOLOGY (CPDM) – EVALUATION

9.1 CPDM Evaluation

CPDM consists of six design phases. However, given the importance that the needs relating to comfort are captured in the early design phases, the evaluation concentrated only on the first three phases (Planning, Task Clarification, Concept Generation) as the AEIOU, the requirement list, and the PCAM were all developed to be used mainly in these three phases. The remaining phases of CPDM do not differ significantly from the current prosthesis design process, but the focus on comfort in the first phases is expected to impact the decision-making in these phases resulting in more comfortable prostheses. We were unable in the context of the PhD research to extend the evaluation beyond the Concept Generation phase and, hence, comfort changes could not be measured. Future work will include the evaluation of the whole process (Section 9.3).

The evaluation of CPDM seeks to answer RQ4. "How can the Comfort-driven Prosthesis Design Methodology provide usability and usefulness to the prosthesis design process?" In the following sections, the evaluation is explained in detail.

9.2 Evaluation Questions and Hypotheses

The evaluation questions and hypotheses chosen to answer RQ4, were those that were considered essential to the core of CPDM and could be answered given the limitations and focus of the evaluation. The questions and related hypotheses were grouped under three categories: Understanding and Communication; Tools and Measures; and Usability and Usefulness.

a) Understanding and Communication

- Does using PCAM as part of CPDM increase understanding of user comfort, needs, experiences and expectations?

H.1 Compared to prosthetists not using the CPDM, prosthetists who were using CPDM developed a greater understanding of user comfort, needs, experiences and expectations.

- Does using CPDM improve communication between the prosthetist and prosthesis user?

H.2 Compared to prosthetists not using the CPDM, prosthetists who were using CPDM felt improved levels of communication between themselves and the prosthesis user.

b) Tools and Measures

- Does using the AEIOU, Requirements List, and PCAM give the prosthetists a feeling of confidence in capturing use, user environment, experiences, and expectations for the design and its requirements?

H.3 Prosthetists felt convinced that the use, user environment, experiences, and expectations information was captured when using the assessment tools and measures.

- Does using the requirement list tool provide support to identify requirements, factors of comfort, and help to prioritize the comfort requirements?

H.4 Prosthetists using the requirement list tool were able to identify the requirements, factors of comfort and prioritize these findings for the design.

c) Usability and Usefulness

- Does the experience of a prosthetist affect the usability and usefulness of CPDM?

H.5a The experience of the prosthetist does not affect the perceived usability of CPDM remains useful and usable.

H.5b The experience of the prosthetist does not affect the perceived usefulness of CPDM remains useful and usable.

- Does the structured approach of CPDM results in new solutions that have greater efficacy?

H.6 Compared to solutions generated without CPDM, the solutions of prosthetists using CPDM fulfil more requirements.

H.7 Compared to prosthetists not using the CPDM, prosthetists who are using the CPDM found the structured approach of the CPDM useful.

9.3 Research Methods

9.3.1 Participants

Four prosthetists and two prosthesis users were recruited for the evaluation. All prosthetists were recruited from the same prosthetics department within a Singapore government hospital. All four had participated in the earlier focus groups but had not been shown the final version of CPDM until this evaluation study. Prosthetists with similar years of experience were chosen to reduce experience-related bias in the study. All prosthetists were trained as Category 1 prosthetists. Three were trained in Australia and one in Thailand. The prosthesis users were deliberately sought to have the same level of amputation, similar ages, and a self-expressed need for a new prosthesis. The study was approved by the Singapore University of Technology and Design Institutional Review Board, and all participants signed the consent form.

9.3.2 Methodology

The prosthetists were divided into two pairs of the same levels of experience. In each pair one prosthetist was tasked with providing a consultation using the departments standard assessment form, which contains Subjective, Objective, Action, and Plan (SOAP) fields of information. The other prosthetist was tasked to use the CPDM approach. The CDPM, PCAM, AEIOU, and Requirements list, were explained in detail to each of the prosthetists who were tasked to use CPDM, and any questions were clarified.

Each pair of prosthetists was assigned one prosthesis user with a need for a new prosthesis who they had not seen before. The current prosthesis of the participants was worn into the consultation room before the study started. The SCS was recorded before the consultation began with the designated format. All prosthetists were given the identification number of the prosthesis user 15 minutes before the scheduled consultation to complete the planning stage (if required). The first consultation was conducted by the prosthetist using SOAP (SOAP-prosthetist), following this a short 15-minute break was given to the user to allow the second prosthetist using the CPDM (CPDM-prosthetist) time to complete the planning stage. This order was chosen to avoid or at least reduce influencing the replies of the prosthesis user by the methods adopted in the CPDM. All consultations were timed, and audio recorded for analysis.

Following the consultations, each prosthetist generated and documented the appropriate prosthesis for the user. Once the documentation was finished the CPDM prosthetists were given an evaluation form with a set of statements about the use of CPDM. Prosthetists were asked to mark an ‘X’ on the line of the Visual Analog Scale (VAS) that represent a continuum ranging from do not agree at all (0) to fully agree (100). The prosthesis users were also given a similar evaluation form but with a different set of statements focusing on the difference between the two consultations. Both evaluation forms can be found in Appendix 8.

Finally, the four prosthetists (SOAP and CPDM) and the two prosthesis user were interviewed and recorded, individually, to clarify their answers to the statements Appendix 9. During the interviews with the prosthetists, they were instructed to prescribe and document their ideal prosthesis for the user if no constraints were applied and to elaborate on their decisions.

9.3.3 Data Analysis

All data was processed using Microsoft Excel for Mac (Version 16.63.1). Consultations were recorded and transcribed to assess for similarities and differences between the formats. The time of the

consultations was analysed using mean. Evaluation statements of prosthesis users were analysed using Mean VAS. Evaluation statements of prosthetists were analysed using mean VAS and standard deviation. Recorded interviews were unstructured and categorised according to themes for further analysis.

9.4 Results

9.4.1 Demographics

The recruitment process successfully recruited prosthetists with the same numbers of years of experience, with one pair having 13 years of experience and the other pair 4 years. Three were trained in Australia and one trained in Thailand (Table 9-1). The assigned tools are shown in the same table.

Table 9-1. Descriptive data Prosthetists involved in the evaluation

Prosthetist	Years of experience	Country of certification	Format
1	13	Thailand	CPDM
2	13	Australia	SOAP
3	4	Australia	CPDM
4	4	Australia	SOAP

The prosthesis user's descriptive data is shown in Table 9-2. Both subjects were of similar age, male, and had a transtibial amputation 12 ± 0.5 years ago due to diabetes. Subject A wore his prosthesis for double the amount of time than Subject B. Both provided a similar high Socket Comfort Score.

Table 9-2. Descriptive data of prosthesis users

Subject number	Age at time of study (Years)	Gender	Time since amputation (Years)	Reason for amputation	Level of amputation	Hours of use per day	Socket Comfort Score (SCS)
A	67	M	12	Diabetes	Transtibial	18	9
B	74	M	13	Diabetes	Transtibial	9	8

9.4.2 Understanding and Communication

H.1 Compared to prosthetists not using the CPDM, prosthetists who were using CPDM developed a greater understanding of user comfort, needs, experiences and expectations.

The hypothesis was confirmed, and the results are supported by the evaluation results of the PCAM in Section 7.6, even though in the evaluation study, the new version of PCAM was administered. The PCAM identified 31 factors of comfort which PCAM-prosthetists all administered and received feedback on. In contrast, the SOAP-prosthetists identified less than 20% of the PCAM factors. The SOAP prosthetist for Subject A identified only waterproof, weight, activities (Tai Chi, and Aikido), durability, QOL as the factors. The SOAP-prosthetist for Subject B identified QOL, pain, easy to wear, durability, safety, and socket feel. Both results for the SOAP formats resulted in less identified factors, reducing their understanding of the user's comfort and needs.

The PCAM was sensitive enough to be able to Identify the areas that needed improvement to change the comfort levels, despite the high SCS's given at the start of the study (Table 9-3). The comfort of both the subjects was affected by physiological factors, in particular sweating issues. Subject B also identified aesthetics and QOL issues which lowered their psychological determinant score and identified these areas for improvement. The generation of solutions later identified as "ideal" reflect the understanding of the user's comfort level identified with PCAM.

Table 9-3. Comparison of PCAM results

Subject number	Expectations	Psychological	Physical	Physiological	Context	Communication	Total
A	10.0	10.0	9.4	6.6	10.0	10.0	9.3
B	9.1	7.0	10.0	6.6	9.1	10.0	8.6

H.2 Compared to prosthetists not using the CPDM, prosthetists who were using CPDM felt improved levels of communication between themselves and the prosthesis user.

According to the two users, communication levels were better during the consultations with the CPDM prosthetists than with the SOAP prosthetists, confirming this hypothesis. The evaluation statements in Table 9-4 indicate that the two users felt more understood throughout the consultation and expected a more comfortable prosthesis as a result of this.

Table 9-4. Evaluation statements of prosthesis users (n=2)

	Prosthesis User evaluation Statements	***Subject A***	***Subject B***	***Mean VAS***
1U	When CPDM was used, I felt that I was better understood by the Prosthetist	82	100	91.0
2U	When CPDM was used, the consultation felt faster	82	47	64.5
3U	When CPDM was used, I felt that I was better helped by the prosthetist	89	81	85.0
4U	When CPDM was used, I felt the prosthetist would design a more comfortable prosthesis	91	100	95.5

Furthermore, the interviews revealed the line of questioning generated by the tools encouraged them to share specific points about comfort and their experiences with the prosthesis. There was also an impression that the prosthetists really cared for them during the consultation, and they felt listened to and part of the process (Table 9-5). These results were supported by the 100% agreement of the prosthetists that CPDM did improve communication and the atmosphere during the consultation (See Table 9-6, Qn. 7 & Qn. 9).

Table 9-5.Quotes from prosthesis users (n=2) during the closing interview about the usefulness of CPDM on the second consultation as compared to the first consultation which involved the traditional SOAP tool.

Positive Quotes	**Negative Quotes**
"I'd want the second prosthetist (CPDM protocol) to make my leg. He found out more information to rectify the faults with my current leg" "The type of questions asked by the second prosthetist is exactly the questions I want to hear as they reflect who I am." "CPDM makes the prosthetist a lot more thorough in their assessment." "The use of PCAM was a great way to understand my comfort levels and where improvement is needed. I could really explain it all."	"It does take a bit longer than what I am used to."

9.4.3 Tools and measures

H.3 Prosthetists felt convinced that the use, user environment, experiences, and expectations information was captured when using the assessment tools and measures.

This hypothesis was confirmed. The evaluation of the statements (Table 9-6) by the 2 CPDM-prosthetists showed good agreement that the tools and measures (Qn's. 1-3) provided information necessary for the generation of a new prosthesis. The PCAM verification in Chapter 7.6.4, VQ.3 also

found 100% agreement (n= 10) that all information was captured. The 80% increase in the number of factors identified through the use of PCAM over SOAP further supports this hypothesis.

H.4 Prosthetists using the requirement list tool were able to identify the requirements, factors of comfort and prioritize these findings for the design.

This hypothesis was confirmed. Table 9-6, Qn. 4 & 5 indicate general agreement that the requirements list was helpful in identifying the requirements for the design, though there was a large difference between the scores of the two prosthetists. The demographic data suggests this result is link to experience levels as a prosthetist. The more experience prosthetist felt the requirements list was more useful. Her list of requirements was also longer. Both prosthetists reported they could easily identify the important requirements for their respective subjects in the interviews.

Table 9-6. Evaluation statements scores of the prosthetists (n=2)

	Prosthetist Evaluation Statements	***Prosthetist 1***	***Prosthetist 3***	***Mean VAS***
1	Use of the AEIOU tool helped me to make a clear assessment of the user	100	90	95.0
2	When using the AEIOU, I gathered more information about the user and their needs than I normally do	100	100	100.0
3	Use of PCAM helped me to make clear the prosthesis user's comfort levels faster	100	100	100.0
4	Use of the requirements list helped me to make clear the user's prescription to generate a solution	100	71	85.5
5	When using the requirements list, the areas were useful to identify the requirements, factors of comfort, and to prioritize these findings for the design	100	72	86.0
6	The prosthesis user would have a more comfortable prosthesis when following the CPDM design process	100	69	84.5
7	The atmosphere in the consultation was better when using the CPDM	100	100	100.0
8	My work routine was more efficient when using the CPDM	100	60	80.0
9	Communication with the user was better when using the CPDM	100	100	100.0
10	I felt more professional when following the CPDM	95	91	93.0
11	My work routine was hindered when following the CPDM	30	93	61.5

9.4.4 Usability and Usefulness

H.5a The experience of the prosthetist does not affect the perceived usability of CPDM remains useful and usable.

H.5b The experience of the prosthetist does not affect the perceived usefulness of CPDM remains useful and usable.

These hypotheses were confirmed. Experience of the prosthetist did influence the results of CPDM. Both prosthetists using the CPDM were able to develop the requirements list, despite CPDM-prosthetist 1 indicating that they did not fill in the requirements list until after the consultation, potentially omitted some requirements. The interview with the less experienced prosthetist revealed that the usability of the requirements list was difficult, but she felt confident that continual use would help to improve this factor. The less experienced prosthetist also indicated a stronger negative effect of CPDM on her usual routine of assessing the user, when compared to the experienced CPDM-prosthetist (Table 9-6, Qn. 8 & 11).

Both prosthetists indicated during the interviews that the AEIOU tool was helpful in communicating the questions to the prosthesis user to gain greater understanding of their needs. They were also able to easily identify follow up questions to answers given by the user to gain greater understanding of their needs. The prosthetists impression was that this improved the confidence of the prosthesis user and made them feel more comfortable and open to sharing (Table 9-7). This is further reflected in the number of insights of comfort generated when compared to the SOAP-prosthetists and the confidence of the prosthesis users in the CPDM-prosthetist to make a more comfortable prosthesis (Table 9-4, Qn.4U).

Table 9-7. Usability and usefulness summary of the positives and negatives from interview feedback with prosthetists.

	Positives	**Negatives**
Usability	*"The AEIOU was a great method to ask questions. It made the conversation seem very natural."*	*"The requirement list is difficult to fill as I am unfamiliar with this approach."*
		"I tend to ask the patient the questions first and then document at the end, given the number of points to address."
Usefulness	*"The CPDM helps build a rapport with the patient, so they develop trust in me (the prosthetist)."*	*"Even if I know what the patient wants, I may not be able to do anything to improve it, so I don't worry about it."*
	"It (Requirements list) is very helpful to generate information and improve communication."	*"It does take a bit longer than what I am used to."*

H.6 Compared to solutions generated without CPDM, the solutions generated of prosthetists using CPDM fulfil more requirements.

The CPDM-prosthetist consulting Subject A generated an appropriate solution that match their ideal solution which involved the use of digital processes. The SOAP-prosthetist generated the appropriate solution that was the same as the current solution. Given the high SCS for the current solution, the

SOAP-prosthetist did identify any new changes to the design. The PCAM results obtained by the CPDM-prosthetist indicated areas where improvement was necessary, and the CDPM-prosthetist utilized these in the generated appropriate and ideal solutions and felt digital processes would enhance the user comfort. A slight variation to the design involved the form of the 3D printed socket. The appropriate prescription included a nylon socket, whereas the ideal solution would be to incorporate variable stiffness into the socket design. The ideal solution generated of both prosthetists included digital processes in the shape capture, modification, and manufacturing processes. 3D printing was the manufacturing method of choice for the ideal, with the prosthetists confident that 3D printed sockets would enhance user comfort. Both prosthetists expected that the use of variable stiffness through multi-material designs would address the prosthesis user comfort best (Table 9-8). The prosthetists expressed during the interview their desire to improve comfort through digital processes, although they felt a lack of technical skills to change the generated solution accordingly.

Table 9-8. Comparison of current, appropriate, and ideal generated solution for Subject A

		Shape Capture	**Modification Method**	**Manufacturing Method**	**Socket**	**Suspension**	**Foot**
	Current	Hand cast	Hand	Lamination	Fiberglass	Vacuum	Proflex
1 CPDM	Appropriate	Digital Scan	Software	3D printing	Nylon	Vacuum	Proflex
	Ideal	Digital Scan	Software	3D printing	Multi-material	Vacuum	Proflex
2 SOAP	Appropriate	Hand cast	Hand	Lamination	Fiberglass	Vacuum	Proflex
	Ideal	Digital Scan	Software	3D printing	Multi-material	Vacuum	Proflex

The prosthetists consulting subject B also generated and documented a similar solution to the current prosthesis. The SOAP-prosthetist cited "*if it ain't broke, don't fix it*"" as a reason. The CPDM-prosthetist changed the appropriate solution to a 6mm cushion liner. When interviewed, the reason identified was that it will help to ease the pain and make wearing the prosthesis easier, which addressed her earlier findings. As with the other pair of prosthetists, the ideal solution involved digital technology such as scanning and 3D printing (Table 9-9). The CPDM-prosthetist documented a multimaterial design would work best for the prosthesis user, and the SOAP-prosthetist suggested a nylon socket. The use of an improved cosmesis such as a silicone cover commonly used by the prosthetists in this study from Aqualeg (Thouaré-sur-Loire, France) was suggested by the CPDM-prosthetist to address the psychological findings in PCAM. The interviews with both prosthetists expanded their solutions to describe a need for a better suspension to mitigate sweat accumulation, although they were unaware of any suitable products. When asked by the researcher whether they thought that "*a sweat reducing liner would be beneficial to improve comfort levels*", they both agreed.

Table 9-9. Comparison of current, appropriate, and ideal generated solution for Subject B

		Shape Capture	Modification Method	Manufacturing Method	Socket	Suspension	Foot	Cosmesis
	Current	Hand cast	Hand	Lamination	Fibreglass	6mm pin lock	Trias	Foam
3 CDPM	Appropriate	Hand cast	Hand	Lamination	Fiberglass	6mm Cushion liner	Trias	Silicone
	Ideal	Digital Scan	Software	3D printing	Multi-material, Variable stiffness	Sweat less reducing liner	Triton	Silicone
4 SOAP	Appropriate	Hand cast	Hand	Lamination	Fiberglass	6mm pin lock	Trias	Foam
	Ideal	Digital Scan	Software	3D printing	Nylon	Cooler liner	Trias	Foam

Given the desire of all prosthetists to change to digital processes, the interview was also used to understand the constraints that prevented them designing the ideal prosthesis. All four prosthetists cited the same constraints:

- Lack of skills
- Awareness of technology and components
- Availability and location of technology
- Ease of technology use
- Hospital system requirements
- Time
- Materials durability
- A lack of multi-materials in design
- Preference for familiar products
- Consistent results with current methods

H.7 Compared to prosthetists not using the CPDM, prosthetists who are using the CPDM found the structured approach of the CPDM useful.

H.7 is confirmed affirmed as both prosthetists using CPDM describe in their interviews the introduction of the tools, design phases, and impact of the methodology on comfort for the prosthesis positively.

> "*The CPDM was great at finding out what the patient wants and what needs to be improved, but I need more time to become familiar with the processes. It would have been good to see if the requirements I made would actually translate into higher comfort scores and prosthesis use*"

Despite the additional time taken the CPDM-prosthetists found it useful Table 9-10. The more experience SOAP-prosthetist spent 15 minutes longer than the less experienced SOAP-prosthetist, but

this was likely due to that fact that the more experienced prosthetist conducted all muscle strength testing, and the less experienced prosthetist did not. There was similar time spent for both CPDM-prosthetists and being longer in duration was noticeable by the prosthesis users (Table 9-4. Qn. 13).

Table 9-10. Consultation Time

Prosthetist	SOAP or CPDM	Time taken for consultation (mins)
1	CPDM	45
3	CPDM	47
AVERAGE		***46***
2	SOAP	36
4	SOAP	21
AVERAGE		***28.5***

The Embodiment Design, Build Design, and Final Design, Testing, and Review Phases were evaluated hypothetically through the interview. To evaluate the Embodiment Design Phase, during the interviews with the CPDM prosthetists, the hypothetical question was asked, "*Had this process been applied for a new user, would the use of an interim prosthesis be valuable to determine comfort as part of the Design for change task in the Embodiment phase? Why or why not?* " The prosthetists were in favour of such a design step. Prosthetist 1 suggested,

> "*It would help the user experience the prosthesis so they could inform us what to make better*", and *"they could try out the prosthesis first with different components, but we (the prosthetists) should narrow the choice of options."*

Prosthetist 3 suggested

> "*Using an interim leg would help adjust the expectations of the user."*

As the Build Design phase does not differ from current methods, this was not evaluated. To evaluate the Final Design, Testing and Review phase, users were asked "*how often would you review this user after fitting an interim prosthesis and the definitive prosthesis?"* The prosthetists answers for the interim were

> *"Within 1-7 days may prevent lengthy periods of discomfort if there is any from the last fitting*"

However, both prosthetists suggested that these timelines may not be possible given the tight prosthetist time constraints currently. For the definitive prosthesis, both prosthetists were happy with the current workflow.

"Our standard approach seems to work, one month review after fitting, then every six months."

9.5 Discussion

This chapter focused on the evaluation of CPDM, a methodology that aims to improve comfort-driven design in prostheses by providing a structure of necessary phases to undertake with various tasks in each phase contributing to the comfort of a prosthesis. The focus was on the first three phases. In this section, the evaluation results are discussed under the three categories of hypotheses (see Section 9.2): Understanding and Communication; Tools and Measures; and Usability and Usefulness.

9.5.1 Understanding and Communication

H.1 Compared to prosthetists not using the CPDM, prosthetists who were using CPDM developed a greater understanding of user comfort, needs, experiences and expectations.

H.2 Compared to prosthetists not using the CPDM, prosthetists who were using CPDM felt improved levels of communication between themselves and the prosthesis user.

The findings suggest that the use of CPDM improves the understanding of comfort and communication between the user and prosthetist during the consultation. In CPDM user involvement is critical to determine the comfort factors, their importance and influence in the user's life with a prosthesis. The value of user involvement in prosthesis design has been established in previous work (Anderson, 2022; Beckerle et al., 2013). These findings also signify the importance of understanding the human factors before addressing the technical factors and supports the growing body of literature to provide psychological comfort to users to address their expectations, the effects of the prosthesis in their life, and adaption to social challenges (Ostler et al., 2014).

In aiming to understand the human factors first, the prosthetists and users involved in the study agreed that the communication between them improved and led to greater depth of understanding of the real requirements for the prosthesis. The importance of making the users feel heard was shown to lead to users feeling understood and listened to, in other words "comforted" and better sharing of the issues that matter most to the users. The tools and measures used in this study (AEIOU, Requirements List, PCAM) were considered to enable the identification of the real needs across all comfort factors and

suggests a way forward to whole person understanding, and particularly helpful for less experienced prosthetists.

The user's responses suggest a level of appreciation that the prosthetists took time to understand them, their lives, and the impact of the prosthesis. Despite the users having many years of experience with a prosthesis and having gone through multiple prostheses, the questioning provided a level of confidence between the user and a prosthetist they had not seen before, which helped in developing trust, a key factor of psychological comfort.

9.5.2 Tools and Measures

H.3 Prosthetists felt convinced that the use, user environment, experiences, and expectations information was captured when using the assessment tools and measures.

H.4 Prosthetists using the requirement list tool were able to identify the requirements, factors of comfort and prioritize these findings for the design.

The tools developed for CPDM were valuable in creating a qualitative understanding of the comfort factors. The PCAM version verified in Chapter 7, was found to be extremely helpful in capturing all required information. Used in the context of the CPDM evaluation, the updated PCAM was shown to address the limitations of current available prosthesis comfort assessments. The traditional one-item SCS results of the two participants were 8 and 9 out of a possible 10, respectively. This is considered high in terms of comfort and would normally not elicit design changes from the prosthetists. However, the PCAM revealed areas for improvement in physiological (sweat issues) and psychological determinants (aesthetics), showing a deeper understanding of the actual user's comfort and the specific areas to address to further increase performance experience with the prosthesis. The SCS does not provide any understanding of the comfort determinants, and hence will not provide any indication of which areas to improve. This finding is supported in the literature of other studies (Gailey et al., 2019; Jonkergouw et al., 2019). The depth of understanding and the repeated use of PCAM within the CPDM can benefit subsequent prosthesis.

The adapted AEIOU, the requirement checklist, and PCAM proposed in this research were viewed by the prosthetists as valuable aids in obtaining the relevant needs of the users in a more consultative and holistic approach and in linking those findings to measurable requirements to be incorporated into the prosthesis design. Although the evaluation did not include the actual design of the prosthesis, research has shown that involving the user through utilizing the AEIOU tool in the needs gathering improve outcomes (Ma & Qi, 2017; Maykut & Hung, 2017; Tonelli & Warick, 2022).

As previously mentioned, the lesser experienced prosthetist found the line of questioning with the AEIOU tool helpful in developing a natural conversation with the user, creating trust and a more open sharing environment. However, this same prosthetist found it harder to generate requirements from this information. This could be due to an unfamiliarity with the use of the requirements list, in combination with a lack of experience of how to translate needs and wishes into prosthesis requirements. Instructions incorporated in the requirement list tool, as well as training for users to develop requirements based on the information obtained via the AEIOU tool may help improve the requirements list's accuracy and usefulness.

9.5.3 Usability and Usefulness

H.5a The experience of the prosthetist does not affect the perceived usability of CPDM remains useful and usable.
H.5b The experience of the prosthetist does not affect the perceived usefulness of CPDM remains useful and usable.

H.6 Compared to solutions generated without CPDM, the solutions generated of prosthetists using CPDM fulfil more requirements.

H.7 Compared to prosthetists not using the CPDM, prosthetists who are using the CPDM found the structured approach of the CPDM useful.

The generation of solutions in the Concept Generation phase by the prosthetists using CPDM or the traditional SOAP were similar in many respects, suggesting that at least in this phase of the design process, CPDM has no advantage over SOAP. A possible explanation for the lack of difference in concepts, is that the prosthesis users in our study were experienced users with high SCS, suggesting an appropriate prescription to begin with. This would have made it difficult to improve the designs, irrespective of the approach used. An alternative explanation is that all prosthetists were affected by design fixation. This term refers to situations where creative output is limited because of an overreliance on features of pre-existing designs, in this case probably unconsciously (Youmans & Arciszewski, 2014). The users wore their prosthesis into the consultation, which supports this alternative view. It would be useful to follow-up studies to include users with higher and lower SCS that allow prosthetists to see or not to see user's prostheses, and that include experienced and new prosthesis users. This will be part of planned future research.

Although the study did not show an impact of the use of CPDM on the prosthesis generation, a clear impact on the confidence of the CPDM-prosthetists was found. These prosthetists mentioned that they had greater confidence in their generated solutions as they felt they had a greater understanding of the user and their requirements. This confidence was reflected by both the more experienced and the less experienced CPDM-prosthetists, suggesting its usefulness to different levels of prosthetic experience.

When asked to generate and document their ideal prosthesis for the users if there were no constraints, all four prosthetists in this study changed their prescriptions. Existing (or perceived) constraints clearly affect the prescription and can therefore affect comfort levels for prosthesis users. The barriers to the ideal prosthesis mentioned by the prosthetists were a lack of knowledge and skills with alternative approaches or technology, and preference for particular componentry because they were successful in previous designs or because of a limited supply. Often healthcare institutions provide contracts to deliver more cost-effective components to reduce the costs to users (Tan, Feng, Gordois, & Wong, 2011). These other constraints may be detrimental to the successful outcomes (comfortable prostheses) and, as this study shows, creates an inherent bias in the prosthetis''s decision-making.

The use of digitalization remains a priority for prosthetists and healthcare institutions when designing prostheses despite the barriers and constraints. The ideal solutions proposed by the prosthetists in our evaluation involved the extensive use of digital technology from scanning to capturing the shape, to 3D printing of the sockets. The prosthetis''s mentioned their preference for digital solutions stemmed from the idea that they were faster, cleaner, and easier to use, which have been identified in the digitalization study from Chapter 5. These ideas have been identified as significant advantages with digital processes in the prosthetic industry to encourage adoption (Binedell, Meng, et al., 2020), with 3D printing often being touted as the next big transition for the industry (Nguyen et al., 2018).

However, problems remain with the sockets. The lack of variable stiffness of 3D printed sockets is seen as a barrier to optimize comfort by the prosthetists in our study. The use of multi-material designs that vary stiffness offer opportunities to overcome this barrier. While new technology is seen as the solution to a more comfortable prosthesis, it needs to be clinician-friendly, i.e., easy to use, quick, accessible, and adding value to decision-making in a clinic setting. Prosthetists face significant time constraints, at least in Singapore, influencing their decision-making and prosthesis design. Therefore, technology that improves efficiency and decision-making could lead to a higher adoption rate, which in turn could lead to more comfortable prosthesis. The evaluation of CPDM, however, showed that it took prosthetists 38% more time to complete the early design phases. This could be a significant problem given the time pressure under which the prosthetists work if it were not for two other findings. First, the much higher confidence of the prosthetists in their prescription as being comfortable, and the areas of improvement potential identified through PCAM suggest that the remaining phases of the design process will result

to a more comfortable prosthesis and will result in less visits back to the clinic for adjustments or repairs. Second, the users appreciated the extra time with the prosthetist to share their views. It is this human touch and personal attention that provides comfort to the user.

The structure of CPDM into six design phases was clear and easy to follow. The use of the developed tools was helpful in developing the communication to elicit design needs to be converted into requirements. By advocating the use of interim prosthesis or check sockets, the opportunities to experience the prosthesis and its impact into the users' life can be better articulated to the prosthetist. Insights thus gained are important to note before significant prognosticative decisions are made. Studies have shown that fitting an interim mechanical prosthesis shortly following amputation greatly facilitates mobility training and rehabilitation, leading to improvements in functional ability and a shorter period of rehabilitation (Smith, McFarland, Sangeorzan, Reiber, & Czerniecki, 2003; Van Velzen et al., 2006). However, the results of our study suggest a further advantage of such interim solution: it can aid in the comfort decision-making process by allowing the user time to adjust their expectations and needs. The prosthesis users will also be better positioned to compare how different components, interface materials etc., may affect comfort. Literature suggests that users may not be aware of the limitations of a prosthesis and find the new prosthesis disorientating (Jefferies, Gallagher, & Philbin, 2019; Murray & Forshaw, 2013). Allowing the users time and space to experience comfort levels in a variety of environments and over some time could lead to improved outcomes and increased prosthesis use.

9.6 Generalization of CPDM

The CPDM has been developed from the need for comfortable prostheses to improve the QOL for many users and tested in the context of lower limb prostheses. However, the CPDM is developed to have a much wider applicability and is expected to be particularly useful for customized products and wearable technologies that are user specific. The structured approach to product design is expected to provide the pathway to improving comfort in both medical and non-medical designs. When designing a customized product for comfort, the role of user in determining requirements and their experience through the use of the product can help to optimize comfort in the final design. The PCAM tool plays an important role in evaluating comfort. PCAM can be altered for any product, especially when comfort is critical to QOL. The 6 determinants are generic, although their weight may different depending on the product and the specific requirements. The factors may not all be (equally) relevant for each product, but these can be easily adapted to reflect the product that is being designed. As an example, the comfort of a customized wheelchair can be designed with CPDM and its tools. The comfort factors can be captured using CPDM, pressure sensors, LoNE, PCAM, AEIOU and the Requirements List. The suspension factor may not be as relevant to wheelchairs as prosthesis design however it could be altered to capture whether the user is slipping forward in the chair during its use which may indicate a tilt in space option as a better design.

It is still necessary to capture the use, user, and user environments to ensure a successful outcome in much the same way as designing prostheses. The time of exposure would also change since wheelchair users are unable to remove themselves easily from the chair as opposed to removing a prosthesis to alleviate discomfort. Capturing what alternatives the user puts in place when not using the chair could indicate design changes for enhanced comfort for the wheelchair. CPDM could also be useful for the design of non-medical products that are user-specific such as footwear with emphasis potentially placed on the aesthetics, context, and physiological responses. The use of the same tools used in medical design could be applicable. The footwear designs could be optimized for comfort by allowing movement along the LoNE and using appropriate materials to provide breathability and support. Communication may not be as important in this context and could be altered to service provision factors.

9.7 Limitations

There are limitations associated with the evaluation that may have impacted the findings and our ability to draw conclusions. The evaluation took place in a real-life context, but only covers the first 3 phases, in less than an hour of consultation for existing prosthesis users. A standard consultation is 45 minutes. One task of the Conceptual Design phase (shape capture), the Embodiment Design, Build Design, and Final design phases were not investigated. These processes were excluded for reasons of time as they do not differ from the current approaches of the prosthetists in Singapore. The question concerning the Testing and Refinement phase provided some insight into the prosthetists' expectations, rather than experienced reality. The focus on the first three phases also did not allow us to determine if the prostheses designed using CPDM are more comfortable long-term and if the number of repeat visits to the clinic are reduced. This will be a focus of a follow-up study.

The CPDM was evaluated with only four prosthetists and two prosthesis users, both of which already use a prosthesis. New users were not included. Furthermore, the prosthesis was worn into the consultation possibly creating a fixation effect for the prosthetists as suggested by their solutions. The prosthesis users were also consulted by the two prosthetists in quick succession possibly creating a fatigue effect of their answers, as they mentioned *"it was quite a long afternoon*." Although generalization of the findings is not possible, the evaluation has given insights into the possible strengths and weaknesses of the use of PCAM and the individual tools in a real-life situation. These insights are very useful for its further development and evaluation at a larger scale and under different conditions.

The study was also limited by three external factors. COVID-19 measures limited unnecessary visits to the clinic for prosthesis users, reducing the number of participants. The introduction of a national based medical record system in Singapore meant additional training and education to use this system, which

effected the availability of the prosthetists. Finally, the CPDM was developed and tested only in the Singapore context. Some suggestions may already be common practice in other countries, such as the use of interim prosthesis. The approach, however, we believe is relevant and translatable, and flexible enough to be adaptable to specific contexts.

9.8 Conclusion

The CPDM is a design methodology comprising of six design phases. The CPDM was designed following a systematic process modeled of existing customer satisfaction and product design methodologies to ensure both human and technical factors are addressed in the prosthesis design process. The CPDM and its methods emphasize the importance of understanding the user, the use and the environment, and identifying the impact of the various factors that influence comfort as experienced by the individual user, as this is critical to improve the user's QOL.

The evaluation of CPDM addressed three areas: Understanding and communication, tools and measures, and usability and usefulness.

The use of CPDM was found to improve the understanding of comfort and communication between the user and prosthetist during the consultation. In CPDM user involvement is critical to determine the comfort factors, their importance and influence in the user's life with a prosthesis. The prosthesis users appreciated the CPDM phases as it guided the prosthetists to better understand them, their life with a prosthesis and its impact. The greater understanding provided a level of confidence between the user and a prosthetist and developed trust which is a key factor of psychological comfort.

The tools developed for CPDM were valuable in creating a qualitative understanding of the comfort factors. Needs capturing through the AEIOU framework was found beneficial to understanding the user and a valuable method for less experienced prosthetists as it provided areas to assess comfort with the user. The requirements checklist was helpful in organizing the needs in the prosthesis, while the PCAM was sensitive to detect small changes to improve user comfort levels and identifies determinants of comfort that are lacking.

The CPDM was usable and useful for prosthesis design. The structure of CPDM into six design phases was clear and easy to follow. The use of the developed tools was helpful in developing the communication to elicit design needs to be converted into requirements. The prioritization of these requirements led to the generation of new solutions that varied from the current prescription of the prosthesis users. The changes could be expected to improve comfort levels and include the use of digitalization opportunities. Improving the skills and knowledge of the prosthetist to use digitalization

processes should be considered to increase adoption as these were identified as barriers to comfort driven designs.

10 CONCLUSIONS AND FUTURE RESEARCH

10.1 Conclusion

This chapter summarizes the research in this thesis, discusses its contribution to the field of prosthesis design and outlines proposals for future research.

The rehabilitation process with a prosthesis focuses on the key goal of functional mobility. For a prosthesis to achieve this, it must not only fit well against the residuum but be comfortable to wear and add value to the user's QOL. As much as the prosthesis aims to be an extension of the skeletal system to improve functional outcomes, the lack of comfort limits the ability of the prosthesis to serve as an extension of the human behind the system. In response to years of clinical practice with prosthesis users who often complained their prosthesis was uncomfortable, leading to underutilization or worse, device abandonment, this thesis sought to improve comfort through a series of objectives and goals, to achieve the main aim of Comfort-driven Prosthesis Design.

In order to understand the phenomenon of comfort in prosthesis use and propose a new approach for prosthesis design, the research addressed the following objectives:

1. Identification of the influencing factors of comfort
2. Identification and evaluation of digital technology potential
3. Development and verification of a comfort assessment tool, and
4. Development and evaluation of comfort-driven prosthesis design methodology

The research undertaken was divided broadly into three phases, the conclusions of which are described below.

Descriptive phase I (Chapters 2, 3, 4, 5, and 6)

A detailed literature review was conducted in Chapter 2 to understand comfort and to provide an overview of the human and technical factors in prosthesis design. The definitions of comfort directly concerning prostheses are inclined towards viewing discomfort and comfort as a linear continuum, although this thesis identifies independent factors for each term. Comfort depends on the personal experience and the physiological, physical, psychological (PPP) state of the person over time in a contextualized environment. The use of both qualitative and quantitative methods is necessary to capture all factors and their impact to the prosthesis user and the emergence of digital technologies (DT) can support the design approach for prostheses as they offer potential in both short-term and long-term comfort analysis.

Chapter 3 describes the research methods that were used to do address the gaps found in literature and to establish an approach to assess and develop comfort in prostheses designs that result in better physical, physiological, and psychological comfort for the user. It also describes the methods used to inform, develop, and evaluate a comfort-driven prostheses design methodology (CPDM). Following the DRM approach to design research, the thesis used literature, user perspectives, experiments, surveys, focus groups, case study, interviews, and questionnaires to meet the objectives.

The use of interviews with prosthesis users (Chapter 4) provided insight into the user's views on comfort and the factors they felt determined comfort. Building on the literature findings in Chapter 2, the interview results added three determinants of comfort to the PPP already established. Comfort for lower limb amputees is further determined by 1. understanding the users' expectations of the prosthesis and its functionality, 2. identifying the needs-based context that affects comfort, and 3. communicating the needs and requirements between the prosthetist, the user, and the social network. The interviews revealed a comfort zone where the prosthesis seamlessly integrates into the user's life and lifestyle to such an extent that it becomes unnoticeable by the user and others. A critical issue that remains is the translation of the comfort zone into quantifiable indicators for designing a comfortable socket.

To understand what process methods would be helpful to determine comfort, Chapter 5 used pressure sensors to quantify pressure between the residuum and socket. The sensor also helped in substantiating the user's feedback and quantification of any changes made to the residuum-socket interface by the prosthetist. To assess whether using digital technology (DT) such as sensors to quantify comfort was appropriate for various countries and to ensure its use in the developed methodology would be applicable, an international survey was conducted to ascertain the adoption of DT, its perceived usefulness, and barriers, to determine the technological readiness of the industry. The use of DT showed advantages for the on-going assessment and continuity of care for the prosthesis users and has the potential to enhance comfort levels. Right citing the user with the appropriate technology and answering what needs the technology is addressing is essential.

The findings from the literature (Chapter 2) and the interviews with prosthesis users (Chapter 4) highlighted factors that were found to have a particularly large influence on comfort. Among these are the physiological factors due to their prominence in prosthesis disuse and abandonment. These include thermal regulation (sweating), pressure distribution, and pain. Solutions were developed and experiments were conducted to assess their influence on comfort. The use of Lines of Non-Extension (LoNE) showed design opportunities to improve comfort for prosthetic sockets as these LoNE were not found in locations where wounds or other skin breakdowns occur. The sweat reducing liner results indicate its design microchannels are effective in removing sweat from within the liner, keeping the residuum dry and comfortable. The forequarter prosthesis case study further provided evidence that

customized, digitalized, and optimized solutions that address the user needs, result in enhanced comfort levels. The results of these solutions show design changes can mitigate discomfort and help to achieve a higher comfort experience with the prosthesis.

Prescriptive phase (Chapters 7 and 8)

In Chapter 7, the Prosthetic Comfort Assessment Metric (PCAM) and in Chapter 8, the comfort-driven design methodology (CPDM) containing the AEIOU, Requirements Checklist, and PCAM were developed to aid in design decisions to improve the levels of comfort in prostheses. The PCAM metric uses six main determinants for assessing comfort: 1) Physical, 2) Physiological, 3) Psychological, 4) Expectations, 5) Context, and 6) Communication in response to information gathering in Chapters 2, 4, 5, and 6. The PCAM increased prosthetist'' knowledge and understanding of comfort and had high internal consistency making it suitable to detect comfort levels for prosthesis users. The CPDM combined all comfort information from literature, user perspectives, experiments in previous chapters into a design methodology to for comfortable prostheses. The CPDM contains six design phases with necessary tasks to complete in each phase.

Descriptive phase II (Chapters 7 and 9)

The evaluation of CPDM addressed three areas to ensure both human and technical factors are covered: Understanding and communication, tools and measures, and usability and usefulness. The use of CPDM improves the understanding of comfort and communication between the user and prosthetist during the consultation. The tools developed for CPDM were valuable in creating a qualitative understanding of the comfort factors. Needs capturing through the AEIOU framework was found beneficial to understanding the user and a valuable method for less experienced prosthetists as it provided areas to assess comfort with the user. The requirements checklist was helpful in organizing the needs in the prosthesis, while the PCAM was sensitive to detect small changes to improve user comfort levels and identifies determinants of comfort that are lacking. The CPDM was overall usable and useful for prostheses design and the structure clear and easy to follow. Prosthesis users found an increased level of confidence and trust in the prosthetists as a result, leading to improved comfort levels with the prostheses. Future work involves a longitudinal study and to evaluate the methodology in a wider setting.

10.2 Research Contributions

Through the development of CPDM, the main contributions of this work are summarized as follows:

1) This thesis presents an overview of all comfort factors that contribute to prosthesis comfort. The literature has identified three determinants of comfort with prostheses including physical, physiological, and psychological. This study further adds to this list by including user expectations, context, and communication as necessary for prosthesis comfort.

2) The key contribution of the research is the development of the CPDM that is specific for designing comfortable prostheses and addresses both human and technical factors of comfort. CPDM uses proven design concepts and processes adapted from various industries and is designed to be used with new and existing prosthesis users. Its structure of six clear design phases and necessary tasks, use of design tools such as AEIOU, Requirements Checklist and PCAM provide a deep understanding of comfort and areas for comfort to be improved. The usability and usefulness of the developed methodology emphasizes the importance of understanding the user's needs and requirements early in the design of prostheses.

3) The development of novel tools and measures of comfort. These include the adaption of the AEIOU framework to provide areas for discussion and assessment, enabling greater communication with the prosthesis users. The use of the requirement checklist to capture and define the success criteria for the final design of a prosthesis to be compared with. The evaluation metric, PCAM, for identifying the comfort level for a prosthesis user and the contribution of each factor towards comfort with a prosthesis. The PCAM uses a traffic light system and is colour coordinated to easily determine the factors of comfort and their importance to the user to the prosthetist can make informed and timely design decisions.

4) The potential of digital technology such as pressure sensors has been demonstrated in this work as successful and suitable to aid comfort-driven design. These sensors provided valuable insights into the pressure tolerance of the residuum and served to objectively confirm both the experienced level of comfort for the user and the modifications made to the prosthetic socket by the prosthetist when adjusting the socket to reduce pressure. The forequarter prosthesis case study highlighted the application of DT to enhance user comfort through a human-centered design approach. This was the first fully 3D printed prosthetic arm of this level in the world.

5) Of significant contribution is the investigation into mapping the Lines of Non-Extension through low-cost methodologies that could be easily incorporated into clinical practice.

Through this investigation we were able to identify areas of the residuum that could be used to design a structured frame of hardened materials to support the limb with minimal shear forces. This could aid the development of new multi-material designs that enhance comfort levels and prevent device disuse or abandonment.

6) The investigation into the novel use of microchannels to improve thermal regulation. (sweating) within prosthetic liners using capillary action principles has shown to be effective in mitigating sweat related issues. Knowledge gained from this research could be useful in the design of new prosthetic liners to control thermal regulation responses, reducing the need to remove the prosthesis and improving the user's QOL.

10.3 Limitations and Future Research Directions

Possible future directions of the research are as follows:

1) **Furthering small sample studies to a larger cohort**: As preliminary studies were conducted in this research, there is a need to evaluate CPDM and the PCAM evaluation tool in a larger cohort. This could involve the testing in multiple countries and in various languages.

2) **Need to evaluate the use of interim prostheses**: Current practice in Singapore does not include the provision of an interim prosthesis to users. As comfort should be experienced, the results in the CPDM study suggest the use of an interim prostheses may have significant benefits to the user and their comfort experience. There is also a need to evaluate the long-term cost benefit analysis associated with interim prosthesis as many users need to pay for their prosthesis in Singapore.

3) **Longitudinal studies that compare standard practice with CDPM:** A longitudinal study would help to determine the long-term usability and usefulness of the methodology. Suitable measures are differences in prosthesis designs, number of visits per year to the clinic, reasons for these visits as well as the number of days the user was unable to use their prosthesis.

4) **Education and Training**: Given that current prosthetics and orthotics education focuses on physical and functional outcomes, the introduction of CPDM could create awareness of the importance of understanding both the technical and human factors in prosthesis design and provide an approach and methods to develop prosthesis that take these factors into account in order to create prosthesis with a high level of comfort for individual users.

5) **Digital technology optimization**: The use of sensors and other digital technology such as scanning, 3D technologies and AI should be explored as methods to determine parametric data that optimizes digital design processes. The use of sensors in one of the experiments in this thesis has shown the viability of their use in a clinical setting. The cost of the other technologies and a lack of clarity on their actual value to add to the design process remain significant barriers to their use. Further development and research are required.

6) **Further iterations of prosthetic liner**: The introduction of microchannels in a prosthetic liner to reduce sweat accumulation has shown limited effectiveness. The use of hydrophilic materials should be explored to assess performance improvement. Furthermore, the combination of microchannels with phase change materials may help to further improve thermal comfort by delaying the sweat development.

7) **Lines of Non-Extension**: The identification of the LoNE was conducted using manual methods for point correspondence. Future work involves the development of the code to identify 2D images through colour separation to generate the lines of maximum and minimum strain and determine the LoNE for a given body segment. The LoNE should be used in the design and development of a prosthetic liner and socket to test whether such designs enhance user comfort and reduce device abandonment.

In summary, the results from this work address comfort-driven prosthesis design. This work contributes to both the process of designing prosthesis through the identification of factors, AEIOU framework, Requirements Lists, PCAM, and CPDM, and also contributes to the prosthesis itself through solutions that address particularly significant factors that affect comfort such as the Sweat Reducing Prosthesis Liner, LoNE, and digital technologies to detect pressure changes, and the design and development a 3D printed Forequarter Prosthesis, which helped to demonstrate the potential of digital technologies.

APPENDICIES

Appendix 1. Comparison of design and development processes in the literature

Design and development process			**Medical Device Design "Biodesign"**	**Prostheses Design Process**
(Ogot & Kremer, 2004)	(Gericke & Blessing, 2012)	(Pahl et al., 2007)	(G. Herr, 2010)	
Needs Assessment/ Problem definition Includes the definition of the problem and the customer/client's needs as part of the requirements review of the product or process.	*Establishing a need* Initiation of the design process by a product idea, or the identification of a need or a problem		*Needs Finding / Empathy* Finding important unmet health needs, observe and ask questions of the user	*Assessment* Includes medical history, physical condition, user needs
	Analysis of task Detailed analysis of the initial description of the task/need/product idea; additional information is gathered	*Task Clarification* Collecting, formulating and documenting the requirements of the product to be designed.	*Needs Screening / Define* Iterative process, with progressively deeper dives into the needs that have the most potential, arriving at the two or three most promising needs which can be solved or have major impact	
Conceptualization The design team develops several concepts from which the best suited to the defined need is selected. A concept is a very preliminary description of the form, required principles and required technology for the solution.	*Conceptual Design* Development of abstract/principle solutions (concepts) which solve the problem	*Concept Generation* Identify the basic principles and outline of a design solution (or concept)	*Concept Generation / Ideate* Brainstorming solutions for the top needs identified. Objectively compare them against key criteria for satisfying the needs. Create rough prototypes and iterate often.	*Casting* Develop a replica of the residuum

Preliminary Design and Evaluation Evaluation of feasible concepts for concept selection and to determine system and component design.	*Embodiment Design* Detailing of the conceptual solution	*Embodiment Design* Elaborates the design into a layout that satisfies various technical and economic criteria	*Concept Screening / Prototype* Filter solutions against any intellectual property, business models to reimbursement, and regulatory pathways. From results develop a lead concept to explore further.	*Modification* Detailing pressure tolerant and sensitive areas into the residuum replica to determine appropriate force distribution.
Detailed Design and testing Development of technical drawings and system specifications.	*Detailed Design* Integration of sub-solutions, refinement, and finalisation of the solution	*Detailed Design* Finalises the design and prepares production documents	*Strategic Development / Test* Prototyping and testing their technology, developing their approach to patenting, regulatory approval, and reimbursement.	*Fabrication* Integration of components, materials and modified design to a finalised prosthesis
Production Planning of production process.	*Implementation* Integration, manufacturing, installation, test, approval, launch of the product		*Business Planning* Charting the market potential for the innovation	*Fitting and Delivery* Fit the prosthesis to the user, check fit, adjusted alignment, and provide to user
	Use Operation, monitoring, maintenance of the product		*Project Launch* Launch the product	*Review* Check fit and function of prosthesis. Provide and maintain and repair of prosthesis if necessary.
	Closeout Recycling, disposal, update/evolution of the product			

Appendix 2. Semi-structured interview questions

Semi-structured interview guide	
Domain	Questions
General	How would you describe comfort? What does a comfortable prosthesis mean to you? Tell me about any of the concerns you may have with the prosthesis comfort? Describe how a lack of comfort is limiting? How would you recommend improving it? Describe the activities where comfort is important to you? Describe the activities where comfort is not so important to you?
Physical	Describe the importance of a good socket fit? Where and when do you use your prosthesis? How does comfort impact these decisions? How easy is it for you to use your prosthesis? Why? or Why not?
Physiological	Can you describe the feeling between your prosthesis and your leg? How do you know if your socket is uncomfortable? What actions do you take?
Psychological	Can you share with me the experience of having a prosthesis in your daily life? Describe the actions you take when the prosthesis is uncomfortable? Describe your ideal state of comfort with the prosthesis?

Appendix 3. Digitalization Survey

* 2. In which country do you work or live?
Singapore
Thailand
Malaysia
Philippines
Myanmar
Sri Lanka
Indonesia
India
Hong Kong
Cambodia
Other (please specify)

* 3. Age
Under 18
18-24
25-34
35-44
45-54
55-64
65+

* 4. Gender
Male
Female
I do not wish to state

* 5. Please select the option below that best represents you
Patient (Lower limb amputee)
Prosthetist/Orthotist

* 6. What level is your amputation?
Partial Foot
Ankle disarticulation
Transtibial (Below knee)
Knee Disarticulation (Through knee)
Transfemoral (Above knee)
Other (please specify)

* 7. How many years has it been since your last amputation?

* 8. What was the cause of your amputation
Trauma / Accident
Diabetes
Vascular disease (not diabetes)
Cancer
Congenital (born this way)
Other (please specify)

* 9. What walking aids do you currently use?
Cane / Walking stick–- single point
Walking stick–- quad point
Single crutch
Two crutches
Walking frame
Wheelchair
I do not use any aids
Other (please specify)

* 10. How would you rate your mobility?
I do not walk
I mostly walk at home
I can walk outside the home but I must be careful not to fall
I can walk outside without any issue
I can perform recreational activities i.e sports

* 11. How satisfied are you with your level of mobility?
Very satisfied
Satisfied
Dissatisfied
Very dissatisfied

* 12. Use the slider to show many hours you use your prosthesis (artificial limb) each day?
0 hours 24

* 13. Do you have a problem with comfort when using your prosthesis (artificial limb)?
Left Right
Very often
Often
Not often
Never

* 14. How comfortable is your prosthesis (artificial limb)? If you are bilateral, please only rate your least comfortable limb with 0-least comfortable, 10–- most comfortable

* 15. What are the three major problems with your prosthesis (artificial limb)? Indicate NA if there are no problems

* 16. When you last got a new socket made, how did the Prosthetist capture your stump shape?
Plaster wrap
Scanning
Measurements alone
Other (please specify)

* 17. Please rank the following items that most impact your mobility with your prosthesis (artificial limb).
Pain
Easy to put on and take off
Durability
Access to care
Weight
Breathability / temperature
Appearance
Stability

* 18. How much are you willing to contribute towards your prosthesis (artificial leg)? (enter whole numbers and indicate currency)

* 19. How easy is it for you to attend a prosthetic facility?
Very easy
Easy
Somewhat easy
Not very easy

* 20. How satisfied are you with your follow up care from your provider of the prosthetic leg?
Very satisfied
Satisfied
Dissatisfied
Very dissatisfied

21. Why are you satisfied or dissatisfied with your follow up care?

* 22. Have you missed any appointments in the last year?
Yes
No

* 23. What are the top 3 reasons for doing so
No transportation
Too far
Nothing wrong with my leg
No one to accompany me to the appointment
Cost of transport
Forgot to go
Other (please specify)

* 24. Would you rather attend a prosthetic facility or have the prosthetic specialist come to you?
Go to the facility
Have the specialist come to me

* 25. Would you be willing to pay for this home service?
Yes
No

* 26. If this home service was done virtually over the internet, would you still be willing to pay for this service?

Yes
No
Maybe (please specify when)

* 27. What kind of mobile phone do you use?
Basic (calls and simple text only)
Smart phone (has internet connection)
I do not own or use a phone

* 28. Does your phone have a camera?
Yes
No
I do not own or use a phone

* 29. Do you take photos on the phone?
Yes
No
I do not own or use a phone

* 30. Do you have access to a computer?
Yes
No

* 31. Is your internet connection stable?
Yes
No
Sometimes

* 32. Would you rather use your computer to see the prosthetic specialist virtually or online, instead of a face-to-face consultation?
Yes
No
Sometimes (please specify under what conditions)

* 33. How confident are you to adjust your own prosthesis (artificial limb)?
Extremely confident
Very confident
Somewhat confident
Not so confident
Not at all confident

* 34. If you were guided over the internet, by your prosthetic specialist on how to adjust your own prosthesis (artificial limb), how confident would you be?
Extremely confident
Very confident
Somewhat confident
Not so confident
Not at all confident

* 35. Did you need any help to fill in this survey?
I did it myself
Wife / Husband
Child / Children
Relative
Prosthetist
Nurse
Other (please specify)

* 36. How many years have you been working?

* 37. On average, how many patients do you see per day?

* 38. Do you use digital technology where you work? i.e scanners, 3D printing, CADCAM
Yes
No

* 39. List 3 reasons for not using digital technology in your practice? List in order of major reason to minor reason

* 40. Do you use computers where you work?
Yes
No

* 41. Do you have stable internet connection?
Yes
No

Sometimes (please explain)

* 42. Would you like to use more digital technologies where you work when seeing patients?
Yes
No
Maybe (please explain)

* 43. What types of technology would you like to use?
Virtual or Online assessments / consultations
Virtual or Online fittings
Scanning of patients
3D printing devices
Become a central fabrication facility
Other (please specify)

* 44. How many years have you been using digital technology as part of standard patient care?

* 45. What kind of digital scanner(s) do you use? List in order of your preference

* 46. What is the name of the P&O software do you use?

* 47. Does your facility have a CADCAM /Milling machine?
Yes
No

* 48. Would you be happy to use 3D printed P&O devices?
Yes–- I currently print my own
Yes–- but I would need to use an external source to print for me
No
Maybe (please elaborate)

devices
* 49. Please rate your own technology skills according the scale. Please select one option per row. (Not Familiar – Advanced)
Set up and scan with an tablet (i.e. ipad) and download the details to the relevant software
Rectify scans using your previously mentioned P&O software
Set up and carve CAD files
Save and send .STL file extensions for 3D printing
3D print my own devices

* 50. How often do you integrate digital technologies into your work? Please select one option per row. (Regularly – never)
Take digital photos of a patien''s limb for documenting purposes
Offer a digital solution to your patient during the consultation
Prescribe a 3D printed Ankle Foot Orthosis
Scan for an Ankle Foot Orthosis
Scan for below knee socket
Scan for an above knee socket
Scan for a TLSO / Spinal brace
Scan for custom Footwear

Other areas you use digital technology (please specify the area and frequency)

* 51. Please evaluate each of the following statements. Please select one for each question. (Strongly agree – Strongly disagree)
My internet connection speed is insufficient for digital technologies to work
I feel confident in my ability to incorporate digital processes with my patients
The amount of time needed to prepare to use the digital technology prevents me from utilising it.
Digital technology improves patient outcomes
Patients prefer me to use digital technology when making their devices
It is important to practice with the hardware/software to be more efficient and effective when using it.
I do not have the technical skills to use digital technology with my patients.
Digitally produced devices always fit better
3D printed devices enable high cost-effectiveness
I mostly use digital technology for making check sockets
I am less efficient when using digital technology than traditional methods, when making my devices.
I find it inconvenient to use digital technology
I would use digital technology for all my jobs if I could
The future of P&O is digital

* 52. What are up to five factors that prevents you from integrating more technology with your patients? List them in rank of most important to least important.

* 53. Concerning the use or integration of technology, list the areas in which you would most like to receive training, beginning with the highest priority?

* 54. Do your patients have difficulties in coming for their appointments?
Yes
No

* 55. What are the three biggest challenges your patien''s face in getting a prosthetic leg? (List in order of biggest challenge first)

* 56. Can your patients afford to pay for their prosthetic leg?
Yes
Sometimes, but they require government or other types of assistance
No
All the legs are completely free to the patient

* 57. What are the 3 top reasons your patients do not make it for their appointments? List in order of most common to least common

* 58. Do you think virtual/online assessments would be beneficial for this patient group?
Yes
No

* 59. What percentage of your daily patients can you immediately think of that would benefit from virtual or online assessments/ fittings?

* 60. If virtual/online assessments were made possible by your facility, would you likely use them?
Yes
No
Maybe (please elaborate)

* 61. Do you have stable internet connection?
Yes
No
Sometimes (please explain)

* 62. What are some platforms you could use in your country for virtual/online assessments and/or fittings?
Computer
Mobile Phone
Other (please specify)

* 63. List 3 potential difficulties you could see with virtual assessments. Please list in order of most difficult to least difficult

* 64. List up to 3 potential benefits of using virtual assessments? List in order of biggest benefit to smallest benefit

* 65. Would you be open to providing prosthetic fitting advice online (virtual fitting) and have someone else make the adjustment?
Yes
No
Maybe (please elaborate)

* 66. Please answer the following statements. Strongly agree – strongly disagree
Virtual/Online assessments will improve patient outcomes in rural settings
Virtual/Online fittings will improve patient outcomes in rural settings
I would use virtual/online assessments if it was available
I would use virtual/online fittings if it was available
Patients would benefit from virtual/online assessments
Patients would benefit from virtual/online fittings
P&O clinicians should be the only ones to measure or capture (scan) an ampute''s limb.
I would be willing to train others to only digitally capture a patien''s limb
More patients could be helped if virtual/online assessments or fittings were conducted in my country

* 67. I would be willing to be contacted for a follow up interview if required.
No
If agreeable, please provide email below (this email will be kept separate from your answers to keep the data anonymous)

Thank you for taking the time to complete this survey.

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(54) Title: PROSTHETIC LIMBS, PROSTHETIC LINERS, AND METHODS FOR MANAGING, CONFIGURING, AND USING PROSTHETIC LIMBS AND PROSTHETIC LINERS

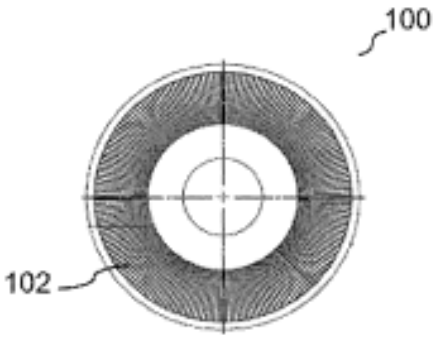

FIG. 1

(57) Abstract: Embodiments relate to prosthetic limbs and liners. An embodiment of the prosthetic liner is housed in a prosthetic limb and includes a liner body. The liner body includes a first end for receiving a body part of a user. The first end includes a liquid-retentive portion. The liner body includes an inner surface. The inner surface contacts with the body part. The inner surface includes a plurality of microchannels. The microchannels are formed along the inner surface. The microchannels are connected at one end to the liquid-retentive portion. At least one of the plurality of microchannels is configured to receive liquid droplets and direct the received liquid droplets to the liquid-retentive portion. The liner body also includes an outer surface opposite to the inner surface. The outer surface faces an interior surface of the prosthetic limb and is provided in an interior cavity of the prosthetic limb.

[Continued on next page]

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Appendix 5. Prosthetic Comfort Assessment Metric (PCAM)

Determinants	Factors	Symbol	Unsatisfactory = 0	Fair = 1	Satisfactory = 2	Score
Expectations	Early Rehabilitation Success	E1	User has had poor success with the early stages of rehabilitation	User has had some success with the early stages of rehabilitation	User has had good success with the early stages of rehabilitation	2
The way in which the prosthesis meets the needs of the user, often expressed as an experience or goal	Suitable for actiivity needs	E2	User is not satisfied with the amount of activities they can do with the prosthesis	User is somewhat satisfied with the amount of activities they can do with the prosthesis	User satisfied with the amount of activities they can do with the prosthesis	1
	Freedom from design limitations	E3	The user has many design limitations affecting its use	The user has some design limitations affecting its use	The user has no design limitations affecting its use	2
	Ease of wearing	E4	Prosthesis has a high number of steps (>5) involved in wearing	Prosthetsis has a fair number of steps (3-5) involved in wearing.	Prosthesis has a low number of steps (<3) involved in wearing.	0
	Experience	E5	Prosthesis does not provide a positve experience to the user when wearing	Prosthesis somewhat provides a positive experience to the user when wearing	Prosthesis provides a positive experience to the user when wearing	1
Equation (1): Metric Expectations = E = [9 x ((E1+E2+E3+E4+E5) / 10)] + 1					**Calculated Metric$_{Expectations}$**	6.4
Psychological	Aesthetics (size, colour, shape)	W1	User finds the aesthetics of the prosthesis poor	User finds the aesthetics of the prosthesis fair	User finds the aesthetics of the prosthesis good	0
The perception of the prosthesis and its impact on the user's life	Reliability	W3	The prosthesis is not reliable	The prosthesis is somewhat reliable	The prosthesis is reliable	2
	Satisfaction and QOL	W4	User feels unsatisfied with the prosthesis and their QOL	User feels somewhat satisfied with the prosthesis and their QOL	User feels satisfied with the prosthesis and their QOL	1
Equation (2): Metric$_{Psychological}$ = W = [9 x ((W1 + W2 + W3) / 6)] + 1					**Calculated Metric$_{Well\text{-}Being}$**	5.5
Physical	Type of activity (walking, running, sitting etc)	F1	Few of the user's activities (<40%) can be fulfilled by the prostheis.	Some of the user's activities (50-70%) can be fulfilled by the prosthesis.	Most or All of user's activities (80-100%) can be fulfilled by the prosthesis.	2
The way the prosthesis design characteristics support the participation in functional activities in the user's life.	Suspension	F2	Prosthesis has major suspension issues for functional performance requirements across time.	Prosthesis has minor suspension issues for functional performance requirements across time.	Prosthesis has no suspension issues for functional performance requirements across time.	1
	Compentry and materials	F3	The componentry and materials are not suitable for the user	The componentry and materials are somewhat suitable for the user	The componentry and materials are suitable for the user	2
	Socket contour	F5	The socket does not match well with the user's residuum	The socket somewhat matches with the user's residuum	The socket matches well with the user's residuum	2
	Trimlines and ROM	F6	The prosthesis trimlines are not comfortable affecting ROM	The prosthesis trimlines are somewhat comfortable and somewhat affecting ROM	The prosthesis trimlines are comfortable and do not affect ROM	1
	Shape Capture method	F7	The user prefers a new shape capture method to make the prosthesis (if necessary)	The user has no preference for the shape capture method to make the prosthesis (if necessary)	The user prefers the same shape capture method to make the prosthesis (if necessary)	2
	Weight	F8	The weight of the prosthesis greatly affects the function	The weight of the prosthesis moderately affects the function	The weight of the prosthesis does not affects the function	0
	Safety and Stability (Alignment)	F9	Patient does not feel stable or safe when using prosthesis	Patient has some issues with stability and safety when using prosthesis.	Patient feels stable and safe when using prosthesis	1
Equation (3): Metric$_{Physical}$ = F = [9 *((F1 + F2+ F3+F4+F5+F6+F7+F8) / 16)] + 1					**Calculated Metric$_{Functionality}$**	7.2
Physiological	Volume changes	P1	The residuum is often changing volume affecting the socket fit	The residuum is sometimes changing volume affecting the socket fit	The residuum is stable in volume not affecting the socket fit	2
The interaction between the residuum and the prosthetic socket across time	Pressure Distribution	P2	There are major indications of pressure issues	There are minor indications of pressure issues	There are no indications of pressure issues	1
	Thermal regulation	P3	There are severe sweating or sweat related issues	There are minor sweating or sweat related issues	There are no sweating or sweat related issues	1
	Time of Exposure	P4	The patient cannot wear the prosthesis for very long.	The patient can wear the leg for long amounts of time but often needs to remove it	The patient wears the prosthesis as much as they like	1
Equation (2): Metric$_{Physiological}$ = P = [9 x (P1+P2+P3+P4 / 8)] + 1					**Calculated Metric$_{Physical Interaction}$**	6.6
Context	Environment	C1	The prosthesis is not adaptable to a variety of envrionments	The prosthesis is somewhat adaptable to a variety of environments	The prosthesis is adaptable to a variety of environments	2
The way the user with the prosthesis interacts in the use and user environment.	Duration of activity	C2	User is not free to continuing engaging with chosen activity	User is free to continuing engaging with chosen activity but with some difficulty	User is free to continuing engaging with chosen activity without limitation	2
	Specific requirements (travel, movies, extended periods of sitting)	C3	Specific requirements are not easily performed by the user	Specific requirements are somewhat easily performed by the user	Specific requirements are easily performed by the user	2
	Cultural/Religious activities *(Enter score 2 if not applicable)*	C4	User is not able to participate in religious activities	User is somewhat able to participate in religious activities	User is able to participate in all religious activities	2
	Financial position	C5	There are major issues to finance the prosthesis	There are minor issues to finance the prosthesis	The are no issues to finance the prosthesis	2
Equation (5): Metric$_{Context}$ = A = [9 x ((C1 + C2+C3+C4+C5) / 10)] + 1					**Calculated Metric$_{Context}$**	10.0
Communication	Relationship with service provider (professionalism, service delivery)	C'1	There is a poor relationship between provider and user	There is a good relationship between provider and user	There is a great relationship between provider and user	2
This metric describes how effective the communication is between the user and support networks.	Trust in process, product and technology	C'2	User does not trust the prosthesis, process or technology	User has some trust in the prosthesis, process or technology	User totally trust the prosthesis, process or technology	2
	Access to care	C'3	User cannot easily access care	User can access care with some difficulties	User have no issues accessing care	2
	Social support network	C'4	User is not well supported with a network	User is somewhat supported with a network	User is well supported with a network	2
Equation (6): Metric Communication = S = [9 x ((C'1+C'2+C'3+C'4) / 8) + 1					**Calculated Metric$_{Communication}$**	10.0
					Total comfort score	7.6
					Socket comfort score	9

Appendix 6. PCAM Pre and Post Survey

PRE-SURVEY

1. Your first name (not patient)

2. What is the gender of your patient?
Male
Female
Other (please specify)

3. What is the age of your patient?

4. How well do you understand prosthetic comfort?
A great deal
A lot
A moderate amount
A little
None at all

5. How familiar are you with the comfort assessment metrics?
Extremely familiar
Very familiar
Somewhat familiar
Not so familiar
Not at all familiar

6. What is the type of patient appointment? Check all that apply
Initial consultation
Fitting appointment
Review appointment
New patient
Repeat patient
Other (please specify)

POST-SURVEY

1. How satisfied were you with the time taken to administer this assessment?
Very satisfied
Satisfied
Dissatisfied
Very dissatisfied

2. What would be the ideal time taken to administer this assessment?

3. If this is your second time using the assessment, did you feel more comfortable using it?
Yes
No
Not Applicable

4. Were all factors you consider relevant included in the assessment?
Yes
No
If no, please specify those you would add.

5. How valuable is this way of assessing comfort to your designs? (Very difficult - Very easy)
Extremely valuable
Very valuable
Somewhat valuable
Not so valuable
Not at all valuable
Functionality
Physical Interaction
Well-Being
Expectations
Context and
Environment
Communication

6. How easy was it to understand and determine the following factors?

7. Were there any difficult questions or areas that you had trouble with? Please explain

8. Did you realise anything new after using the assessment? (Please explain)

9. What were 3 things you liked about using the assessment?

10. What were 3 things you would have liked when using the assessment?

11. Would you be willing to use this assessment in your regular consultations at the appropriate appointment?
Yes
No
Maybe (please explain)

12. When is the most appropriate time to administer this assessment? Please select all that apply.
Initial consultation
Fitting appointments
Review appointments
New patient
Repeat patient
Other (please specify)

13. Is there a particular group of patients whom this assessment would be suited to?

14. Overall, how satisfied were you with the results from the assessment?
Very satisfied
Satisfied
Dissatisfied
Very dissatisfied

Appendix 7. Persona's

User Persona

Dennis Goh

ABOUT

Dennis, 61, is a semi retired contractor who as a result of diabetes had an amputation to his right lower limb below the knee one year ago. He struggles to move around the house with ease. He has a wife and two daughters who are at university. He used to be very active in sports like running and badminton but now spends his time mostly sitting or at the local hawker centre with his friends. He works occasionally completing ease repair jobs but is limited by the discomfort and flexibility of his prosthesis. He worries about not being able to return to his previous activity levels or enjoying what he was doing.

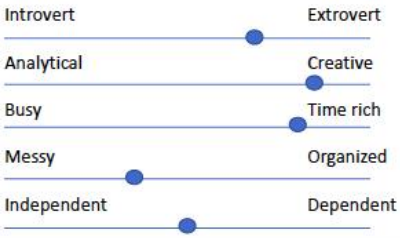
NEEDS

- To earn enough money to retire.
- To be able to sit on different types of seats when meeting his friends at the hawker centres
- Moisturise skin due to dermatitis condition
- Regularly go to the bathroom at night due to diabetes
- Take public transport

DISLIKES

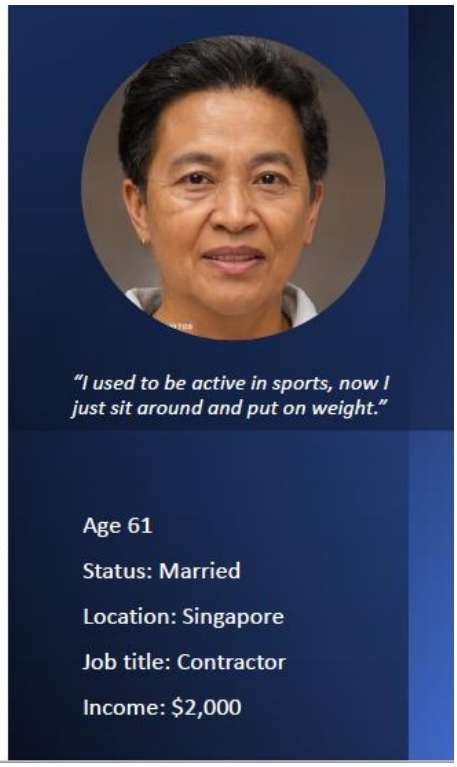
- Having to leave his friends early to remove his leg due to the pain and sweat.
- Time taken to wear prosthesis before going to the bathroom at night.
- Removing prosthesis in public to ease discomfort.
- Inability to kneel and squat for work.

PERSONALITY



GOALS

- Retire with enough savings to support family and pay for college education of his daughters.
- Visit relatives in Malaysia during CNY
- Improve independence and social life
- Return to running.



"I used to be active in sports, now I just sit around and put on weight."

Age 61

Status: Married

Location: Singapore

Job title: Contractor

Income: $2,000

User Persona

JEREMY LIM

ABOUT

Jeremy, 27, suffered a right traumatic below knee amputation 5 years ago. He was previously a national athlete in Judo while completing his finance degree. Now with his new job as a banker he is required to visit the HQ in the USA every quarter. He has a high income and is prepared to spend up to $15,000 on a new prosthesis if it was more comfortable. He also enjoys, photography, fast cars and socialising with his friends. He is engaged and is to be married next month.

NEEDS

- Walking with his fiancée
- Travels often for work
- Attends social gatherings with friends.
- Maintain independence
- Able to stand for lengthy periods during his upcoming wedding
- Remain still when taking photographs

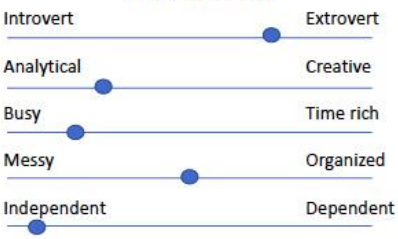
DISLIKES

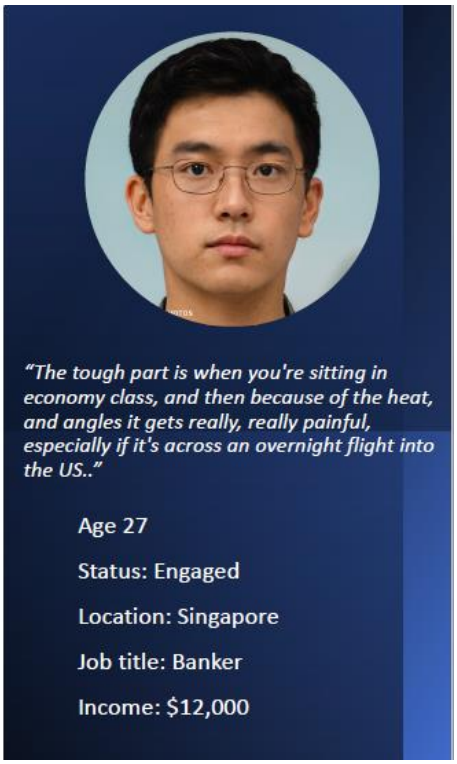
- Feeling tired after walking short distances.
- Often needing to sit down when going out.
- Feeling awkward if he sits in a disability allocated seat on the public transport due to his young looks.
- Feeling hot and sweaty

GOALS

- Financially independent by 40 years old.
- Married with three children
- Return to active lifestyle and riding his bike.
- Publication of his wildlife photos in a book.

PERSONALITY





"The tough part is when you're sitting in economy class, and then because of the heat, and angles it gets really, really painful, especially if it's across an overnight flight into the US.."

Age 27

Status: Engaged

Location: Singapore

Job title: Banker

Income: $12,000

Appendix 8. CPDM Evaluation

Prosthetist evaluation statements.

1. Use of the AEIOU framework helped me to make a clear assessment of the prosthesis user.
I_____I
0 100

1b. When using the AEIOU I gathered more information about the user and their needs.
I_____I
0 100

2. Use of PCAM helped me to make clear the prosthesis user's comfort levels with the prosthesis faster.
I_____I
0 100

2b. Use of the checklist helped me to make clear the prosthesis user's problems and complaints concerning the residual limb faster.
I_____I
0 100

3. When using the checklist, I gathered more information about the prosthesis user's dissatisfaction with the prosthesis.
I_____I
0 100

4.When using the checklist, I gathered more information about the prosthesis user's residual limb problems and complaints.
I_____I
0 100

5. The atmosphere in the consultation was better when using the CPDM.
I_____I
0 100

6. My work routine was more efficient when using the CPDM.
I_____I
0 100

7. Contact with the prosthesis user was better when using the CPDM.
I_____I
0 100

8. I felt more professional when using the CPDM.

I_____I

0 100

9. My work routine was hindered when using the CPDM.

I_____I

0 100

Prosthesis Users Evaluation Statements

1. When using the CPDM, I felt that I was understood better by the Prosthetist.

I_____I

0 100

2. When using the CPDM, the consultation felt faster.

I_____I

0 100

3. When using the CPDM, I felt that I was helped better by the Prosthetist

I_____I

0 100

4. When using the CPDM, I felt the Prosthetist would design a more comfortable prosthesis.

I_____I

0 100

Appendix 9. CPDM Interview Questions

Semi-Structured Interview Guide	
Domain	**Interview Questions and Guides**
Usability	What are your initial thoughts/opinions of the CPDM? How easy or difficult is it to navigate through the sections? Why or why not? Do you find the CPDM to be helpful? How would you recommend improving? How was the AEIOU helpful or not in gathering the needs of the user? What did you think of the length of the consultation?
Comprehensibility	How comprehensible is the content in the CPDM? What do you like and dislike? Are you happy with the final prescription? Why or why not? What constraints did you consider? What would be your final prescription if all constraints were removed? Is there any ideal tool you would like developed to help with the early design phase e.g., shape capture?
Accuracy	Do you find the tool to be accurate? Why or why not? What do you like? Do you think it's important to measure the parametric data for the design of comfortable prostheses?
Implementation/Future Use	Could you talk about how you might see this being used in a clinical encounter with a prosthetist/patient? Do you perceive any barriers in using this CPDM in the clinical setting? If so, what are they? What training or additional support might be needed to use the CPDM in the clinic setting?

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