EXPLORING THERMAL DISCOMFORT AMONGST LOWER-LIMB PROSTHESIS WEARERS

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This dissertation is submitted for the degree of Doctor of Philosophy

January 2020

DECLARATION

I, Rhys James Williams, confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated in the thesis

Signed: ____

Date: ____

ABSTRACT

Amongst lower-limb prosthesis wearers, thermal discomfort is a common problem with an estimated prevalence of more than 50%. Overheating does not just create discomfort to the user, but it has been linked to excessive sweating, skin damage caused by a moist environment and friction. Due to impermeable prosthetic components and a warm moist environment, minor skin damage can result in skin infections that can lead to prosthesis cessation, increased social anxiety, isolation and depression. Despite the seriousness of thermal discomfort, few studies explore the issue, with research predominantly constrained to controlled laboratory scenarios, with only one out of laboratory study. In this thesis, studies investigate how thermal discomfort arises and what are the consequences of thermal discomfort for lower-limb prosthesis wearers. Research studies are designed around the principles of presenting lived experiences of the phenomenon and conducting research in the context of participants' real-life activities. A design exploration chapter investigates modifying liner materials and design to create a passive solution to thermal discomfort. However, this approach was found to be ineffective and unfeasible. Study 1 presents a qualitative study which investigates the user experience of a prosthesis, thermal discomfort and related consequences. Study 2 explores limb temperature of male amputees inside and outside the laboratory, with the latter also collecting perceived thermal comfort (PTC) data. Finally, Study 3 investigates thermal discomfort in the real-world and tracks limb temperature, ambient conditions, activities, and experience sampling of PTC. While there were no apparent relationships presented in sensor data, qualitative data revealed that in situations where prosthesis wearers perceived a lack of control, thermal discomfort seemed to be worse. When combined, the studies create two knowledge contributions. Firstly, the research provides a methodological contribution showing how to conduct mixed-methods research to obtain rich insights into complex prosthesis phenomena. Secondly, the research highlights the need to appreciate psychological and contextual factors when researching prosthesis wearer thermal comfort. The research contributions are also converted into an implication for prosthesis design. The concept of 'regaining control' to psychologically mitigate thermal discomfort could be incorporated into technologies by using 'on-demand' thermal discomfort relief, rather than 'always-on' solutions, as have been created in the past.

IMPACT STATEMENT

This thesis investigates how prosthesis wearers actually experience thermal discomfort and does so using data collected in real-world contexts wherever possible. The research question which guided the three research studies of this thesis focussed upon investigating the causes, modalities and consequences of thermal discomfort in the real-world. Within academia, this research has vastly expanded the depth at which we understand the consequences of thermal discomfort. For example, we knew from previous research that discomfort causes social anxieties. However, here, it has been found that for some individuals, the reason is that thermal discomfort causes sweat staining in intimate places, smells which make people self-conscious, and limb detachment which could cause socially embarrassing scenes. Additionally, study 3 failed to identify any clear relationships between PTC and limb temperature- the founding assumption of active solutions which are currently in development. Instead, a theme of control- or lack of control- was identified as being important in thermal discomfort arising. By investigating the consequences in detail, researchers, engineers, and designers, can begin to consider how technology and science can help to prevent these scenarios from arising. The lack of trends between limb temperature and PTC, as well as the indication of perceived control of a situation to PTC present an interesting direction for solution development in the field of prosthesis thermal discomfort. For example, there may be a direction of solutions which could provide ‘relief’. In many situations, this may be all that is required to negate the worst effects of thermal discomfort. Such a shift in addressing the phenomenon would represent considering thermal discomfort as being also a psychological phenomenon, rather than solely a challenge in maintaining thermodynamic equilibrium. For thermal discomfort to be addressed at scale for prosthesis wearers, it will be necessary for solutions to be available from commercial producers of prosthetic limbs. However, with many thermal discomfort solutions still at the ‘lab-bench’ phase of research and development, research like the work presented in this thesis, which progresses our understanding of thermal discomfort accelerates the process of solutions being released commercially and being used by prosthesis wearers.

PUBLICATIONS

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ACKNOWLEDGEMENTS

Soon before you apply for a PhD, oftentimes you encounter PhD students in their natural habitats, and at various stages of their academic pilgrimages. Almost all will tell you words to the effect of “*PhD’s are hard… really hard…”* followed by a steely look into the distance. Well, I now understand that look, and the real meaning of those words, because this wasn’t just difficult in the way that I thought it would be. Instead, over the last four years I’ve discovered a multitude of *new,* and *exciting* ways in which PhDs can make you *uniquely* miserable…If I were to have catalogued all of the occasions that I considered quitting my studies, I’m certain it would equal the length of this document. However, time and time again, what has kept me here through all of the challenges has been my family, friends, and the people I have had the privilege to call colleagues, many of whom I am lucky to now call friends. So, in time honoured tradition, I offer thanks.

Cathy- I could write an essay on all of the reasons why I’m thankful, however, I know these sorts of things make you terribly embarrassed, so I’ll keep it to three points. Firstly, thanks for you unwavering faith over the years in me, especially in the moments when I had none in myself. Without that, I really would not have been able to summon those ‘just one more try’ efforts, when you really think you have nothing left to give. Secondly, you’ve always been incredibly understanding, flexible and genuinely caring, particularly at the more turbulent times of my studies. I cannot overstate how much this has meant to me, and I can say with certainty it always enabled me to at least *hang in there.* Finally, thanks for just being some who just bloody well gets *‘it’*-the bigger picture- frustrations, the *‘gahhh’* moments- even if you couldn’t always solve them, you at least let me rant and helped me laugh at whatever was happening. Whatever country/ time zone you are in, and however many meetings you are double/triple/(quadruple!?) booked for, I look forward to catching up with a kindred spirit for many years to come.

Mark- many thanks for providing such interesting conversations about the work- particularly in the earlier years. It’s a pleasure to discuss at length and in detail with someone with such knowledge and passion. I hope to have sprinkled some of that same spirit through the thesis, and more importantly to take that forward with me.

Giulia- my partner in crime and academic sibling! I can hand on heart say that without the coffee breaks and after work pints, I just would not have made it. You’ve been an absolute rock of a friend throughout, and I count myself lucky to have been able to have worked alongside you. I haven’t said it enough times, but I have so much respect for you- you are an outstanding individual, incredibly intelligent, and I have no doubt that you are one of the rare few who’ll leave the world better than you found it.

Aneesha- how lucky I am to have shared an office with one of the most intelligent and hilarious individuals I’ve ever met. I appreciated all of the occasions you provided sensible intellectual input, and I appreciated even more the times when we’ve had the complete opposite- they always brought a smile to my face (even on days when I wanted to throw my laptop through the window…)

UCLIC- the saying goes that it takes a village to raise a child, but it definitely takes a similar number of people to get a thesis to completion. A PhD student could not ask for a better group of creative, intelligent, and kind collection of individuals than I encountered during my time at UCLIC. Amid, Anna, Ann, Britta, Dafne, Dilisha, Duncan, Enrico, Frederik, Geraint, Ian, Jake, Joe, Judith, Julia, Kathy, Laura, Louise, Mark, Marta, Maryam, Melanie, Nadia, Nic, Nikki, Roxana, Steve, Susan, Temi, Tao, Youngjun and Yvonne. You are all amazing, I’ll forever look back at this time period of my life with fond memories.

Toru, the NRCD, and JSPS- I offer my sincerest thanks to Toru Ogata, without whom an entire study would not have been possible. Your guidance, kindness and tenacity made a researcher far from home able to complete work that I’m proud of. To my lab mates in the NRCD, I could not have asked for a better group of individuals to make me feel at home- I apologise for my utterly *atrocious* Japanese. To the JSPS, thank you for making it all possible with the generous funding.

Finally, to my amazing and loving family- Mum, Dad, Sophie, Bethany, Kenny, Harris- we share this. Without all of your love, kindness, continued support and guidance I would never have even made it to the start of the PhD, let alone the finish. Mum and Dad, at every possible turn you've nurtured my curiosity, answered the infinite supply of 'whys?', and taken deep breaths when I've disassembled/reassembled/reconfigured whatever I could get my hands on. Sophie and Bethany, I offer my apologies for all of the times I've been the quintessential *little brother*- despite the many reasons you could have to tell me to sod off, you've always been there with open arms, a listening ear, and ready to provide a swift kick if I've needed it! Kenny- at three of the most challenging times in my life, you've offered cool, logical and collected counsel- you have no idea how much that helped me. You're a great addition to the family, and I'm lucky to be able to call you a brother. Harris- for all of the smiles and laughter you've brought me over the last year- you keep me silly when life is making me too serious for my own good. I look forward to all of our adventures as you grow up. To you all, I may sometimes be chaotic to be around, absorbed in my own thoughts, and bad at replying to messages or calls- but ***you will always be my priority***. All of my love, and always.

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GLOSSARY

Amputee:
An individual who has had a limb surgically removed

Anterior:
Anatomy term used to describe the front of the human body

Bilateral amputee:
An individual who has lost both arms or both legs

Congenital limb loss:
An individual with a partially formed or unformed limb from birth

Distal:
Situated away from the centre of the body or from the point of attachment

Doffing:
The term used to describe removing one's prosthesis (used frequently in the context of liners)

Donning:
The term used to describe putting on a prosthesis (used frequently in the context of liners)

Experience sampling device:
A simple electronic device that acts as an input to record an individual's experience of a researched phenomenon

Experience sampling method (ESM):
A data collection method that can record information about a researched phenomenon, as it happens, away from the laboratory

Heat-impact relationship:
The proposed relationship between increases in prosthesis interface temperature, increased sweating, increased prosthesis displacement and skin damage

Hyperhidrosis:
Medical term for excessive sweating

ICEROSS:
Icelandic Roll-On Silicone Socket; a modern technique to attach a prosthetic, coined by Össur Kristinsson and used in Össur products.

Intraosseous Transcutaneous Amputation Prosthesis (ITAP):
A method of attaching anchoring a prosthetic limb directly to the bone. This method does not require a liner or socket.

Lateral:
Anatomy term that describes the side of the body or a body part that is farther from the middle or centre of the body.

Liner:
A rubber, silicone or foam cover that is placed directly onto the residual limb, with the intention of improving mechanical coupling to the prosthetic leg.

Medial:
Anatomy term that describes the side of the body or a body part that is close to the middle or centre of the body.

Patellar Tendon Bearing (PTB):
A suspension method that selectively loads the patella tendon, providing relief for another surround tissue

Perceived Thermal Comfort (PTC):
An individualistic representation which combines the perceived temperature, and an individuals’ acceptance of that current thermal environment.

Percentage of People Dissatisfied (PPD):

A value derived from Fangers' predictive mean vote (see PMV) which shows the percentage of people in an environment that will be unhappy at a predicted level of thermal comfort

Pistoning:
Pistoning refers to unwanted vertical movement of the liner and/or socket in relation to residual limb skin. This vertical movement can subject the skin to shear forces.

Posterior:
Anatomy term used to describe the back of the human body

Predicted Mean Vote (PMV):
A term from Fangers' thermal comfort model that reflects the mean thermal comfort of a group of individuals in an environment, as per the ASHRAE 7-point thermal comfort scale

Pressure comfort:
The concept that level of pressure applied to a residual limb by a prosthetic device influences the overall device comfort

Prosthesis:
An artificial replacement limb

Prosthesis wearer:
Any individual with limb loss (either amputated or congenital) who wears a prosthesis

Prosthetic interface:
The boundary between skin at the residual limb and the prosthetic device

Prosthetist:
A chartered clinician who specialises in prosthetic prescription, fitting and rehabilitation

Proximal:
Situated towards the centre of the body or from the point of attachment

Residual limb:
The remaining limb after amputation, or due to congenital defect

Residuum:
Synonym for residual limb

Socket:
Refers to a hard cover that is placed over the residual limb, that translates movement forces over the residual limb surface

Stump:
A colloquial term used to describe a residual limb/ residuum

Suction Socket:
A term used to describe a socket that relies on a slight vacuum to suspend the prosthesis from the residual limb

Suspension:
The term used to describe the mechanical connection between the residual limb and prosthesis

Thermal comfort:
The concept that temperature levels at the interface influences the overall prosthesis comfort

Through knee amputee (TKA):
When the line of amputation is directly through the knee joint

Total Surface Bearing (TSB):
A suspension method that applies pressure onto the whole residual limb surface equally

Transfemoral amputee (TFA):
When the line of amputation is below the knee joint (knee joint preserved)

Transtibial amputee (TTA):
When the line of amputation is above the knee joint (knee joint removed)

Unilateral amputee:
An amputee with only one arm or leg missing on a particular side of the body

Vacuum Assisted Socket:
A suspension method that uses elevated vacuum, created by an electronic pump connected to the socket

Vasoconstriction:
The constriction of blood vessels, which decreases blood pressure and acts to increase the amount of blood near the skin surface in thermoregulation

LIST OF APPENDICES

1 INTRODUCTION

Lower-limb prosthetics have benefitted from the rapid advance in computational and micromechanical technologies that enable impressive levels of function and independence for prosthesis wearers. In addition, society is becoming increasingly more accepting and aware of the diverse issues surrounding limb loss, and prosthetic devices are beginning to be seen as an opportunity for individual expression through art and design. This is evident in the emergence of design artefacts that are customised, as one-off pieces of art, often being displayed in galleries and modelled on fashion runways. This accelerated development of function and aesthetic have partially overshadowed comfort, something that is extremely important to satisfaction, quality of life of amputees and preventing device abandonment [1,60,71,79,208]. Whilst there have been many important and noticeable comfort improvements over the last thirty years such as improvements to liner technologies, issues relating to pain, fit, itching, sweating and overheating are still commonplace. Prosthetic literature has responded to this by using surveys, clinical observation and experimental analysis to provide some quantification of these problems. Some data sets exist that quantify metrics such as pressure [3,5,13,23] or temperature [49,110,130,154,183], and distribution and prevalence of conditions such as sweating [14,82,92,114,166,199,200]. However, these data sets are scarcely representative and offer little insight as they are collected in controlled laboratory settings and provide no reflection of how these quantities impact or affect prosthesis wearers lived experience, other than from a projected clinical or scientific perspective.

Improvements to prosthetic limb technology are vital as the prevalence of amputation is steadily increasing [55] due to disease complications, industrial and traffic accidents and violent conflicts [39,81]. At present, between 5-6,000 patients undergo major limb amputation each year in England [171]. This is matched with an estimated 1.6 million people in the United States that have some degree of limb loss. This figure set to more than double to 3.63 million by 2050 due to an ageing population and an increase in dyvascular diseases [242]. In addition, when Africa, Asia and Latin America are considered, there are an estimated 25 million potential prosthesis wearers, most without access to basic prosthetic services [176]. The scale of these figures demonstrates that issues related to prosthetics are of national and international importance.

1.1 Thesis Motivation

The research theme of prosthesis comfort, and specifically *thermal discomfort* emerged naturally from an initial literature survey, in an attempt to identify current areas of required research. Through initial interviews with prosthesis wearers, thermal discomfort was reinforced as a contributory factor which negatively influences comfort and the general prosthesis wearing experience. This then became the focus of the thesis.

Despite the minimal attention, thermal discomfort is an issue which is estimated to affect more than 52% of all prosthesis wearers [82]. The limited research which has been conducted has been almost exclusively limited to quantitative laboratory studies where the aim has been to simplify the complexity of the phenomenon and focus solely on objective and quantifiable data. However, in doing so, the lived experiences and perspectives of prosthesis wearers have largely been neglected. As a result, little is known about how and why thermal discomfort arises, and what are the consequences of the phenomenon, as interpreted by those who experience it and as experienced in real-world contexts. In recognition of this opportunity, the subject of this PhD is thermal discomfort in lower-limb prosthesis wearers. However, rather than approach the problem using existing techniques and experimental protocols, research presented in this thesis takes a mixed-methods approach, where human perspectives are augmented with quantitative measures, and the complexity of thermal discomfort is embraced and explored, rather than reduced or simplified to abstraction.

1.2 Research Question and Objectives

To make a novel and worthy contribution of the subfield of thermal discomfort amongst prosthesis wearers, this thesis aims to answer the following research question:

> *Under what circumstances does thermal discomfort arise in real-life for lower-limb prosthesis wearers, and what are the consequences of this phenomenon?*

To answer this question, a series of objectives are addressed in the thesis:

- Develop a contextual understanding behind the status quo of the prosthesis wearing experience via an extensive literature review. This step ensured that knowledge contributions created from this thesis are strategically situated in the broader prosthesis literature.

- Understand the prosthesis wearing experience and how thermal discomfort is experienced from the perspective of prosthesis wearers. Investigating the topic of this thesis within the wider context of life with a prosthesis helped to position findings relating to thermal discomfort within the prosthesis wearers lived experience.

- Establish the feasibility of translating research approaches which investigate prosthesis thermal comfort to independent out of laboratory research. In doing so, establish what is required from a sensing perspective and sensing deficits in pre-existing research approaches.

- Address deficits in sensing strategies and research protocols by creating novel protocols and sensing tools which are developed specifically for independent multi-day research.

- Conduct real-world research using created research tools. Implementing the created tools and research protocol created a rich and multi-modal data corpus which can be probed to address the thesis research question.

When the chapters and studies presented in this thesis are combined, this thesis provides a substantial contribution of foundational knowledge relating to the nuances of when, where, and why thermal discomfort arises. Additionally, the thesis is able to present how thermal discomfort impacts prosthesis wearers and their everyday lives.

1.3 Research scope

This thesis aims to develop a rich foundational understanding of thermal discomfort, as it is experienced in prosthesis wearers' daily lives. This thesis briefly forays into solution development and offers suggestions on how research from the studies can be translated into practical solutions and prototypes. Research also exclusively focussed on lower-limb prosthetics, not upper-limb prosthetics. Therefore, it is not appropriate to assume that the produced knowledge contributions will necessarily translate to upper limb amputations. Additionally, as almost all participants could be considered as active, relative to the majority of the general amputee population, findings are constrained to developing solutions for active prosthesis wearers. Finally, research presented in this thesis did not aim to capture all potential variations of seasonal thermal discomfort- (e.g. studies 2 and 3), but the experience of thermal discomfort in the season that research studies took place. Studies 2 and 3 were conducted in summer months (in *particularly* hot summers) and therefore, interpretations developed from those chapters likely represent thermal discomfort at its worst.

1.4 Thesis Structure

Over twelve chapters, this thesis introduces the problem space of the research, the methodology and methods used, three research studies and a general discussion of the contributions to knowledge which are constructed as part of this research.

Chapter Two aims to provide readers with a relatively brief overview of general features of amputations and also of typical prosthetics. The chapter begins by introducing general physiology of amputated limbs, including the different structures which are found in human skin. The chapter then progresses to establish a basic foundation in modern wearable prosthetic componentry. The focus of this chapter remains firmly on interface components by introducing liners, sockets and methods of suspension. The chapter then establishes how the prosthesis wearing experience is typically evaluated and discussed in the literature. The chapter begins by introducing a discourse relating to how a 'good' prosthesis wearing experience can be defined, before breaking this down into indicators of success. Through an investigation of success indicators, the concept of comfort was established as a critical determining factor. This chapter continues by breaking down what constitutes a comfortable prosthetic and the consequences of an uncomfortable prosthetic – particularly in relation to skin health. The chapter concludes by reflecting on the state of the prosthesis wearing experience. It establishes that based on available research, prosthetics have many areas which require improvement. Specifically, the area of comfort could be established as an aspect of the prosthesis wearing experience which warrants further research. When interrogated further, prosthesis comfort stratified into three components, and thermal comfort was identified as an under-explored area of research.

Chapter Three expands upon the concept of thermal comfort, initially doing so from the perspective of thermoregulation and thermoregulation in prosthesis wearers. This chapter progresses by introducing and developing thermal comfort in relation to the built environment as an independent area of research which has been active since the 1900s. Important concepts and models are introduced from this field of research. Investigating thermal discomfort in the built environment helped inspire the research protocols for the studies which are introduced in later chapters. The last part of this chapter focuses specifically on research studies which have investigated temperature changes of residual limbs of amputees under various circumstances, the consequences of overheating and the potential solutions. However, the chapter concludes by highlighting that although there are a few studies which have been carried out, our understanding of thermal discomfort amongst amputees is still relatively superficial. More importantly, the lack of a solid knowledge foundation of the phenomenon of thermal discomfort amongst prosthesis wearers, therefore, introduces significant risk in the development of proposed solutions. Therefore, chapter four establishes gaps in knowledge which this thesis addresses.

Chapter Four formalises the methodological approach and epistemology, which was used to conduct the three research studies which constitute this thesis’ body of work. This chapter illustrates the direction of this thesis, whilst also making it clear how the perspective work will be conducted and interpreted. In addition, chapter five also introduces the specific quantitative, qualitative and mixed-methods research methods which are used in the subsequent chapters.

Chapter Five introduces design exploration relating to the material selection and structurally design of the liner component. Liner research picks up where the literature suggested investigating first. However, through experimental testing, it is shown that given the limitations of modern materials, a material based solution will be unlikely to solve thermal discomfort. With this design direction explored.

Chapter Six explores the first part of the thesis research question by trying to understand the consequences of thermal discomfort through the lived experience of prosthesis wearers. To do so, ten lower-limb amputees were recruited to participate in semi-structured interviews. The experiences derived from an additional ten blogs were also used to supplement the data corpus. Braun and Clarke's thematic analysis was used to analyse the data.

Chapter Seven presents two studies which aimed to work towards thermal comfort research conducted in real-world environments. Both studies were conducted in Japan at the National Rehabilitation Centre for Persons with Disabilities. The first study adopted a similar protocol of investigating limb temperature for prosthesis wearers, by involving an indoor self-paced 55-minute treadmill protocol whilst wearing thermistors. The second study involved the same participants who were free to conduct activities of their own choosing for a few hours whilst wearing thermistors away from the lab. These individuals were also asked to track perceived thermal comfort in the same time period. The main outcome of both studies was to understand the practicalities of conducting both lab-based and real-world thermal comfort research with prosthesis wearers. Specifically, the output of the lab research scenario made it clear that future real-world protocols would need to last for much longer than a few hours and more research was required to design a sampling mechanism which was suitable for studies lasting multiple weeks.

Chapter Eight introduce the methods, results and discussion of a real-world thermal comfort investigation. In these chapters, experimental equipment such as a skin temperature sensor, activity monitor, ambient sensor and an experience sampling tool are introduced. A mixed-methods protocol is also presented, which enabled the collection of both qualitative and quantitative data. Participants were asked to use the experimental equipment whilst continuing with their normal daily lives, with a target observation duration of 2-weeks. In total, five prosthesis wearers participated in the study. Analysis of the data indicated activities where thermal discomfort was experienced more frequently. However, sensor data provided no clear indications as to conditions which lead to thermal discomfort. Some evidence and a discussion relating to potential intangible and psychological factors which may be implicated in resultant perceived thermal discomfort are presented.

Chapters Nine and Ten present the knowledge contributions of this thesis in a general discussion. The knowledge contributions which are presented are an improved understanding of circumstances and potential factors which lead to thermal discomfort in real-world situations. In the overarching discussion, the potential future directions for research into thermal discomfort, areas of interest and barriers which should be solved to improved future research attempts are presented.

2 BACKGROUND

2.1 Technical information

Prosthetic research is a complex and interdisciplinary field. To situate this thesis firmly within prosthetic research, it is necessary to introduce relevant biological, technical and experiential concepts formally. Therefore, biological and technical concepts are introduced in this chapter (Background), and experiential concepts are introduced in the following chapter (Wearing Experience). There are multiple levels of lower-limb amputations, with each level resulting in different challenges and complications requiring additional or specialised prosthetic componentry.

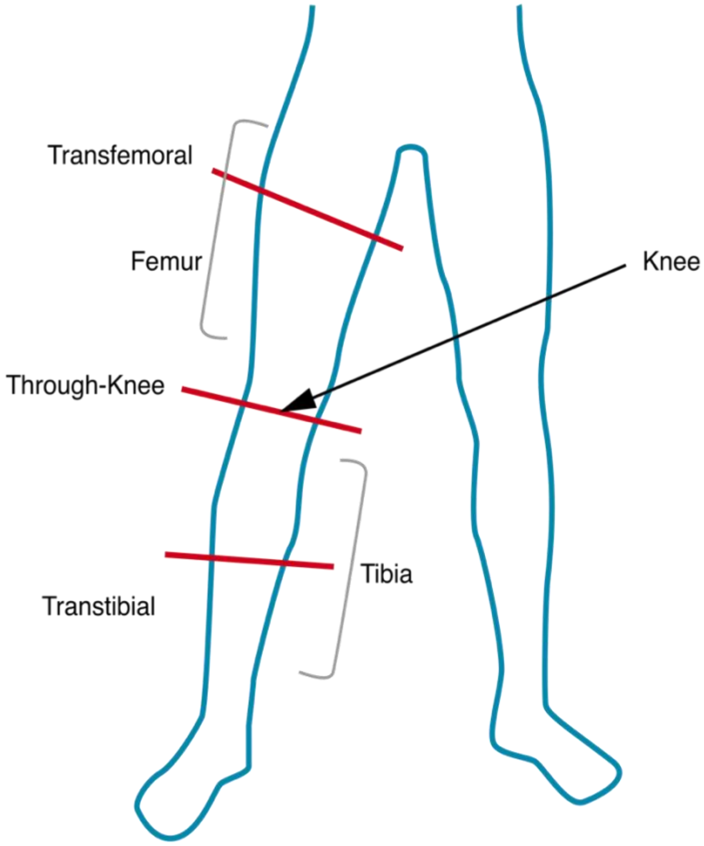


Figure 1: Amputation levels- There are multiple possible levels of lower-limb amputation, each requiring specially adapted prosthetic limbs.

The most common types of amputations (Figure 1) are below-knee amputations (transtibial), followed by above-knee amputations (transfemoral). Hip disarticulations and through knee amputations are less common that transtibial and transfemoral amputations.

Once an amputation is performed, there is a considerable variation in size, shape and physical features within residual limbs, all of which can contribute to difficulties in establishing a comfortable and secure prosthesis fit [204]. Also, amputations as a result of trauma or congenital formation may not fall into typical residuum categories. The residual limb categorisation will dictate what patients need in terms of prosthetic components [53]. For example, an individual with an even shaped limb with large amounts of soft tissue coverage will be able to use most types of prosthesis. However, a bony residual limb may require prosthetic components with extra cushioning, something that could restrict subsequent choices of say, socket design and suspension type. In all circumstances, the aim of prosthesis componentry should be to ensure that the limb can be successfully attached at all times- a state which is referred to as *limb suspension*.

2.1.1 Skin anatomy

The skin-prosthetic interface is critical to comfort, stability and good skin health [3,5,129,150]. For these reasons, it is crucial to understand the structure and function of the skin. The complete integumentary system of skin, hair, glands and nails provides humans with an invaluable barrier against the external world. Primarily, skin acts as a waterproof defence from pathogens and bacteria, abrasion and UV radiation [167,179,229]. As well as passive protection, the organ provides a dynamic sensory interface between the body and external environments and can readily respond to both temperature and pressure changes as well as pain cues.

2.1.1.1 Skin Structure

In order to provide precise homeostatic regulation, defence and protection, many substructures are present within skin. Skin can broadly be separated into 3 sub-layers; the epidermis, dermis and hypodermis.

The epidermis is formed of a vascular stratified squamous epithelium and is approximately 30-50 cells thick [179,229]. This layer can be further separated into 5 layers with the most active layer being the stratum basal. This location is the primary mitosis site and is the closest layer of the epidermis to the blood supply [167]. As cells divide, half are forced into the upper layers, away from the blood [179,229]. These cells die and are filled with keratin by keratocytes and form a flat, scale-like waterproof barrier [167,179,229].

The dermis is highly vascularised and is composed of a mixture of connective tissues (collagen, elastin, reticular fibres), numerous oil and sweat glands, hair follicles and sensory receptors [179,229]. The dermis is made up of a layer of dermal papillae that are interwoven into the epidermis [167,179,229]. This provides oxygenation and nutrition to the first few layers and is formally known as the papillary layer. Below this, there is a reticular layer that is in direct contact with the hypodermis [167].

The hypodermis is composed of a mixture of areolar and adipose tissues and a network of blood and lymph vessels [167,179,229]. This layer binds the skin structure to underlying organs and musculature and acts as an insulating and cushioning lipid layer. This layer also contains the various exocrine glands, where an exocrine gland is a cluster of cells which secrete substances such as sweat towards an epithelial surface. In the focus of this work, the sudoriferous glands (or sweat glands) are more relevant, given they are highly active in thermoregulation [37].

2.1.2 Skin health

Prosthesis comfort is inextricably linked to skin health. Due to its unique characteristics, the prosthesis interface is a challenging and demanding environment for skin. The combination of high shear forces, stress and pressures can all cause skin damage to occur [58,142–145,164,165]. Heat, subsequent sweating and prosthesis displacement also culminate in discomfort and skin problems at the residuum interface [58,143,144,150]. The humid microclimate is perfect for bacterial colonisation, and any minor skin damage can rapidly become infected [103,105,110,143,164]. In a study conducted by Dudek et al., 40.7% out of 828 prosthesis wearers had at least one skin problem [58], and transtibial amputees were 4 times more likely to have skin problem as opposed to transfemoral amputees, likely due to the increased prominence of bony structures [58]. The incidence of skin problems in the amputee population is extremely variable and has been reported as 16% [68], 25% [56], 40% [58], 50% [14], 54% [135] and 63% [164]. This variability can be attributed to differences in sampling methods, study population and assessment methods [165]. Most data are collected on a case-by-case basis or user reported, resulting in general descriptions of the problems experienced (redness, swelling, etc.) as opposed to a formal clinical diagnosis.

In one study, many participants experienced eruption (46%), itching (60%) and odour (43%) and rated these issues as ‘important’ [85]. Skin issues were also reported to bother 59% (on average) of Vietnam, Afghanistan and Iraq war veterans [14], negatively affecting the prosthesis wearing experience [210] and many activities of daily living [166].

The prevention of skin issues is of crucial concern, particularly in cases of mechanical damage and eruption. Although it has already been mentioned, it must be reiterated that bacterial colonisation of a lesion must be regarded as a catastrophic event for a prosthesis wearer [26]. The result of a deteriorated skin interface is that prosthetic devices must not be worn until skin has healed [150]. Given that residual skin wounds have been shown to take between 177.6 ± 113 days to recover [107], this can confine prosthesis wearers to wheelchairs and have disastrous consequences for confidence.

2.1.3 Component overview

A brief overview of prosthetic devices has been conducted and is presented below. The purpose of this is to demonstrate how technology has been implemented in the past, to provide an indication of the types of issues that have been addressed, and to identify potential technological gaps. A modern prosthesis is generally composed of a liner (usually made of an elastomeric material) that is placed onto the residual limb (Figure 2). The liner and limb are then inserted into a rigid socket (typically constructed out of a thermoplastic or carbon fibre). Metal couplings are screwed onto the socket so that more components can be securely attached. To this, transfemoral amputees will attach a mechanical (or mechatronic) knee mechanism. Both transfemoral and transtibial amputees will connect a metal pylon to substitute tibia/fibular, and then an ankle and a foot.

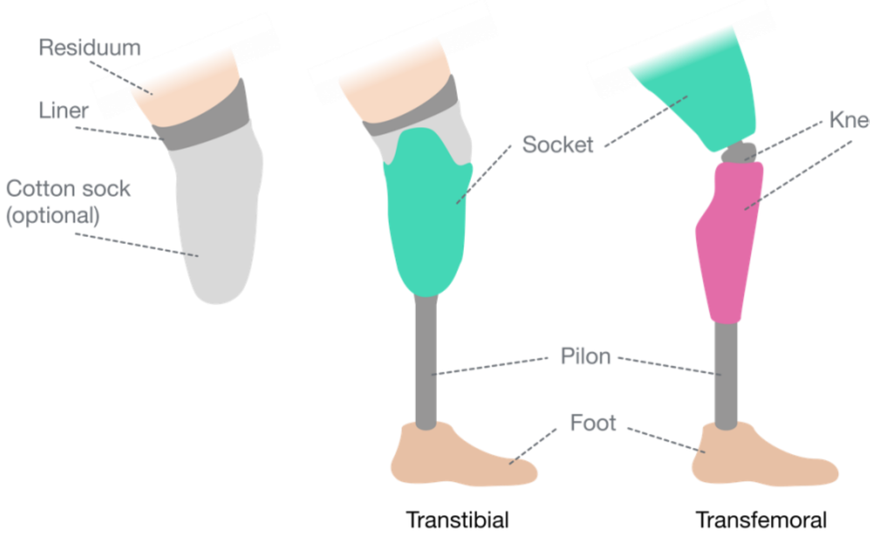


Figure 2: Modern prosthetic limbs are typically made up of a liner, socket, pylon and foot component with mechanical and mechatronic knee joints for transfemoral amputees. Cotton socks may be worn under or over liners.

Comfort has been indicated to depend mostly on the socket and the liner components [79]. This is unsurprising as they provide the mechanical coupling between the prosthesis and the wearer. For this reason, the liner and socket interface will remain the focus of this work.

2.1.3.1 Liners

Classically, work relating to the comfort of prosthetics has examined pressure distribution and how this affects gait during daily life. This type of research has led to an increase in prosthetic components (most notably liners), that are specifically designed to alleviate pressure related ailments and malignancies. Liners were traditionally made from open and closed cell foams as a way of providing cushioning under loading [202,204], however, since the 1980s [11], there has been a shift toward silicone elastomers, thermoplastics and gel liners. These liners are often preferable due to enhanced suspension characteristics, improved skin protection and better cushioning of the residuum compared to direct suspension or foam liners [5,10,13,45,80,205]. Increased liner thickness has also been shown to be effective in reducing interface pressure over bony prominences which might cause discomfort and lead to skin damage [23].

The liner component arguably has the greatest variety of choice of all components within a prosthetic, with individual companies often offering 10 or more different styles of liner. Liners can be made with mineral oils mixed into the material, be antibacterial, have different softness levels and flexibility levels on different parts of the residuum (e.g. [162,178]). They do, however, have a limited usable lifetime at between 6-7 months and represent a significant financial burden to prosthesis wearers, healthcare providers and insurers [97,177]. In addition, they have been implicated in increased levels of sweat discomfort [58,128]. The silicone liner is increasingly prescribed for reasons of better suspension and socket comfort, compared to the likes of pelite, or foam liners. However, these claims are on the whole unsubstantiated by evidence in the literature [11].

2.1.3.2 Sockets

The ideal socket has been described by prosthesis wearers, clinicians and researchers as one that can offer temperature, moisture and shape control at the prosthesis interface. Sockets must provide excellent suspension to prevent slippage, and tightly fit to create a stable and comfortable connection that translates forces and motion from standing, sitting and ambulation [131,151,201]. Unfortunately, currently available socket technology often falls short of this. The most common complaints from users are excess heat and humidity at the interface and an inability to adapt to changes in residual limb volume [131:09]. Sockets are mostly handcrafted for each individual prosthesis wearer, with comfort and fit being highly dependent on the ability of the individual prosthetist. This ‘artisan’ approach to socket manufacture has yet to be advanced, though 3D scanning and printing provides the potential to create easy to remake pressure optimised sockets. There is a knowledge barrier, however, that must be overcome before this is possible, as we do not know the ideal interface pressure levels for optimum socket fit [139,239] and there is a lack of understanding of how biomechanical interactions affect the residual limb and prosthesis [201].

Despite these issues, the current state of the art is indeed much more advanced than historical approaches. The first type of socket to discuss is the patella-tendon bearing socket (PTB) [190]. This design was introduced in 1959 [134] and moved away from the classic girdle and belt design to achieve limb suspension. In the PTB load-tolerating regions such as the patella tendon, anterior medial flare, anterior muscle compartment and popliteal area are selectively pressurised [190]. This aims to relieve pressure on the fibular head, anterior crest and anterior distal tibia. It also prevents excess pressure on soft tissues to avoid pressure sores/ blistering. Whilst load-bearing areas are able to tolerate this extra loading, the comfort of TSB sockets is highly dependent on the skills of the prosthetist making it. They are created using casting techniques, so positive moulds of the residual limb can be used to develop the PTB socket. The positive mould has to be altered, with material being removed from below the kneecap to produce an exaggerated indentation. As a result, ill-fitting PTB sockets are widely regarded to result in limb deterioration and cause shrinkage of the residuum and oedema [69].

The more modern and widely adopted socket design relies on the principle of total surface bearing (TSB). TSB sockets are more dependent on the mechanical properties of the liner component than PTB sockets [200]. The main advantage is adequate control of the residual limb volume, improved suspension and reduced shear forces [11]. The most common TSB socket utilises the Icelandic Roll-On Silicone Socket (ICEROSS) concept developed by Kristinsson et al. at Össur Ltd. [133]. These sockets are based on anatomical geometry and require no alterations of the positive cast, minimising the artisanal nature of the component. Instead, the cast is made by distributing tissue evenly using a pressure bladder. This method of casting ensures the socket can establish hydrostatic pressure over the entire residual limb surface during loading [133,168]. TSB sockets are adapted to include one-way air valves that allow air to escape from the socket when placing the residual limb into the socket. The use of a passively maintained vacuum to suspend the prosthesis has led to the TSB socket to be referred to as a seal-in, cushion (when used with a liner) or suction socket. This type of suspension method has often been used in conjunction with pin locking mechanisms (a mono-directional ratchet mechanism in the socket that connects to a barbed pin at the distal end of a liner), or lanyard systems (a pin-on-string that is threaded through the bottom of the socket and pulls and keeps the liner in the socket).

In the last five-to-ten years, sockets have been improved upon once again, with the concept of Vacuum-Assisted Suction (VAS) sockets. VAS sockets actively create and maintain elevated negative pressure to provide suspension [181]. They are created using a similar casting technique to TSB sockets, however, VAS sockets include an active vacuum pump, as well as one-way air valves. After stepping into a VAS socket, the prosthesis wearer will activate this vacuum pump (which is often located directly on or under the socket). These sockets are purported to increase the rate of fluid drawn into limb; thus minimising the degree of limb volume change [20]. They have been reported to reduce pain, lower interface pressures, as well as decrease pistoning, rotation and translation in TSB sockets [4,13,20,27]. Here, pistoning refers to unwanted vertical displacement of the limb during ambulation and represents a failure in suspension. There is, however, limited evidence regarding the efficacy of VAS systems [43,85,129,158,218].

Although TSB and VAS sockets provide many benefits over PTB, complications often arise for prosthesis wearers with vascular diseases, geriatric wearers, or those who experience residuum volume changes, as suction, and thus suspension of the limb is reduced or lost [243]. In these cases, hybrid PTB-TSB sockets can often be made by prosthetists.

2.1.3.3 Intraosseous Transcutaneous Amputation Prosthesis

As well as wearable prostheses, intraosseous transcutaneous amputation prostheses (ITAP) are being suggested as an alternative to the current convention. By anchoring to the bone, it has been reported that problems relating to the prosthetic socket (i.e. chafing, pain, discomfort and poor suspension) are reduced [75,86]. Twelve lower Swedish lower limb amputees with ITAP limbs supported this claim. One patient noted that although the ITAP did not feel as good as a healthy leg, it was more ‘normal’, perhaps being “70% as good” as a real limb [148]. This compared to their experience using socket-based prosthetics, which they rated as being approximately 25% as good as a real limb [148].

In addition, ITAP users reported a feeling of freedom, particularly as they did not have to consider suspension. However, ITAP devices still face significant barriers to widespread adoption. The first is that patients must endure between 6-18 months of treatment to have the prosthesis implanted. There is also a significant risk of infection immediately after surgery, during rehabilitation and on much longer timescales. In addition, if knee and hip replacements are used as a parallel example of bone anchor-based surgeries, it is also likely that multiple surgical revisions will be required over an amputee's lifetime. Overall, this means ITAP is a highly costly and time-intensive procedure [70,87,223,227]. Unless major improvements are made in surgical techniques, wound care and rehabilitation, ITAP's are unlikely to be widely implemented. Thus, it is imperative that wearable solutions are continuously developed and improved to reduce the perceived gap between ITAP and socket prostheses.

2.2 Wearing Experience

To frame the research topic of this thesis, a detailed and thorough evaluation of life with a prosthesis was necessary to provide a solid contextual foundation. Therefore, this chapter introduces concepts in prosthetic research which are used to evaluate life with a prosthesis, as well as concepts which have been found to be important to the experience of a prosthetic limb.

To first understand the wearing experience, it is useful to understand what makes a 'good' prosthesis. To some, a positive prosthesis wearing experience may simply be equated with regular use. Other wearers might wish for a prosthesis that allows them to interact with loved ones, maintain independence or to work. A certain number of prosthesis wearers may even desire a prosthesis that enables them to participate in extreme sports and activities. When we shift our focus away from the person wearing the limb, to the clinicians prescribing the limb, a different interpretation of a positive experience may exist. It could be that a positive experience is a prosthesis that prevents any further medical damage to the limb, to one that results in a symmetric gait. To confuse this even more, different measures of 'satisfaction', 'outcomes', and 'quality of life' (QoL) are often interchangeably used to quantify how 'good' or 'bad' a prosthesis is and to gauge life with a prosthetic limb. In this research, these individual aspects will be referred to under the general heading of *'prosthesis wearing experience'*. Although the service side of prosthetic care is extremely influential in the overall *'success'* of a prosthesis, service delivery will not be examined in detail but will be mentioned when appropriate.

The requirements placed upon a prosthetic leg are variable as a prosthetic limb for one person may act to restore their independence and symbolise ability. In direct contrast, for some, it may be the physical embodiment of their loss and disability. The prosthetic limb can even be a tool to hide the individuals' disability as a way of preventing stigma and enhancing social integration [210]. Prosthetics are therefore not just a device for functional ability but also social ability – an affordance that is often compromised as by the direct results of lower-limb amputation [28,46].

There are distinct demographic differences within the amputee community, with 80% being over 60 years of age [17]. This sub-population is much more likely to have diabetic or vascular comorbidities [131:09], and individuals within the sub-population (specifically those with vascular diseases) are mostly sedentary with significantly reduced levels of physical activity, in comparison to non-vascular patients [46]. There are also a number of civilian trauma-related amputees who are estimated to make up between 10-20% of lower-limb amputations in the 'developed' world. Of this, 55% are transtibial, 40% are transfemoral, less than 5% are through knee, and 1% are bilateral amputees [184]. These individuals may have wildly differing expectations when it comes to the affordances of a prosthesis. Another large portion of the amputees are comprised of military individuals, who are more likely to be younger, (male) and have military standards of fitness pre-amputation [131:09]. The most recent USA conflicts in Iraq and Afghanistan resulted in 1,184 combat-related amputations between 2001 and 2009 [65]. This adds to the well-studied cohort of the 2,500 living US Vietnam veterans [195]. Other conflicts, such as the Iranian-Iraqi war between 1980 and 1988 resulted in 20,801 amputations, with 12,981 lower limb amputations [60]. In all cases where combat-related amputations are reported, it is assumed that data only captures soldier amputations, and not civilian or combatant amputations. Therefore, the total amputations resulting in these conflicts could be higher.

Attempts have been made by the clinical community to come to a concise consensus on a definition of a positive prosthesis user experience. A panel of experts using the Delphi technique [50] deemed a good outcome as restoring and maintaining function to the fullest extent possible over the prosthesis wearers lifetime [194]. This definition is a good start, as it recognises the non-static nature of the prosthesis wearing experience and aims to reinstate lost functional ability. However, it falls into the trap that many clinical definitions do by exclusively focusing on functional ability. In addition, this definition does not take into account the views, goals and aspirations of the prosthesis wearer. A limb that provides maximum functional ability but prevents a prosthesis wearer from achieving their own goals should not be thought of as a positive limb replacement experience. For example, a prosthetic limb which enables an individual to participate in exercise activities may be functionally ‘acceptable’. However, if that limb inhibits the wearer in more social aspects of their life such as meeting friends, or going on dates, the limb may not align with their holistic lifestyle needs, wants, goals and aspirations. Additionally, a replacement limb that has a maximum function level that is below parity with a natural limb could also falsely be thought of a success.

An improvement to this definition is that a prosthesis may restore function as well as quality of life to the fullest extent possible [195]. This definition extends beyond function and begins to consider other aspects of the prosthesis wearers life. However, it still appears to be a definition of success from a clinical perspective. Instead, a definition of positive prosthesis experience should be one where care is person-centred, and the people actually receiving care should be setting future goals to determine success [219]. Therefore, another definition is that a good match between person and prosthetic is achieved when the device meets the wearers’ performance expectations and is easy and comfortable to use [212]. This positive step towards a patient-centred experience evaluation is good, but it may overly focus on performance. The best definition may lie somewhere in between and be thought of as a prosthetic that meets the wearers’ performance expectations, is easy and comfortable to wear and restores quality of life to the fullest extent possible. This definition considers function, general overall quality of life and is directed by the prosthesis wearer, as opposed to the clinical service provider. Developing a prosthetic device that can satisfy all of these conditions simultaneously is extremely difficult and previous definitions may be limited by the realities and limitations of current prosthetic limb technologies. To provide a deeper contextual understanding of the *‘status quo’* of the prosthesis wearing experience, commonly used dimensions of ‘success’ such as prosthesis usage, satisfaction, quality of life and abandonment are now examined in detail using prior literature.

2.2.1 Prosthesis usage

The number of hours in a day that a prosthesis is worn is a potential metric to gauge the overall success of the device. It is plausible that a device providing a positive experience would be worn more than a device that provides a generally negative wearing experience. Prosthesis wear can range from 49-95% of the amputee population [186,195,208,214], with current devices being typically worn for an estimated 66 hours per week for dyvascular amputees and up to 71 hours per week for other amputees [186]. This variation can also be linked with factors such as advanced age, level and number of lower-limb amputations, increased comorbidities, impaired vision and impaired cognition, all of which negatively affect usage [214,226]. In addition, ambulatory status prior to amputation, smoking [226] and pain [62] are also linked to reduced prosthesis usage. Most of these contributing factors to reduced prosthesis wear are not surprising, as it is highly likely that these are symptoms that are prevalent amongst elderly and diabetic populations, who make up the majority of the general amputee population.

Factors that increased prosthesis usage have been found to be full or part-time work, higher education level, and being married or living with a partner [191]. The employment status of an amputee is unsurprising as the demands placed on maintaining working life would likely mean that increased prosthesis wear is simply a matter of practicality. The positive association with higher education could possibly be a confounder, given that employment status may be linked to employment; however, it is not possible to discern if this is the case. Marriage or living with a partner is a surprising positive factor for prosthesis usage, as previous studies have not found a relationship between social support and functional status [175].

Given the potential complexities regarding a prosthesis wearers lifestyle context, prosthesis usage can be a shallow metric to represent the prosthesis wearing experience. Additionally, it is important to note that individuals may wear the prosthesis frequently, but be deeply dissatisfied with the replacement limb [186], as some individual may wear the limb out of necessity rather than choice. Once again, this highlights the weakness of ‘usage’ metrics such as hours of time wearing prosthesis or frequency of use as a sole indicator of outcome [18,124]. It is an inappropriate reflection of the prosthesis wearing experience and does not help when exploring issues with life with a prosthesis. However, it has been explored here due to its commonality in the prosthetic literature.

2.2.2 Satisfaction

Satisfaction may provide a better insight into the prosthesis wearing experience compared to usage as it is can provide a direct reflection of the prosthesis wearers experience from their own point of view. In prosthetics, satisfaction has been defined as an agreement between a user’s priorities and experiences [76]. This definition provides flexibility to accommodate any influencing factors that are deemed important by the prosthesis wearer. However, without standardised measures of satisfaction, it becomes difficult to quantify satisfaction. As a result, the satisfaction as perceived by prosthesis wearers is often gauged by using a number of self-report satisfaction instruments.

As a general overview of current satisfaction levels with prosthetics, studies have shown that, in higher-income countries, there is an overall *‘moderate’* level of satisfaction [14,22,76,123,149,186]. It may be natural to assume that in lower-income countries, satisfaction may be lower as prosthetic devices are likely to be more basic and provide limited functionality. However, in an overview of Vietnamese prosthesis wearers, only 10% of wearers of the International Committee of Red Cross (ICRC) polypropylene prosthesis were dissatisfied [116,228]. This high level of satisfaction despite a relatively basic prosthesis indicates that the device is not the sole determinant of prosthesis satisfaction [156]. It may be that prosthesis wearers in higher-income countries have a higher expectation of the ability of their prosthesis, reflecting in moderate satisfaction levels with room to improve.

These studies provide an insight that although prosthetic limbs may be beneficial and many prosthesis wearers have a degree of satisfaction with their prosthesis, there is still room for improvement. As such, associated literature was reviewed with a focus of factors that lead to dissatisfaction. As a first generic factor, a USA study found that lower satisfaction levels were linked to individuals feeling that their personal needs were not addressed by the device or the service provision [21]. This is reflected by the sentiment that there are perceived issues along every step of the amputee journey [131]. Lack of prosthesis comfort and fit are highly linked to dissatisfaction [4,11,14,79,133,140,186]. Dissatisfaction caused by comfort has been determined to mostly be down to the socket fit, lack of flexibility and function in the ankle and foot components, issues with alignment, and usability issues [131]. Suspension also has a significant effect on prosthesis satisfaction [4,11,133]. Consequential issues that arise due to poor comfort, fit and suspension are excessing sweating, irritations, pain, sounds [79] and skin problems [32]. There is also evidence of a highly negative correlation between body image disorder and satisfaction with the prosthesis [157,169].

The effect that service provision has on overall satisfaction cannot be ignored, as service provision profoundly affects satisfaction [14,22,95,98], and user satisfaction reflects the effectiveness of healthcare systems [81]. As a healthcare system, prosthetic services should be viewed positively if they provide effective and efficient treatment that delivers evidence-based interventions resulting in improved health outcomes for individuals and communities. The service should also maximise resources, minimise waste, be equitable and accessible, patient-centred, and safe [31]. Satisfaction with prosthesis services is important as these services are significantly associated with frequency of use, functional ability, and levels of physical activity [1]. Prosthesis wearers' often have a reduced satisfaction in prosthesis services when there is poor communication from the service provider during prescription [186] when wearers do not feel included in the prescription process [14,207], and when there are increased prescription waiting times [186]. Prosthesis wearers' also demonstrate concern about access to new prosthetic devices and rehabilitation that fails to treat each patient as an individual [131:09].

In summary, the current state of prosthetic technologies and services result in a moderate level of satisfaction amongst prosthesis wearers. It is possible to identify that device issues such as fit, comfort, suspension, sweating, skin health, pain and irritation negatively influence prosthesis satisfaction. Not feeling involved with prescriptions, poor communication, a lack of information about new devices and a lack of personally adapted rehabilitation negatively influences satisfaction with prosthetic services. It should be noted, however, that studies researching satisfaction predominantly featured transtibial amputees [79], meaning that the factors identified may not represent satisfaction as perceived by transfemoral amputees.

2.2.3 Quality of life

There is no doubt that amputation has a significant effect on a prosthesis wearers quality of life (QoL) [18,77]. Quality of life provides additional insights into the prosthesis wearing experience beyond satisfaction, as satisfaction metrics may predominantly focus on opinions and perceptions relating to the prosthesis and prosthesis service delivery.

Quality of life instead provides an overview of how wearing a prosthesis generally affects the wearers' life. It is no surprise, therefore that QoL is extraordinarily complex and multidimensional, with many different measures being used to quantify it [73]. This is complicated further as there is no real agreement on the measures and dimensions to assess prosthesis QoL [73,241]. Usually, however, QoL instruments may include health status, physical, social, mental and emotional functions, pain, relationships, life satisfaction and wellbeing [241]. When assessing QoL, there are often two approaches, with the first being condition-specific tools, and the second being general-purpose assessment tools. Condition-specific instruments have the advantage of being focussed to the condition at hand, such as prosthetics in this case, but are unable to provide comparisons amongst other groups with different impairments or generally healthy populations [7]. Their refined focus may also make it impossible to discover unexpected findings- for example; prior work serendipitously discovered that reduced quality of life could be caused by sexual dissatisfaction or financial problems [241]. QoL instruments are also heavily susceptible to subjectivity and individuality, as QoL is heavily dependent on a person's perceptions based on their life experiences, education, values, expectations and their living environment [241].

Post-amputation, there are many different problems that can reduce QoL [232]. Social support, perceived mobility and participation in social activities impact QoL [9], with mobility level being shown to account for only 6% variation in QoL scores and social support accounting for 2% of QoL variation [241]. The largest influencing factor for quality of life has been found to be depression, accounting for a 30% variation in QoL scores [241]. These metrics, however, only account for lower-limb amputees three months' post-rehabilitation, meaning that many amputees could still be coming to terms with amputation and adapting their lives accordingly. No studies were found that quantified the effect of influencing factors on QoL over a longer period of time.

The concept of adaption to amputation is best demonstrated by how individuals with limb-loss adapt to their body image. There are three different types of body-images that prosthesis wearers experience; the image before an amputation, the image post-amputation and post-amputation with a prosthesis [221]. It is unsurprising that amputation can often lead to a negative perception of body image [32], which is directly related to depression and thus quality of life [44]. Amongst prosthesis wearers however, it has been shown that there is a positive correlation between body image and physical activities [67,141,225,238]. This correlation could, therefore, be exploited using sport as a therapeutic tool to improve QoL and demonstrates the importance of rehabilitation and a prosthesis that affords high mobility. When considered away from sporting activities, the prosthetic device plays a large part in determining QoL, with the skin socket interface having a crucial role in determining QoL and the overall prosthesis wearing experience [2,9,241]. Quality of life is specifically decreased by poor socket fit and comfort, with heat and sweat being the most common reported issue affecting 72% of prosthesis wearers followed by skin irritation amongst 62% of prosthesis wearers [86]. As comfort, fit, heat and sweat and skin irritation can lead to limited ability to conduct activities of daily living and reduce social participation [27,45,56], it is not surprising that they can negatively impact overall quality of life.

2.2.4 Abandonment

If the prosthesis wearing experience is sufficiently bad, wearers' may outright reject the prescribed limb and abandon it. Often in higher-income countries, the main concern surrounding assistive technology is not if people have access to assistive technologies, but rather if the assistive technologies they access will be abandoned [16,193,212,213]. As technological complexity of prosthetic devices has increased, and limb loss prevalence has increased, non-use is associated with significant financial and productivity wastage for healthcare providers and insurers [74,172,186,187,208,242]. Therefore prosthesis abandonment is a serious concern, and it is important to understand why individuals will use, underuse or not use prosthetic devices [208].

Disappointment with prescribed tech is the most important factor in device abandonment [74,186,187,196], with 98% of prosthesis wearers' stating that fit was their top concern [140,200]. Some amputees may abandon due to pain, dissatisfaction or other comorbidities [71], and variables such as personal motivation and device function are also associated with non-use [56,174,210,211]. In a survey of 70 amputees that abandoned their device, 43% said it was due to excessive weight, 20% needed replacement, 13% needed a revision, 7% could not use it due to an ulcer and/or pain, 6% had skin problems and 1% either disliked it, needed a repair or had a neuroma [60]. Advanced age, being female, owning a wheelchair, higher levels of physical disability, additional cognitive disabilities, poor self-perceived health, and being unsatisfied were also associated with prosthesis non-use [18]. However, as this study exclusively focused on elderly amputees, it is highly probable that these factors are related to advanced age, rather than being applicable to abandonment in younger amputees. Finally, excluding prosthesis wearers from the prescription process has been shown to result in greater rates of prosthesis abandonment [153], which is unsurprising given that prescription decision making, satisfaction and abandonment are linked [14]. A future focus on making prosthesis services patient-centric, and improving comfort, fit and therefore suspension of prosthetic devices may be an effective strategy to reduce abandonment [160,195].

2.2.5 Comfort

A repeatedly mentioned contributing factor to use, satisfaction, quality of life and a deterrent towards abandonment is prosthesis comfort. Comfort is like any other sensory perception in that it is a private experience that is variable between people [151]. However, although phenomena such as comfort are difficult to quantify, quantification and understanding what impacts comfort is necessary for product development [131]. Despite recognising the need to measure comfort, formalised assessments of prosthesis comfort are usually made in terms of satisfaction with prosthesis comfort. Using this approach, one study found that only 43% of prosthesis wearers were satisfied with prosthesis comfort [56]. This is much lower than another study which examined comfort satisfaction between Vietnam, Iraq and Afghanistan veterans, where between 71-76% of veterans were *‘happy’* with comfort and fit of socket [14]. Comfort of a prosthesis can be determined by a number of different factors. These are predominantly reported as being the mechanical compliance of the interface, fit of socket, aesthetics, prosthesis slippage and lubrication [88,105,140,199]. From this, it is possible to stratify prosthesis comfort into pressure, visual and thermal.

Pressure comfort has been well explored by studies that have experimentally defined pressures during laboratory recreated activities. This has led to the creation of many different types of liners, sockets and other components that ‘appropriately’ distribute pressure over the limb and provide necessary cushioning and relief. This is arguably the most developed comfort strand as it is heavily coupled to function. Visual comfort has been explored predominantly by artists and designers and as such a body of literature has yet to emerge. However, many artefacts have been created that have considered individuality and context. These explorations have yet to manifest themselves into mainstream products in the same way pressure comfort research has done. Arguably one of the least researched areas is thermal comfort. This has been approached in a similar way to pressure comfort, by obtaining datasets in contrived scenarios, and while some products have been developed (see Section 3.7), they still remain niche.

2.2.6 Reflection

In light of the review of the current state of lower-limb prosthetics, it is clear that there is much work to be done before we can consider prosthetic limbs to have parity with biological limbs. For prosthesis wearers to obtain a satisfying prosthetic device, they must be matched with technology that meets their physical needs, restores function, but also enables psychological and social satisfaction [210]. Unfortunately, often this process involves trial and error- taking time, persistence, and acceptance of ‘boundary pushing’ [51,159]. Assessment of prescription requirements are mostly based on subjective experiences of physicians, therapists and prosthetists [207]. Thus, most prescriptions are based on assumption, rather than an established evidence base [147]. In recognition of this, 30% of patients investigated in one study were deemed to be ‘under’ prescribed, due to a lack of agreement among prosthetists on prescription for different functional tasks [72]. This method of prescription has brought strong criticism to the field of prosthetics, with suggestions that it has fallen far behind other fields in evidence-based practices and prescriptions [52] and skewed data sets towards periphery arterial disease patients, and younger civilian amputees [18,38,74,187]. Academic studies have collected data sets (predominantly survey data) on a variety of topics, but these data exist in an abstract state, with little human context. That is to say that current studies have simply obtained data, rather than found out how and why the identified issues arise and influence the prosthesis wearing experience.

The skin-prosthesis interface is critical to prosthesis success, as it is predominantly responsible for good mechanical coupling and comfort for the wearer. Functional success from a mobility perspective has been relatively well explored and receives much attention. When we consider the definition of a perfectly functional artificial limb, it would likely be an imitation that can match or exceed a biological limb for the individual. Whilst we can postulate a definition for prosthesis comfort, it is more difficult due to subjectivity of the concept of comfort. We can borrow the proposed definition of functional success to define comfort success as a limb that perfectly mimics a biological limb. However, a biological limb is neither comfortable nor uncomfortable; it simply exists, unnoticed. This highlights the implication of limbs that are ‘worn’ vs limbs that simply ‘are.’ In the current paradigm where limbs are worn, a comfort definition will likely have to be closer to clothing. On a basic level, for clothing to be comfortable, it should feel pleasant against the skin, be visually styled to the wearers’ preferences and personality and keep the wearer cool or warm depending on the environment.

3 THERMAL COMFORT

In the previous chapter, the importance of skin health and comfort for a positive prosthesis wearing experience was highlighted. Preserving skin health at the skin-prosthesis interface is also of critical importance, but overheating and excess sweating can threaten skin health. It has been found that excessive perspiration is linked with an increased risk of developing a skin problem, as 78.3% of participants who experienced excessive sweating also experienced skin damage [6]. Excess sweating also results in 2.89 times ‘worse’ outcome than subjects with normal perspiration [6]. Amputees are susceptible to overheating and hyperhidrosis as thermoregulatory responses are less efficacious due to reduced body surface area [128]. Normal thermoregulatory responses are also inhibited by prosthetic devices, as prosthetic and liners act as a barrier that retains heat and sweat due to their low thermal conductivity [127,128,233] and impermeability [199]. Overheating and perspiration are more than just nuisances, as they interfere with daily activities [92], are implicated in reduced quality of life for prosthesis wearers (more so than pain) and for upper-limb prosthesis wearers are one of the most common reasons to abandon a prosthetic device [29]. The hot and humid interface is also the perfect breeding ground for bacteria, something that can cause unpleasant odours to develop. Among Vietnam, Afghanistan and Iraq war veterans, 33.5% were bothered by these sweat related smells [14]. A study by Saradjian et al. explored this further and noted that excessive sweating caused some prosthesis wearer’s social anxiety, and resulted in social isolation [206]; behaviours that have been significantly linked to post-amputation depression and device abandonment [220].

In this chapter, a thorough review of thermoregulation, thermal comfort, temperature research and proposed solutions has been conducted in the context of prosthetics. Past explorations of prosthesis thermal comfort have mostly failed to consider the '*human*' side of the data. Literature has mostly used experimental studies to define abstract temperature values collected in artificial scenarios that attempt to imitate daily activities encountered by prosthesis wearers, in laboratory settings. By failing to ask about the impact of overheating on wearers, these datasets convey a one-dimensional understanding of the issue. To add depth to our understanding of thermal discomfort, this thesis postulates that the human wearer must be consulted to understand how changes in data correspond to changes in the prosthesis wearing experience. The literature review presented in this chapter helped to inform the design of research studies conducted for this PhD.

3.1 Thermoregulation

Core temperature regulation is a critical function of the body, with deviations from as little as ±3.5°C resulting in serious and potentially fatal physiological impairment [37,118]. As such, the body has a number of regulatory mechanisms such as vasoconstriction and vasodilation to regulate blood flow, sweating to remove excess heat and muscle shivering to generate heat [37,146]. These mechanisms are controlled by the preoptic anterior hypothalamus and are efficient in maintaining a core temperature of 36.8 ±1°C [37]. It is important to note that whilst core body temperature is relatively stable, skin temperature varies significantly more [37,126,146]. The main reason for wide variations in skin temperature are that most of the thermoregulatory structures are embedded in the cutaneous layer [120,179,229]; meaning skin temperature is a slave to the core temperature. In addition, the skin is likely to be in direct communication with the ambient environment and as such, is influenced by environmental temperature and humidity.

The easiest way to gain an understanding of how exactly the brain coordinates a cooling thermoregulatory response is to think about how the body adapts to the scenarios of exercise and uniform heating. The body at rest has a skin blood flow of approximately 250mL/ minute and a heat dissipation of 80-90 kcal/hour [120]. Passive dissipation is adequate in a steady-state, as it roughly matches resting metabolic heat production [118,120]. As soon as exercise begins, metabolic heat production undergoes a 10-20x increase from the resting rate [146], with only 30% of this energy being converted into mechanical energy. In non-glabrous tissue, the primary response is the activation of sympathetic vasodilator nerves [37]. These signal the brain to both increase blood flow and vasodilate cutaneous vessels. This blood flow increase can be as much as 6 to 8 L/minute, corresponding to 60% of cardiac output [96]. As blood flows away from the core, through the vast network of cutaneous arteries and into sub epidermal vessels, heat can dissipate into the surrounding environment. Whilst vasodilation is an effective first response to both local and systemic temperature rise; it is usually unable to match the increased metabolic heat production alone [37]. As such, the secondary response to heat increase is to initiate sweating. As sweat pores open, sweat collects on the outermost skin layer, evaporates and cools the skin surface, which in turn, cools the blood heading back to the body core. The level of vasodilation will increase to a peak value, and the sweating response will continue until heat dissipation roughly matches heat generation. The response to environmental heating is more or less the same. However, in this scenario vasodilation is less effective due to the smaller temperature gradient between blood temperature and environmental temperature. If the person is in a humid environment, sweat will not be able to evaporate as easily, and as such, will be less effective as a thermoregulatory response.

3.2 Thermoregulation in prosthesis users

Individuals who have undergone amputation will have a reduced ability to thermoregulate due to reduced total body surface area [128]. Among transtibial amputees, there are also additional complications because a significant portion of them suffer from peripheral arterial disease and/ or diabetes, particularly in elderly patients, which can prevent or minimise vasodilation [165]. In a residual limb with an attached prosthetic system, the vasodilation response will be initiated (if vasculature has not been excessively damaged in amputation), along with sweating. However, because the skin cannot communicate with the external environment, heat will be retained. This trapped heat increases the localised environmental temperature and initiates sweating. Because liner materials are usually impermeable, this thermoregulatory response is rendered ineffective and results in a hot and humid microclimate [105,110,142,143,145,165,183]. Thus, small temperature changes in the total body system (e.g. from light exertion) can cause amplified rises in the residuum temperature [110,183].

3.3 Thermal properties of liner and socket materials

To try to understand the reasons for overheating amongst amputees, the thermal characteristics of prosthetic components have been researched. This data is not provided by prosthetic manufacturers, but Klute et al. [128] conducted research into the thermal conductivity of 23 liners and 2 sockets of various materials. Results from the study provided a useful industry benchmark of the thermal properties of common prosthetic componentry. By implementing a heat flux transducer-based testing rig, the thermal conductivity was found by setting a cold plate at 30°C and a hot plate at 40°C. These temperatures were chosen to give a reflection of the thermal conductivity of the materials used in prosthetics, within temperatures of similar values to skin surface temperature.

This study found that liner materials, varying from silicone, mineral oil gel, thermoplastic elastomer and closed-cell foam have a thermal conductivity of between 0.085-0.266 W/mK- which can be thought of as a relatively low thermal conductivity. In conjunction with this data, Klute et al. created a simple model (Equation 1) that predicted the temperature differential between the skin surface and the environment when a layered prosthetic system is worn.

Equation 1

$$\Delta T = \frac{q \cdot \sum \left(\frac{L_i}{k_i}\right)}{A}$$

ΔT = temperature differential between skin and environment
q = heat flux across materials
L_i = layer thickness for component i
k_i = thermal conductivity for component i
A = surface area of specimens

From this equation, if we assume that in any given situation the heat flux, layer thickness and surface area remain fixed, to reduce ΔT, we must increase k_i. Klute et al. noted that to minimise thermal discomfort, reducing thermal conductivities of prosthetic components could be a viable strategy. Klute et al. also suggested that socket material has a relatively small effect on stump skin temperature in comparison to liners due to being much thinner.

A further two replication studies were conducted by researchers from the University of Akron [127,233]. In these studies, thermal grease was not used, even though it had been used by Klute et al. [128]. The University of Akron’s studies reasoned that a lack of thermal grease preserved the natural likeness to the in-vivo environment of the prosthesis-skin interface [233]. Both studies utilised similar test equipment as Klute and tested the thermal conductivity as per the ASTM C518-10 standard for testing thermal conductivity. One-inch circular samples were placed in-between a temperature gradient, and a thermal flux sensor was used to subsequently infer the thermal conductivity of the material being tested. The first study [127] tested five unspecified elastomeric materials and found the thermal conductivity to range between 0.1036 - 0.1521 W/mK. Thirteen known elastomers were also tested, with a thermal conductivity range of 0.1020 – 0.1389 W/mk, and an additional eight socket materials were tested and found to have conductivities between 0.1153 – 0.1805 W/mK. The second study [234] used the same methodological protocol but seemingly tested different (unspecified) materials. Three elastomer tests yielded conductivities between 0.145 – 0.155 W/mK and six sockets had conductivities between 0.11 – 0.189 W/mK. The five liners that were tested were reported to be from manufacturers OttoBock, Össur and Ohio WillowWood and had conductivities between 0.116 – 0.143 W/mK. In comparison to the original study by Klute et al, the liners were all of a similar conductivity range (0.085 – 0.266 W/mK [128] vs 0.1020 – 0.1389 W/mK [127] vs 0.116 – 0.143 W/mk [234]). The sockets were also all of similar ranges (0.148 – 0.15 W/mk [128], 0.1153 – 0.1805 W/mk [127] vs 0.133-0.189 W/mk [234]). This additional characterisation of prosthetic material conductivities reaffirms that thermal conductivities of prosthetic components make heat transport difficult, and likely contributes to thermal discomfort.

3.4 Thermal comfort in the built environment

Overheating has already been highlighted as a contributing factor to skin issues and prosthesis satisfaction and comfort. However, rather than simply use the vague term *‘comfort,’* in the context of overheating, it is more appropriate to use the concept of an individuals perceived thermal comfort (PTC). The concept of thermal comfort has a rich and deep body of literature that extends back into the early 1900s and is a distinct field of research in its own right. Literature has mostly focussed on thermal comfort in the context of healthy individuals in the built environment. Heating and air conditioning are used to create the best environmental conditions for comfortable, productive and happy inhabitants, whilst using the minimum amount of energy to thermoregulate the environment as possible. Regardless of the different context of thermal comfort to the topic of this thesis, this body of knowledge provides useful experimental and theoretical founding for thermal discomfort amongst prosthesis wearers. Given the scale of thermal comfort research in the built environment, only key or particularly relevant concepts and models are introduced in this thesis, with the intention of extracting relevant insights to be applied to prosthesis thermal comfort research.

3.4.1 What is thermal comfort?

The concept of thermal comfort is easy to relate to from anecdotal experience; however, it is a deceptively difficult concept to quantify and evaluate due to variability of human perception. Thermal comfort can be best explained as an emotional experience, that can be described using terms such as “pleasant” and “unpleasant” [161]. Thermal comfort is often confused with thermal sensation, where sensation is used to refer to a rational, objective response to a global system condition. Therefore, when an individual reports their perceived sensation, words relating to “hot” and “cold” are used [100]. It is necessary to clarify the distinction between thermal comfort and thermal sensation because it is easy to falsely assume that a neutral thermal sensation may have parity with a comfortable perceived thermal comfort. In reality, research shows us that many individuals may have a thermal comfort preference that tends towards a hot or cold environment, meaning that non-neutral thermal sensations may be required for thermal comfort to be achieved [111,112]. The confusion between thermal comfort and sensation are exasperated by building environment standards such as the ANSI/ ASHRAE 55 standard, where thermal sensation scales are used to develop models of thermal comfort.

3.4.2 The first thermal comfort model

The first model of thermal comfort was created by Bedford in 1936. In his seminal work, he researched the thermal environments experienced by British factory workers in an English winter. His paper *‘The warmth factor in comfort at work’* presented results from an extensive large-scale field study where 3085 predominantly female participants across 12 factories reported their current level of perceived thermal comfort, along with physiological and environmental measurements. Whilst an original copy of the paper could not be sourced, a methodological description has been provided by Humphreys, Nicol and Roaf [113].

Table 1: The thermal comfort scale originally used by Bedford comprised of a 7-point scale.

Comfort rating	Scale value
Much too warm	7
Too warm	6
Comfortably warm	5
Comfortable	4
Comfortably cool	3
Too cool	2
Much too cool	1

Using early apparatus, he was able to record a participant's forehead temperature, room humidity, mean radiant temperature and airflow within the part of the factory where the participant was working. Radiant temperature is a rarely encountered metric which represents the temperature at a point in space as a function of radiant intensity and distance from a heat source. As an example, the radiant temperature when sitting in a chair one metre away from a south-facing window will be higher than sitting in a chair one metre away from a north-facing concrete wall. As well as objective measures, Bedford also collected subjective data using a defined thermal comfort scale. In this situation, participants were asked to report their current perceived level of thermal comfort on a 1-7 scale (Table 1) which captures both comfort *and* sensation. From this large-scale multivariate dataset, Bedford used multiple linear regressions to develop a model (Equation 2), using mechanical calculators to perform the analysis. Although he took physiological measurements, the analysis indicated that these were not correlated with perceived thermal comfort. His model is able to predict an individual's level of thermal comfort (as per his scale) by inputting measures of air temperature, mean radiant temperature, partial pressure of water vapour in the air and air velocity.

Equation 2

$$S = 11.16 - 0.03089(t_a - 32) - 0.02989(t_r - 32) - 0.0372f$$
$$+ 0.00144 \times (\sqrt{}0.00508v) \times (100 - t_a)$$

S = Bedford's level of thermal comfort

t_a = Air temperature (˚C)

t_r = Mean radiant temperature (˚C)

f = Partial pressure of water vapour in air (mmHg)

v = Air velocity (m/s)

The work by Bedford represents a monumental effort and still remains one of the largest individual research studies in the field of thermal comfort research. However, the vast majority of participants were asked about their thermal comfort only once. As a result, the model implicitly assumes that participants will *always* feel the same thermal comfort level in a particular environment. The model does not consider the variation in thermal comfort caused by differences in clothing or differences in personal physiology which could influence thermal comfort in the same environment. Additionally, physical activity is also neglected, which will naturally increase internal heat generation and therefore influence thermal comfort. As this was not considered, the model has no way to account for such situations. Whilst a solid foundation for thermal comfort, a more complex approach was needed that considered additional characteristics.

3.4.3 Thermal balance and the PMV

When researching thermal comfort in the built environment, the most influential contributor in the field was Povl Ole Fanger [180]. His book entitled *'Thermal Comfort: Analysis and Applications in Environmental Engineering*' was released in 1970 and redefined our understanding of thermal comfort [64]. His work provided a method to evaluate and analyse thermal environments by proposing that the level of thermal discomfort depends on thermal load (L). Fanger et al. conducted highly controlled laboratory experiments with 1396 students (approximately gender-balanced). Each participant entered a climate-controlled chamber and wore a specific set of clothing (a t-shirt, cotton trousers, underwear and woollen socks with no shoes). Each participant completed activities within the chamber, which represented four levels of physical exertion. Eight environmental conditions were also explored. This historic research by Fanger et al. used what is now known as the American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE) thermal 'comfort' (Table 2) scale as an instrument to provide subjective thermal comfort assessments for each participant. Therefore, the term comfort is used in the studies description in place of the more *correct* term thermal sensation.

Table 2: Fangers' scale focused on an individual's perception of temperature and used a 7-point scale centred around 0.

Comfort rating	Scale value
Hot	3
Warm	2
Slightly warm	1
Neutral	0
Slightly cool	-1
Cool	-2
Cold	-3

In each experiment, participants were asked to report their comfort level using the ASHRAE scale every thirty minutes, providing six reports per experimental phase. This work determined that thermal comfort depends on six factors, two personal and four environmental. Personal factors were determined to be the individual's metabolic rate and the level of clothing insulation. Clothing insulation is reported in terms of the unit *'Clo'*, with 0 Clo representing a naked person and 1.0 Clo a person wearing underwear, shirt, trousers, socks and shoes. Using the unit of Clo, individual items of clothing can be looked up for a corresponding Clo value and added cumulatively to determine the combined insulating effect of an outfit. The ambient temperature, relative humidity of a room, air velocity and radiant temperature were included in the model as environmental factors. Fangers' research presents a rational idea that thermal comfort can only be achieved when the body is in thermal balance; i.e. net heat loss is in perfect balance with heat generation. However, the model has a caveat in that balance alone is insufficient as comfort can only be achieved if sweat rate is equal to a sweat comfort limit $E_{sw}(x)$, and mean skin temperature $t_{sk}(x)$ is equal to a temperature comfort limit. Finally, there also must be no localised areas of thermal discomfort on the body. This concept can be surmised by Equation 3.

Equation 3

$$H - E_d - E_{sw} - E_{re} - L = K = R + C$$

$H = M - W$ = Internal heat production in the human body

$E_d = 3.05 \times 10^{-3}(256 \times t_{sk}(x) - 3373\ P_a)$ = Heat loss by water vapour diffusion through skin

$t_{sk}(x) = 35.7 - 0.0275(M - W)$ = Skin temperature comfort limit

$E_{sw}(x) = 0.42(M - W - 58.15)$ = Heat loss by sweat evaporation from skin surface

E_{re} = Latent respiration heat loss

L = Dry respiration heat loss

K = Heat transfer from skin to outer surface of clothing

R = Heat transfer by radiation from clothing surface

C = Heat transfer by convection from clothing surface

Whilst a positive progression in terms of intellectually understanding thermal comfort, this equation provides little insight as to how the six factors combine to influence human perception of thermal comfort. Therefore, Fanger used the collected data to create the Predicted Mean Vote (PMV) (Equation 4) and Percentage of People Dissatisfied (PPD) (Equation 5) equations. The PMV provides an indication of the mean ‘vote’ of thermal comfort as per the ASHRAE scale for a group of people in an environment. The PPD provides an indication of what percentage of people will be dissatisfied with the temperature of the environment, based on the PMV. One of the most important points of the PMV and PPD equations is that even in a case of a PMV of 0 (i.e. the mean thermal comfort perception of a group in an environment is neutral), 5% of the individuals in that environment will be unhappy. This upper limit of environmental thermal comfort for a group reflects expected variances in perceived thermal comfort amongst a group of individuals. Both equations are reasonably complex and contain many terms derived from the original six factors of thermal balance; however, both equations are included to demonstrate the complexity of thermal comfort, even when using a classical approach.

Equation 4

$$\mathrm{PMV} = (0.303e^{-0.036\,M} + 0.028) \times$$
$$[(M\text{-}W) - 3.05 \times 10^{-3}\{5733 - 6.99(M\text{-}W) - P_a\}$$
$$- 0.42\{(M\text{-}W) - 0.0014M \times (34 - t_a) - 3.96 \times 10^{-8} \times f_{cl}\,\{(t_{cl} + 273)^4 - (t_r$$
$$+ 273)^4\}$$
$$- f_{cl}\,h_c\,(t_{cl} - t_a)]$$

Equation 5

$$\mathrm{PPD} = (100-95) \times e^{-(0.03353\times \mathrm{PMV}^{\wedge}4-0.2179\times \mathrm{PMV}^{\wedge}2)}$$

$f_{cl} = 1.00 + 0.2\ I_{cl}$ when $I_{cl} \leq 0.5$

$1.05 + 0.1\ I_{cl}$ when $I_{cl} > 0.5$

$t_{cl} = 35.7 - 0.028\ (M-W) - 0.155\ I_{cl}\ [3.96\times10^{-8} \times fcl \times\{(t_{cl}+273)^4-(t_r+273)^4\} + f_{cl}h_c(t_{cl}-t_a)]$

$h_c = 12.1\ \sqrt{v}$

M = Metabolic rate (W/m^2)

W = External work (J)

f_{cl} = Clothing factor

I_{cl} = Clothing insulation (clo)

h_c = Convective heat transfer coefficient

v = Air velocity (m/s)

P_a = Vapour pressure of air (kPa)

t_a = Air temperature (˚C)

t_r = Radiant temperature (˚C)

t_{cl} = Temperature at clothes surface (˚C)

This research highlights the importance of considering both human and environmental factors and demonstrates how these objective measures can be combined with a subjective measure such as thermal comfort to create an indicative thermal comfort equation. However, the predominant limitation of the Fangers' PMV and PPD equations is that it is *static*, and it was generated using only laboratory data. These limitations mean that the model has no way to consider how thermal comfort may change when individuals open a window, remove clothing or change the activity they are doing. It also means that in real-world situations, Fangers' model is particularly inaccurate [230]. Despite these limitations, it still remains a frequently used model in buildings to regulate heating, ventilation and air conditioning (HVAC) control.

3.4.4 Modern computing and thermal comfort

In modern research contexts, machine learning and artificial intelligence, when combined with ubiquitous computing (ubicomp), have led to new approaches to researching thermal comfort. Researchers have been able to leverage both machine learning and ubicomp successfully in real-world contexts with a goal of maximising energy efficiency in the built environment. There are many studies that embrace this latest wave of thermal comfort research with most focusing on optimising heating and cooling algorithms. Only select publications which represent relevant and transferrable experimental approaches will be discussed here.

A number of papers have adopted a participatory-sensing approach to use *humans as sensors* to record perceived thermal comfort in an environment [63,91,115]. In these research studies, participants were provided with a smartphone application and asked to record perceived thermal comfort either at set intervals or whenever individuals notice deviations from a baseline level of thermal comfort. In these studies, as well as participatory sensing, ubiquitous computing (ubicomp) sensors are also positioned in the researched environment, or existing sensors that are part of building management systems (BMSs) are leveraged to develop a multidimensional dataset containing room temperature and often humidity. Based on the collected data, research has aimed to provide improved heating or cooling cycles using historical data, or real-time input, where individuals can influence the environment around them by recording their perceived thermal comfort. The goal of all of these studies is simple; to ensure the maximum number of people are thermally comfortable in an environment whilst using the minimum amount of energy possible. In all studies, the method remains the same; conduct research in the wild for a period between 4 weeks to 5 months by deploying smartphones to collect *human* data, and sensors to collect environmental data. Once data is collected, machine learning or other statistical methods are used to generate an *'improved'* control algorithm based on the collected data. Finally, the newly created algorithm is used to control a building management system, and inhabitants are usually asked if they are satisfied with the temperature control in their building, which is compared to a level of satisfaction collected prior to changes in BMS algorithms. Although the specific results from these studies are of little relevance to the research topic of this PhD, the methodological insights are invaluable.

A specific study of interest was conducted by Huang et al. [109]. In this study, the researchers used off the shelf wearable sensors, ambient sensors, and an experience sampling device to infer thermal comfort in a home environment. To create a thermal comfort model in the home, 11 participants took part in a four-week sensor deployment experiment. During that time, each participant was provided with a centralised hub for data storage and a Basis B1 fitness tracker (which collected activity level, skin temperature, galvanic skin response, near skin temperature, heart rate, step count and estimated calorie consumption). AeoTec multiSensors were used to track in-home ambient temperature and humidity conditions. Finally, participants were asked to use an app-based experience sampling device. As opposed to a participatory sensing approach where participants were asked to simply record just one report of perceived thermal comfort or sensation, here participants were asked their thermal sensation (using a 7-point scale), their comfort sensation (using a 5-point scale), current activity, indoor location and any other notes. Participants were asked to respond to at least 6 report requests per day and were sampled every 30-minutes during participant defined time periods. Their thermal comfort and thermal sensation data were mapped onto a new combined comfort and sensation scale to make machine learning classification training easier (Table 3).

Table 3: A combined thermal sensation and thermal comfort scale was created by combining results from a 7-point sensation scale and a 5-point thermal comfort scale.

Comfort rating	Scale value
Uncomfortably warm	5
Slightly uncomfortably warm	4
Comfortable	3
Slightly uncomfortably cold	2
Uncomfortably cool	1

In total, 1,132 comfort reports were completed, with corresponding additional data from other sensors. For each comfort report, the other data types were smoothed using a five-minute moving average filter window. As most data was collected around the comfortable classification (76.1% of PTC reports), classification categories were weighted using methods described Kotsiantis et al. [132]. This prevented a classifier algorithm which *always* predicts comfortable based on biased training data. Once data were processed, various machine learning algorithms were trained. These are not discussed here; as machine learning falls outside the scope of this thesis.

After analysing data and developing the classifier algorithms, exit interviews and experience sampling data was used to investigate possible causes for inaccurate predictions. This investigation led to the identification of a few possible complications that can lead to false predictions when using the trained classifiers. The first confounding factor was the presence of a local heat source (as demonstrated by one participant who was in a cold room, but their laptop heated their lap which made them feel comfortable and warm). Dynamic transitions (e.g. moving from a warm bed to a cold room) also caused difficulties, as there were few appropriate training sets for this scenario. Participants also sometimes did not wear the system or accidentally provided the wrong label which lead to additional confusion. Finally, the authors believed that individual differences, learned behaviour and prior experience lead to further complications (e.g. a participant stating that they had cold hands, but they were used to having cold hands, so they weren’t uncomfortable). In reflection, this study provides an indication of the potential complications that can be expected from a real-world research study over a long period of time. The decision to conduct a localised sensor investigation using wearable sensors is of particular interest to the work conducted for this PhD and shows that wearable sensors are a viable approach to forming a predictive perceived thermal comfort model.

With these studies as a starting point, some *‘lessons learnt’* are apparent. Environmental conditions such as humidity, mean radiant temperature and air velocity should be ideally captured. However, as may be expected, not all of these values are practical to continuously monitor. Therefore, surrogate measures or static estimated values should be used. For example, room temperature may be used in place of mean radiant temperature, and metabolic rate or clothing may be set to a static estimated value. When conducting research in the real-world, a smartphone-based participatory sensing or experience sampling approach provides a tested and valid approach for collecting data. However, a perfect response rate should not be expected; i.e. participants will not respond to every request to log their perceived thermal comfort. Additionally, of the data that is collected, there will likely be a centralisation of data around a neutral/ comfortable classification of perceived thermal comfort.

3.5 Residual limb temperature research

As has been mentioned, heat accumulation at the skin interface of an amputee is indicated to negatively affect skin health, with elevated skin temperature highlighted as one of the major factors that affect tissue health [155]. There have been a few quality experimental studies [110,130,154,182,183,216] that have collected skin surface temperature data to explore this. The Department of Veterans Affairs, Seattle, has performed the majority of these. These studies have mostly opted for a similar experimental procedure- a period of rest (post donning prosthesis), a period of light exercise and a further period of rest. In this section, a review of pertinent results and research protocols has been conducted to help inform the design of original experiments later in this thesis.

3.5.1 The beginning: Peery et al. 2005

The first temperature study [183] recruited 5 male transtibial participants and measured the temperature across 14 residual limb sites and employed a 15 minute rest period followed by a 10-minute walking period. Walking speed was set at a ‘slow pace’ of 0.26ms$_{-1}$, and the paradigm included a 3-minute transfer time from seat to treadmill. This study reported a mean skin temperature (± standard deviation) of all subjects at the start of the experiment (1 minute after donning prosthesis) as 31.4 ± 1.3°C. After 15 minutes of rest, the skin surface temperature rose to a mean value of 32.2 ± 1.7°C. Within the transfer time, skin temperature increased a further 0.1°C to 32.3 ± 1.7°C. Finally, after 10 minutes of walking, skin temperature had risen to 33.1 ± 1.8°C. It was noted that during each period, the temperature had not visibly reached a steady-state, as temperature increase was still noticeable. These mean temperature data values depict an obvious trend- wearing a prosthesis increases skin surface temperature slightly, and exercise increases skin temperature even more. This study also shows a difference in temperature change across the different residual limb sensing sites. When this data is considered, we are presented with a net increase in temperature across all sites, coupled with localised hot spots. The trend is as follows; the anterior section of the limb was coolest, with a mean temperature of 31.7 ± 1.6°C, the medial section was 32.1 ± 1.9°C, the lateral section 32.6 ± 1.5°C and the warmest, the posterior, was 32.9 ± 1.7°C. The coolest recorded temperature was the anterior section during initial donning, and the warmest was the posterior during the final minute of exercise.

Following this initial study, Peery et al. progressed with this research and created a 3D finite element analysis (FEA) temperature model [182]. It is, however, important to note that although this study has been experimentally validated against the initial Peery et al. study, only 5 patients participated. When combined with anatomical data, it is possible to see that the warmest areas of the residual limb contain a high volume of muscle and the coolest areas contain a low volume of muscle, a higher volume of fat and bone or a combination of all three.

3.5.2 Moving forward from Peery: Huff et al.

Another more temporally robust study was published in 2008 [110], which utilised a greater number of temperature sensors (16 vs 14) and a total experiment time of 2.5 hours. This time was split between 1 hour of seated rest (prosthesis donned), 30 minutes of treadmill walking (at a self-selected speed) and a further 1-hour of seated rest. The rationale behind an increased experimental protocol was that the initial data presented by Peery et al. was collected over a time period that was perceived to be too short to establish steady-state. This implies that the original data (particularly the maximum temperature reached) was not a true representation of the absolute maximum temperature that can be reached in the set experimental activity. An initial drop of approximately 0.4°C of the residual limb was reported but was likely attributed to the prosthetic components being at a lower temperature than the limb, probably close to room temperature. One immediate criticism of the Huff et al. study, however, is that room temperature data was not collected at any point during the study, so this cannot be confirmed. As the study continued, an initial resting steady-state temperature of 29.5 ± 0.9°C was reached. In the exercise phase of the experiment, the average surface temperature peaked at 32.8 ± 0.6°C and still appeared to be increasing within the last minute of the 30-minute period. In the proceeding hour of seated rest, the surface temperature only decreased to 32.6 ± 0.6°C. This suggests a tendency for prosthetic components to prevent cooling of residual limbs once temperature has increased, even during rest periods. Although a good study, this paper represents more of a case study, as only one patient was recruited (a 59-year-old transtibial male, 84.5kg in weight and 33 years post traumatic amputation). This means that evidential patterns cannot be thought to represent all amputees.

3.5.3 A larger laboratory study: Klute et al.

Another study from researchers at the University of Washington was conducted by Klute et al. [130]. This study mirrored a similar protocol to previous studies by utilising wearable thermistors underneath the prosthetic liner and periods of rest, exercise and further rest. This study set out to explore two research question, with the first being to explore if residual skin temperature changes as a function of activity and cessation, and if there are regional temperature differences in terms of circumferential location and proximal vs distal location. To do this, 9 male transtibial amputees were recruited, with an average age of 49 ± 15 years, 16 ± 13 years post-amputation, a height of 1.81 ± 0.04m and a body mass of 93 ± 14kg.

Sixteen thermistors were distributed on the residual limb at the tibial crest, tibialis anterior, medial gastrocnemius and the lateral gastrocnemius. The sensors were approximately evenly separated and attached using medical tape. Once the sensors were applied, the participants were asked to sit and rest for 60 minutes with their prosthesis on, followed by 30 minutes of treadmill walking at a self-selected speed and a further 30-minute rest period. Statistical analysis was done using R and the ‘lme4’ and ‘nlme’ linear mixed-effects regression packages, alongside pairwise comparisons using the ‘milcomp’ package.

The results confirmed that activity is significantly linked to skin temperature. Between the end of the first rest period and the end of the exercise period, mean skin temperature changed from 31.0 ± 1.5 ˚C to 34.1 ± 1.3 ˚C, showing a change of +3.1 ˚C. At the end of the second rest period, mean skin temperature reduced to 33.2 ± 1.2 ˚C, signifying a decrease of 0.9 ˚C compared to the end of the exercise period, but still at + 2.2 ˚C increase compared to the end of the first rest period. This showed that although skin temperature is significantly linked with rapid temperature increase ($p < 0.001$), cessation of activity is not linked with rapid temperature decrease. When the topology of the residuum is considered, temperature was found to be higher in the tibialis anterior region ($p < 0.006$), with the tibial crest being 32.6 ± 2.2 ˚C, the tibialis anterior 33.3 ± 1.6 ˚C, the medial gastrocnemius 32.5 ± 1.9 ˚C and the lateral gastrocnemius 32.5 ± 1.7 ˚C. These were average values amongst all participants over the entire experiment. When proximal to distal topology was considered, proximal sensors recorded the higher average temperatures than distal sensors ($p = 0.001$), with sensor 1 (the most proximal) recording 33.1 ± 1.6 ˚C, sensor 2, 33.0 ± 1.7 ˚C, sensor 3, 32.7 ± 1.9 ˚C and the most distal sensor, sensor 4, 32.2 ± 2.1 ˚C.

This study made the important point that conventionally when the general population feels thermally uncomfortable, they can take steps to adjust their thermal comfort by simply donning and doffing layers of clothing. For prosthesis wearers, this choice is often a choice between comfort or removing the prosthesis and reducing mobility and compromising social norms in favour of thermal comfort. This highlights once again that from a comfort perspective, prosthetic limbs do not satisfy the needs and requirements of daily living. It was also the first study to suggest that simply recording skin temperature is not enough, and an assessment of thermal comfort should be considered as an additionally collected metric.

3.5.4 Predictive temperature techniques: Mathur et al.

A slightly different type of temperature study [154] aimed to use Gaussian machine learning techniques to predict residuum skin temperature based on inter socket and liner surface temperatures. The incentive of this is that temperature data collected directly from the skin surface using thermistors is difficult (Peery et al. noted thermistor wiring snapping at the distal tip during measurements on multiple occasions [183]). The experimental paradigm was temporally similar to Peery's initial study and consisted of 10 minutes of seated rest, 15 minutes of walking at a self-selected pace (in this case 0.62 ms$_{-1}$) and a further 15 minutes of seated rest. Data was collected using 4 thermistors (two on skin surface, two on liner surface) placed on lateral and medial sites. Only one patient was recruited (a 68-year-old male of 70kg). The most noticeable difference is that this experiment took into account environmental conditions and performed the experiment in a climate-controlled chamber at 10 °C, 15 °C, 20 °C and 25 °C, 40% humidity with zero wind velocity. The trend described in the other studies is evident in that donning prosthesis causes moderate temperature increase, walking causes a significant increase and rest periods must be substantially long for temperatures to decrease again. The trend of prosthesis donning causing moderate temperature increase, walking causing a significant increase and slow temperature decrease presented in the other studies [49,110,182,183] is reaffirmed. A unique insight was found in that temperature profiles at ambient temperatures of 10°C, and 15°C are ‘significantly’ different from ambient temperatures of 20°C and 25°C. In cooler ambient temperatures (10°C and 15°C), walking does not significantly increase skin or liner temperature (either medially or laterally). In warmer ambient conditions (20°C and 25°C) however, the expected rapid increase in temperature, both skin and liner, is evident. What is particularly pertinent is that in all acquired data, external liner temperature never matches or exceeds skin temperature. This trend is exacerbated in warmer ambient conditions. The authors do not offer numerical data to compare directly with the Peery and Huff studies [110,183], but graphical data is provided which shows a small decrease in skin temperature and a decrease in liner temperature of between 2-3°C over the course of the experiment when ambient temperature is 10°C. When ambient temperature is 25°C however, a distinct increase of approximately 2°C is seen in both liner and skin surface temperature, both medially and laterally. What is interesting is that the outer surface of the prosthetic liner continually decreases in temperature when ambient temperature is 10°C. Although not exactly a transferrable technique to this PhD, Mathur et al.’s. study does show how machine learning techniques could benefit amputee research.

3.5.5 Towards real-world studies: Segal et al.

The most recent study was conducted by Segal et al. [216] and progressed the state of the literature by conducting a temperature study beyond the laboratory environment. This is an essential step to conducting research that truly reflects the everyday experience of wearing a prosthesis. After reflecting on the existing body of research, this study aimed to explore the behaviour of residual limbs in a cold environment, primarily to understand if prosthetic devices that heated, as well as cooled would be required to maintain thermal comfort. To do this, the study recruited 9 active males with lower limb transtibial amputations. These individuals were on average 53 ± 12 years of age, wore their prosthesis for at least 8 hours per day and were 22 ± 14 years post-amputation. Participants were instrumented with 4 thermistors placed on the middle of proximal and distal of tibialis anterior and medial gastrocnemius, avoiding bony landmarks. Internal body temperature was also recorded using an ingestible core temperature sensor, along with heart rate and step rate sensor. Additionally, the researchers asked participants to share their perceived thermal comfort (PTC) using a manually administered 0-10 Likert scale (0 = too cold, 10 = too hot). Once instrumented, participants were driven 45 minutes to a remote location suitable for snowshoeing. They were then asked to stand and rest for 5 minutes, followed by a 30-minute bout of walking. This was repeated once more, and the study ended after a final 5-minute standing rest period. At the end of each rest or walking phase, participants were asked to relay their heart rate from a Polar tech chest-worn heart rate sensor and to provide their PTC level. Participants were also asked to report these data every two minutes during the experiment.

As with the previous study conducted by Klute et al., data was recorded, which once again shows that residual limb temperature is significantly associated with bouts of exercise ($P < 0.002$). Between the first rest period and the end of the first exercise period, skin temperature increased 2.7 ˚C (1.8-3.5 ˚C, 95% confidence interval). Between the first rest period and the end of the second exercise period, residual limb skin temperature increased from 30.6 ± 2.6 ˚C to 34.5 ± 1.7 ˚C, resulting in a difference of 3.9 ˚C (95% confidence interval = 3 - 4.7 ˚C). After the second rest period, skin temperature insignificantly decreased by -0.3˚C (-1.1 – 0.6 ˚C, 95% CI) and by the end of the final exercise period, residual limb temperature had significantly increased by 1.5˚C (0.6 – 2.3 ˚C, 95% CI). The final rest period yielded yet another insignificant decrease in limb temperature of -0.4 ˚C (-1.2 – 0.5 ˚C).

The different periods of the experiment (rest or exercise) were significantly associated with the perceived thermal comfort ($p<0.001$). However, perceived thermal comfort was only associated with activity and rest, not residual limb skin temperature. Residual limb skin temperature changes were only associated with activity. The implication is that although prosthesis wearers may feel an improved sense of thermal comfort when resting, the rest will not decrease residual limb temperature. As limb temperature increases accumulated over time, perceived thermal comfort may be less associated with rest and take longer to return to a baseline, as rest could become less and less effective. However, as the data is not presented or analysed as a time-series, it is impossible to verify this.

One criticism of the study is that the researchers opted to define PTC in terms of thermal sensation. As has been discussed in Section 3.4.1, equating thermal sensation with thermal comfort is an inappropriate way to assess thermal discomfort phenomenon. Additionally, in the study analysis, PTC data were treated as a continuous variable, and thus, the mean and standard deviation are provided. The modal value would have been more appropriate for this data type. The other main criticism revolves around the study design. Whilst is it a positive progression of the research topic, the choice to conduct the study in an abstract environment doing an abstract activity (snowshoeing in a snow laden field), is not the best reflection of general activities of everyday living. However, it should be highlighted that the purpose of the study was *not* to provide a reflection of temperature behaviour in an everyday activity. Therefore, this criticism highlights an opportunity for future research. The final comment about this study is that it experiences the same limitation as all of the other amputee temperature studies, in that participant size is small, and the experiment protocol requires active intervention by researchers.

3.6 Consequences of overheating

3.6.1 Sweating

One of the most effective thermoregulatory mechanisms the body possesses is sweating. However, as has already been mentioned, the combination of low thermal conductivity and impermeability of prosthesis interface components make this response ineffective. Excessive sweating (hyperhidrosis) has been reported to be the most common dermatological complaint among lower-limb prosthesis wearers [166].

A literature review conducted by Ghoseiri and Safari [82] reviewed 38 studies that used (mostly) surveys, clinical examinations, medical records and observations between 1989-2013. From the studies that explicitly reported a heat and perspiration complaint (27 of the 38), they estimated that “more than” 53% of amputee’s experience heat and perspiration discomfort that interfered with daily activities. Sweating has been associated with level of amputation, affecting transtibial amputees more than transfemoral amputees [92]. Hansen et al. [92] suggested this was interesting because TFA’s reduced skin surface area would suggest a lower thermoregulatory capability, thus a greater propensity for excessive sweating. However, it was suggested that the amount of silicone in contact with skin might have a greater effect, as this could be more in TTA’s than TFA’s. Additionally, being less than 60 years of age has been linked to hyperhidrosis- though it is unclear if this is due to differences in physical activity levels usually seen in a younger population, or physiological differences related to advanced age [92]. Finally, perspiration issues are more prominent in men than women [200] due to testosterone, which is hypothesised to enhance the sweating response to facilitate greater endurance in physical activities [114].

As well as physical activity, prosthesis wearers have suggested that climatic conditions have a significant effect on the frequency of heat and perspiration issues [199]. In a small interview study, three out of four participants suggested that warmer climate contributed more than physical activity [199]. However, Hansen et al. noted that although sweat discomfort occurs more in summer, even in winter 49% of the 121 participants reported mild issues and 20% reported moderate-to-severe issues with sweating [92]. Perspiration also has been found to have a direct correlation with the duration the prosthesis is worn for [200], though the exact effect of this would be difficult to discern, as amputee's who wear a prosthesis for longer, will also likely be more active. The amount of sweat that pools within the liner has been estimated to be between a few tablespoons, to half a cup, meaning approximately 30-120 ml of sweat per day can accumulate at the prosthesis interface [199]. Currently, this is often dealt with by frequent removal of the prosthesis and drying the socket, liner and limb with a towel [199]. However, despite the many prior reports highlighting the problem of hyperhidrosis, it is a phenomenon that has yet to be comprehensively characterised.

3.6.2 Displacement

Displacement (also referred to as pistoning) can be thought of as the point of failure of prosthetic fit, as the prosthesis begins to displace up and down as the wearer ambulates. It is the least researched phenomena, and although it has been mentioned in informal discussions with prosthesis wearers and prosthetists, displacement as a result of overheating and perspiration has not been formally described in the literature. This may be because peculiarly, a small amount of sweat can actually act to increase frictional forces between skin and the liner [54]. Increased friction would usually be regarded as a positive outcome, as it can improve suspension. However, if any displacement does occur, rapid degradation of tissue can occur, as skin is more susceptible to mechanical breakdown under high shear and tension conditions [203]. Displacement also causes deviations in prosthesis function (i.e. causing abnormalities in gait). With this in mind, it has been suggested that the measure of effectiveness of any intervention would be the ability to prevent sweat related prosthesis displacement [199].

3.7 Solutions

Broadly speaking, solutions to prosthesis thermal discomfort can fall into two categories; passive prosthesis components or active prosthesis components. The words active versus passive signify either a passive dissipative cooling device or an active powered cooling device which has some form of heat pump to draw heat away. In all cases, there are only a handful of solutions which have been developed, with only the Alpha SmartTemp liner [237], developed by Ohio WillowWood, being commercially available.

A study conducted by Wernke et al. and funded by Ohio WillowWood attempted to comprehensively determine the efficacy of the newly developed liner [235]. In this study, a double-blind clinical study was conducted where a placebo (a plain silicone liner made up to look like a SmartTemp liner) and an actual SmartTemp liner were worn by participants. The SmartTemp liner contains a phase-change material called Outlast, which absorbs heat as it is produced by the limb and changes the phase of the liner material from a relatively hard elastomer, to a soft gel-like material. Sixteen transtibial amputees were recruited including one diabetic amputee, trauma amputees, congenital amputees and one bilateral amputee. Four temperature sensors were placed on the residual limb at the medial anterior, medial posterior, lateral posterior and lateral-anterior. The experimental protocol consisted of 15 minutes of un-recorded temperature equilibration, followed by donning of the specified liner and prosthesis, 25 minutes of stationary cycling and 10 minutes of rest. In between the exercise and rest periods, the prosthesis was removed, and sweat on the liner and residuum was wiped down and weighed to assess perspiration. The prosthesis was reapplied, and the rest period commenced. After completing this first experiment wearing either the placebo or SmartTemp liner, participants rested for one hour before applying the other liner.

By calculating the mean over all limb sites and all participants and calculating paired 1-way student t-tests, researchers were able to find that the SmartTemp liner was 0.2˚C lower than the placebo liner on average between the start and end of exercise ($p = 0.09$). Comparing just the difference in temperatures at the end of the exercise, the difference between the SmartTemp liner and the placebo was 0.8˚C ($p = 0.02$). During the final rest period, skin temperature increased by 0.4 ˚C for the placebo liner and 0.3˚C for the SmartTemp liner ($p = 0.005$). The amount of sweat was also deemed to be significantly lower ($p = 0.048$) for the SmartTemp liner than the placebo liner in 12 out of the 16 participants. For the other 4, the participants did not sweat enough to measure it. For the participants where sweat could be measured, the amount of sweat detected was small (<1.2 g).

This study has many noteworthy merits- most notably, the effort put into ensuring a robust double-blind experiment was conducted. Whilst the initial results of this study are convincing, given the confident statistically significant findings, harsh criticism must be placed on choosing to use T-type thermocouples. These types of thermocouples are wholly inappropriate to be used as a skin contact temperature sensor, being more suited to environmental temperature sensing. Although the brand of thermocouple was reported (GE sensing), the model number is not provided, meaning that accuracy cannot be verified but can be expected to be in the range of ±1 ˚C like other typical T-type thermocouples [244]. The additional lack of identification of the complementary sensing system used means that results, while significant, should be viewed with healthy scepticism, given that changes of ±1˚C should be thought of as clinically significant [183], and the temperature sensing accuracy may be far below other prosthesis temperature studies [110,130,154,182,183,216]. When the quantification method of sweat is considered, concerns must also be raised. As with the temperature sensing system, the model of weighing scale used is not reported, and given that the quantities of sweat measured were between 0-1.2 grams, this may be important. Additionally, simply wiping and weighing the liner and limb may not be the most systematically rigorous method of sweat assessment. It may have been more appropriate to use standardised metrics such as skin wetedness as calculated by skin humidity sensors and galvanic skin sensors [78]. Aside from criticisms of the study, it should be highlighted that although this phase change material was shown to be a good solution in a short experiment, it is unlikely to be a true reflection of how this liner will perform over the period of an entire day. A particular concern is that phase change materials such as this begin to act as a heat source once saturation has been reached and will, therefore, heat the limb, rather than transfer heat away from the residual limb. Therefore, despite this study claiming that the solution significantly reduces residual limb skin temperature, it would be incorrect to state that the SmartTemp liner has conclusively solved the problem.

A more common approach from the research community has been to attempt to develop active cooling systems. Currently, there are four papers from two research groups that have documented different yet similar approaches.

A thermoregulatory system was designed and developed by Ghoseiri et al. [83,84] that aimed to assist in the thermoregulation of a residual limb, in direct response to temperature changes seen during normal prosthesis wear. This system comprised of an aluminium sheath that wrapped around the limb to transfer heat to a central location. At this central location, a heat pump was mounted that consisted of a thermoelectric Peltier device, a heat sink and an electric fan. To monitor temperature, 16 temperature sensors (TMP275; Texas Instruments, ± 0.5 ˚C) were applied over a heated limb phantom. The thermoregulatory system was connected to an Arduino Duemilanove, and a programme was written to facilitate data logging and proportional integral derivative (PID) control of the heat pump.

To test the system, a liner was covered in a layer of plastic to create a simulated socket, and the temperature control system applied. A baseline heat source at 24 ˚C was placed inside the liner, though it is unclear what this heat source was. The thermoregulatory system was then activated, and the time taken for the inside and outside of the liner to equilibrate to temperatures between 18 - 30 ˚C was recorded. Despite this data being collected, there is little justification for the test procedure, and the described temperature range (18-30 ˚C). As such, the results pose little reflection of the validity or efficacy of the proposed system. It is possible however, to acknowledge that an active thermoelectric cooling device has been developed in the prior art.

A different and more rigorously tested approach was adopted by Han et al. [89], who opted against using thermoelectric cooling modules (otherwise known as Peltier's,) in favour of heat pipes, heat sinks and a cooling fan. The device designed by them consisted of rectangular heat pipes with a cross-section of 10.5 x 4.0mm, wrapped around a metal bucket that represented the skin and limb interface. The heat pipes were interfaced using thermal grease onto an 82 x 63 x 21 mm heat sink, which had a low power (3.3W max cooling power) computer fan. The heat pipes were covered in polyurethane foam to represent the socket layer. To evaluate the efficacy of the system, the metal bucket was filled with water, and a central heating rod was used to apply different thermal loads. The authors estimated appropriate thermal loads by estimating the leg as a cylinder with heat generation primarily coming from muscle. They calculated that for an average lower-limb amputee, reclined resting would correspond to a thermal load of 1.72 W; seated rest would be 2.95 W and sedentary activities such as office, house or school work would correspond to a load of 4.06 W. Slightly more demanding activities such as standing with light activity (e.g. shopping) would result in a load of 6.72W and standing with medium activity (shop assistant work, domestic chores and machine work) would correspond to 9.36W.

Using this information, they decided to evaluate the system using 10 thermistors (MA100, NTC Thermistors, GE sensing ±0.1˚) placed on the wall of the bucket. They simulated sedentary activity for 15 minutes, 30 minutes of standing light activity and a further 15 minutes of sedentary activity. The constructed cooling device was run under three conditions. The first condition used a relay and a comparator circuit to simply switch the fan power between 3.3W or 0.3W, depending on the sensed ‘skin’ temperature compared to the reference temperature of 31.4 ˚C and an undefined threshold value. The second condition was to run the fan constantly at 0.3W, and the final condition was to not run the fan at all. The automatic fan scenario resulted in a constant temperature over the different thermal loads of 31.4 ± 0.1 ˚C. The constant fan condition only demonstrated an increase in average skin temperature during the 30 minutes of light activity and resulted in a change from 31.4 to 31.9 ˚C. This skin temperature value did not return to the initial temperature when a sedentary thermal load value was applied again. Finally, with no fan on, the surrogate skin temperature increased from 31.4 ˚C to 32.6 ˚C. This experiment demonstrated that this system had a cooling capacity between 2.1 – 7.0 W at a room temperature of 23 ˚C.

Han et al. progressed their work by creating a new system that replaced the fan system with an array of water channels coupled to an ice pack, where the ice pack acted as a phase change material [90]. By changing the volume of water in the water channels, a greater amount of cooling could be achieved. The water volume change was controlled by a syringe pump and a Boolean logic programme. In contrast from their previous experiment, to represent thermal loads, they decided to simulate walking on level ground at 2 km/h (a thermal load of 8.4 W) and walking on level ground at 5 km/h (a thermal load of 15.3 W). To test the efficacy of the systems, they conducted two phases of experiments. The first phase was to apply a corresponding thermal load for 90 minutes with either no cooling device or an automatically regulated cooling device. In this test, when applying an 8.4 W thermal load, the temperature increased to 34.6 ˚C with no cooling but was maintained at 31.4 ± 0.2 ˚C with cooling. When a 15.3 W thermal load was applied, temperature increased from 31.4 ˚C to 38.3 ˚C but was maintained at 31.4 ± 0.2 ˚C with the cooling device.

In the second phase of research, Han et al. used the same study protocol as in their previous study and ran experiments with 30 minutes of simulated slow walking (at 2 km/h), 30 minutes of fast walking (at 5 km/h) and a final 30 minutes of slow walking (at 2 km/h). In a no cooling scenario, the simulated skin temperature increased from 31.4 ˚C to 35.8˚C. In a scenario where thermal resistance was limited to an 8.4W of cooling capacity by opening 1.2 channels of water, temperature was maintained at 31.4 ˚C for the first 30 minutes but rose to 32.8 ˚C in the fast walking period. In the last slow-walking period, the simulated skin temperature decreased to 32.4 ˚C. Finally, in a scenario where thermal resistance was automatically controlled, skin temperature was able to be maintained at 31.4 ± 0.2 ˚C throughout the entire experiment. Ultimately this system improved the cooling capacity of their previous system from 2.1 – 7.0 W, to between 6.6 – 15.6 W.

The proposed solutions described here show that progress is being made in terms of attempts to address the problem of heat and sweat discomfort. It is a positive step to see solutions enter the market, particularly a solution such as the Alpha SmartTemp liner that can be practically integrated into existing prosthetic systems. However, it is fair to say that although these systems demonstrate different ways in which prosthesis thermal discomfort could be addressed, none have comprehensively solved the problem. The SmartTemp liner has yet to demonstrate its efficacy in a real-world, long-term study, and the magnitudes of temperature changes whilst significant, remain small. The active solutions proposed by Ghoseiri et al. and Han et al. [83,84,89,90] provide an alternative approach, with solutions by Han et al. seemingly able to cope with conditions such as walking at 2 km/h and 5 km/h [90]. However, the real-world practicality of these systems is highly questionable due to the necessity of mobile power sources. Although one system [89] was proposed to have a battery life of between 2.7 – 17.7 hours, the requirement of extra weight to power the devices reduces the feasibility of the devices. The proposed solutions also weigh between 415 – 550 g (with one requiring a 166 g ice pack that would need hourly changing [90]) without any power supplies. It is difficult to see how these devices could be integrated into current prosthetic systems without negatively impacting wearing experience.

Although there have been multiple lab studies and one field study exploring limb temperature and PTC, it is not clear how this base research has been used to proactively improve the development of thermally comfortable prosthetic devices. Prior studies had been short (on the timescale of hours at most), with few lower-limb amputees (usually less than 10 participants) who were exclusively male transtibial amputees. Therefore, to progress understanding of prosthesis thermal discomfort, longer-term real-world research protocols must be considered as a priority, with the acceptance of transfemoral amputees, and females as participants. Further work should also have a grander aim to not just produce exploratory research, but to ensure that research can be converted into tools that bridge the gap from research to prototype and real-world solutions for amputee thermal discomfort.

4 METHODOLOGY AND METHODS

In this chapter, the concepts of methodologies and methods which are relevant to this thesis are introduced. Here, the selected methodology and rationale for choosing said methodology are formally stated, before studies implementing specific methods are presented in later chapters.

4.1 Methodology

When the aim of a thesis is to work towards a knowledge contribution, it is useful to clearly identify an appropriate philosophical epistemology to provide context to a constructed interpretation. Though there are many different stances a researcher can adopt- with epistemology representing an active research field in its own right- conventional research will *typically* conform to a (post)positivist, constructivist or pragmatic epistemology. Positivist research takes the view that objective ‘truth’ can be found [19]- though positivist research has been largely superseded by postpositivist research, which acknowledges that we cannot be certain about our understanding of human behaviour [48]. Postpositivist research predominantly focuses on the careful observation of objective measurements, which are used to test or reject hypotheses and theories. This epistemology is often thought of as mostly aligned with quantitative research, where knowledge is constructed with the assistance of statistical analysis with the aim of reducing the complexity of phenomena [48]. Constructivism instead aims to preserve the complexity of human perspectives, where subjective meanings developed by individuals are used to generate theories or patterns of meanings. Therefore, a constructivist approach is often thought to be exploratory, addressing broad questions and most often used for qualitative research [19,48]. An alternative epistemology to both postpositivism and constructivism is pragmatism. A pragmatic approach instead places the research problem as central and all methods (whether qualitative or quantitative) can be used, providing they work towards answering, understanding or deriving knowledge relating to the research question [48,224]. Rather than concerning themselves with a base rule of philosophy or reality, the pragmatic researcher focuses on whatever *'truth'* works at the time, regardless of how that '*truth'* was determined and believes that the best method is the one that solves the problem [48].

When the topic of this thesis is considered, prior research has predominantly been postpositivist and quantitative. Parred down to simple terms, prior research has established that upwards of 50% of prosthesis wearers will experience thermal discomfort at some point [82]. However, we have not established under what circumstances discomfort arises, how intense thermal discomfort can be, how frequently thermal discomfort arises, and what the consequences of the discomfort are. Therefore, there remains an opportunity to explore thermal discomfort using methods which can capture the lived experiences of prosthesis wearers in rich detail.

Lab-based research has established that residual limb temperature change can range from 1.7 – 3.7 ˚C during a period of ambulation at a self-selected pace [110,130,183]. Hypothesis testing has also lead to establishing that physical activity does lead to significant increases in limb temperature [130]. However, as pointed out by Chu and Wong [40], highly controlled prosthesis related lab-based research does not represent the real-world function, nor activities that prosthesis wearers experience. Therefore, it is contentious to assume that a phenomenon can be appropriately captured, explored, discussed and understood when the phenomenon is explored in an unnatural setting and context.

Finally, researchers have begun developing powered cooling and heating solutions which assume that thermal discomfort is solely dependent on residual limb temperature. However, these are being designed out of context- aiming to solve a felt, subjective human phenomenon by maintaining only one objective measure of temperature. For a phenomenon as subjective and complex as thermal discomfort, basing solutions on the control of just temperature without prior exploration of thermal discomfort in relation to subjective and objective experiences presents a risk of developing ineffective solutions.

4.1.1 Thesis approach

Rather than constructing knowledge with objective quantitative sensor measurements and hypothesis testing as the predominant way of understanding, in this thesis, the phenomenon as experienced by prosthesis wearers' is central and augmented by objective sensor measurement where appropriate. Additionally, wherever practical, logical and safe to, research has strived to be conducted in natural real-world settings and to focus on how thermal discomfort is experienced in a real-world context. In doing so, this thesis represents a novel approach to exploring thermal discomfort amongst prosthesis wearers. This thesis adopts a mixed-methods approach to holistically and flexibly explore the research question. Therefore, an understanding of thermal discomfort using a necessarily pragmatic epistemology is constructed. Research has been structured as a convergent parallel mixed-methods design. The thesis finishes by constructing an overall interpretation based on the three studies, before translating the interpretation to implications for developing solutions to thermal discomfort for lower-limb prosthesis wearers.

4.1.1.1 Study 1

The first study (Chapter 6) acted as the first exploration into the phenomenon. To do so, a qualitative study was conducted, centring around the wearing experience of a prosthesis, with a particular focus on heat and sweat discomfort. A combination of semi-structured interviews and blog data were used to create a data corpus, and thematic analysis was used as the analytic method to interpret the data.

4.1.1.2 Study 2

The second study (Chapter 7) aimed to replicate and extend the status quo of quantitative research studies within the topic of amputee thermal discomfort, by conducting an in-lab study and an out of lab study. However, in the out of lab component of the research, sensor data were supplemented with self-reported perceived thermal comfort data. Though not a full deployment of the experience sampling method, self-reporting PTC acted as a step towards placing human perspectives at the top of the 'data hierarchy' when analysing in combination with objective sensor data.

4.1.1.3 Study 3

The final study (Chapters 8,**Error! Reference source not found.**, and **Error! Reference source not found.**) was designed as an embedded mixed-methods design. To implement a mixed-methods approach, entrance and exit semi-structured interviews were used to ‘sandwich’ a predominantly quantitative real-world longitudinal study. During the longitudinal study, participants were asked to wear sensors which provided an objective reflection of factors such as skin temperature, ambient conditions and activity indicators. However, quantitative data were augmented with an implementation of the ESM to collect perceived thermal comfort data which was tagged with the participants’ self-reported activity and location at the time of reporting.

4.2 Methods

4.2.1 Quantitative methods

When conducting quantitative research, the focus of research is most often to test theories which describe relationships between objective, measurable variables [19,48]. These collected data are often evaluated using statistical methods to determine if the proposed hypothesis should be accepted or rejected and revised. Quantitative research can also be conducted to identify correlations between variables [47] and can be conducted in a more exploratory manner. However, statistical methods are still utilised to identify patterns of correlations.

4.2.1.1 Statistical methods

The modern researcher has access to a vast number of statistical methods that range from simple descriptive statistics to complex statistical learning models. Although these are all applied with relative ease thanks to software packages, the vast majority of statistical techniques expect tens to hundreds of participants to make up a suitable dataset for statistical interrogation. However, disability research studies often have the common trait of relatively small participant numbers [185] in most cases a participant sample size larger than 10 participants could reasonably be considered a standard dataset. Therefore, whilst advanced statistical methods could be applied, the subsequent analysis would have limited conceptual validity and minimal generalisability. Therefore, in this thesis, a prudent approach is taken to statistics, where basic descriptive statistics are employed as the predominant approach to statistical analysis, with most analysis limited to within-subject statistical interrogation.

4.2.2 Qualitative methods

Oftentimes, the *'scientist's'* or *'engineer's'* approach to designing solutions to problems is to interrogate the phenomenon using quantitative strategies. However, whilst quantitative research can be used to create an objective foundation of knowledge by testing hypotheses, a purely quantitative investigation of human phenomena leaves researchers at risk of constructing a shallow understanding of the topic of interest which is abstracted from the human. When '*problem*' phenomena are explored with the aim of converging towards solution design, researchers such as Dourish [57] argue that designers (or researchers acting as designers) must have a rich understanding for the situation which they are designing for. Qualitative data provides an opportunity to collect data which is usually exploratory in nature whilst being rich and varied [19]. Qualitative data sources also acknowledge and take advantage of the concept that through living their lives or experiencing a particular phenomenon, participants should be considered as experts in the topic of interest [19]. In this thesis, exclusive use of quantitative data types would exclude the point of view and lived experience of prosthesis wearers. Therefore, studies in this research make use of qualitative methods when appropriate, to ensure that human perspectives are central to the constructed knowledge contribution.

4.2.2.1 Interviews: semi-structured interviews

One of the most used methods to collect qualitative data is to conduct interviews. Interviewing as a method can broadly be separated into three categories- either as a structured, semi-structured or unstructured interview. In structured interviews, an interviewer will use a predefined set of questions which will be sequentially worked through over the course of an interview. In contrast, unstructured interviews will often focus on a broad topic, but the exact direction of the discussion will naturally evolve over the course of the interview. Semi-structured interviews are a combination of the two [189], where an interview guide is used to provide consistency and structure to the discussion, however, naturally occurring or unexpected topics of interest can be explored in greater detail [19].

The method of semi-structured interviews is particularly relevant to this thesis' topic of thermal discomfort as it is a method which works best when the focus is on peoples' perceptions and experience [19,188]- particularly events which are hard to observe or infrequent [188]. Semi-structured interviews are also selected as structured interviews can be overly restrictive, given limitations to explore topics which arise unexpectedly [19]. As this thesis is exploratory and given how little is known about thermal discomfort amongst prosthesis wearers, a degree of methodological freedom is needed to ensure the unexpected can be appropriately explored. However- as the topic is not completely unknown, it is reasonable to create an interview guide based on pre-identified topics of discussion, rather than a completely unstructured approach.

4.2.2.2 Blogs

One additional form of qualitative data which is relatively easy to access are found sources such as blog data. Existing sources are an excellent way for researchers to build up an understanding based on data which can be considered as background material [19] and as a source which has not been influenced by researcher motivations. However, when using pre-existing sources, although data can usually be collected at scale, appropriate filtering is needed to construct a manageable and relevant data corpus. Therefore, it is important that researchers' transparently and rigorously apply inclusion and exclusion criteria to the collected data [19]. Additionally, as the data is not collected in an interactive way, researchers do not have the ability to ask further questions and are instead limited to data as it is presented [19].

4.2.2.3 Braun and Clarke's Thematic analysis

To analyse the collected qualitative data, Brain and Clarke's Thematic analysis (TA) was used [24]. TA is a process which seeks to identify patterns of experiences [33], and as an analytic process, it is flexible across a multitude of theoretical positions [19], and is accessible and easy to teach and learn [42]. Although there are many analytic methods- for example, interpretive phenomenological analysis [59]- TA is flexible enough to support a phenomenological focus [25,197]. Prior to the study presented in Chapter 6, I had no prior experience in analysing qualitative data and as TA was accessible yet rigorous and flexible, it seemed to be an ideal analytic method to use. Braun and Clarke's Thematic analysis requires researchers to follow a 6-step process:

1) Data familiarisation: researchers should ensure they are familiar with the data corpus by reading or listening to the data corpus multiple times, whilst making basic analytic notes.
2) Coding: once researchers feel that they are familiar with the data corpus, data should be reviewed once again. However, this time researchers create labels

(codes) which represent features of the data, and data which is pertinent to the research question.

3) Theme creation: the data and codes are reviewed once more, and researchers begin to actively code themes. Themes can encapsulate multiple codes and related data and are created- not revealed- by researcher interpretation.
4) Theme review: after a preliminary set of themes are created, they must be reviewed. Researchers must ensure that the themes are compatible with extracts of the data corpus, as well as the data corpus in its entirety. Existing themes may be merged, split or discarded; however, the aim is to ensure themes provide a compelling narrative which reflects the data.
5) Theme formalisation: themes must then be described in detail by researchers with a focus on the internal narrative of each theme. Themes may also need to be renamed, to ensure each have a ‘concise, punchy and informative name’ [42].
6) Write up: the analytic narrative must be written up as part of the process to ensure a coherent and persuasive story is presented, which is situated both in the collected data and also pre-existing literature.

Braun and Clarke highlight that the process is iterative, not linear and analysis often requires researchers to go back and forth between steps as required until a compelling, yet rigorous and honest analysis has been conducted.

4.2.2.4 Experience sampling

The experience sampling method (ESM) is a method which helps researchers to study what people ‘do, feel and think during their daily lives’ [136] by asking participants to report information, at either random or regular time intervals or upon a particular event occurring [215]. The ESM is flexible and has been used to research diverse study topics and phenomenon, varying from heroin abuse to mental health issues and arthritis [99]. Most ESM entries are recorded on paper, disposable or digital cameras, or more frequently, via phones and smartphones [15,30,66,222]. Recently, wearables have also been used to implement ESM [102]. The major advantage of ESM over self-reporting historical experiences of phenomena is that typical memory biases attributed to self-reporting can be avoided [170].

However, ESM requires participants to input data themselves, a task which can be viewed by participants as time-consuming and demanding [170]. Therefore, it has been recommended that ESM tools should aim for each user input to take less than 1 minute to complete (and a maximum of 2 minutes) to minimise disruption to participants lives [52]. If self-report requests are sent too frequently, participants may experience personal notification overload [41] ,which can lead to personal annoyance and disturbance, as well as unwanted attention during normal activities. These issues can result in low rates of report completion or outright withdrawal from a study [215]. However, reducing data input barriers [240], context-aware notifications [163], sampling frequency [106], the device used [15,30,102,222], study personalization [152], data visualization [108] and recruitment compensation [94] have been shown to influence the quantity of data collection. Therefore, when implementing the ESM, it is important to devote time and consideration into appropriately designing and implementing the ESM.

4.2.3 Mixed-methods

Qualitative and quantitative methods, whilst epistemologically different, have the same goal of building relevant and applicable theories by rearranging the intricacies of raw data [137]. Additionally, although some have argued that qualitative and quantitative methods are fundamentally incompatible [224], others consider them to be at different points on a continuum of research approaches, rather than polar opposites [173]. Regardless of the differences, similarities or incompatibilities, principled combinations can strengthen research quality [33,101] by acting as an antidote to bias and weaknesses inherent to either approach [48]. A mixture of methods also enhances research by providing a methodological triangulation, wherein multiple methods converge upon a common understanding of the investigated research topic [117,122].

Mixed-methods research is increasingly popular in a variety of research fields [224], and has even been applied to prosthetics to explore prescription practices [209]. Mixed-methods research necessarily adopts a pragmatic epistemology [48]. Definitions of mixed-methods research often state that a research project must include elements of qualitative and quantitative research to improve breadth and depth of understanding and corroboration [121]. However, others state that researchers should structure how and when methods are used and how methods are used in relation to one another, by using predefined types of mixed-methods research designs [48,119]. The four most common mixed method structures are defined by Creswell et al. [48,119] as:

Convergent parallel: Researchers collect qualitative and quantitative data (at approximately similar times), and an interpretation is constructed using both data types.

Explanatory Sequential: Quantitative data are collected and analysed first, and qualitative data are then collected as a way of exploring the results in greater detail.

Exploratory Sequential: Qualitative data are collected first to either understand the research topic in greater detail, to identify experimental variables, or to develop a quantitative research instrument. A follow up quantitative study is then conducted, and an interpretation of data is constructed.

Embedded procedures: Qualitative or quantitative data are collected alongside the opposite data type; however, data are collected at the same time and are embedded within a study which is either qualitative or quantitative. An example would be a quantitative experiment where participants are interviewed whilst subjective sensor data is collected. Both quantitative and qualitative data are used to develop an interpretation; however, the researcher must decide if the data types should be given equal or unequal weighting when developing their interpretation.

5 DESIGN EXPLORATION

Parts of this chapter have been published in *Rhys James Williams, Elaine Denise Washington, Mark Miodownik, and Catherine Holloway. 2017. The effect of liner design and materials selection on prosthesis interface heat dissipation. Prosthetics and Orthotics International. https://doi.org/10.1177/0309364617729923*

Prior research suggested that increasing the thermal conductivities of interface components could prevent thermal discomfort. Therefore, this ‘solution-orientated’ approach is researched in this chapter, before exploratory research investigates the research question central to this thesis.

This hypothesis was first suggested by Klute et al. [128] after the thermal conductivity of 23 liners and 2 sockets were found to be between 0.085-0.266 W/m°C, showing that many of the materials currently in use are not compatible with the aim of achieving heat transport away from the prosthesis interface. Klute et al. [128] also suggested that the liner is more crucial to improving heat transport than the socket material, as it is often the thickest component of the prosthetic. To improve heat transport, changes could be made to the surface area of the interface, the thickness of interface materials or the thermal conductivities of interface materials. However, the prosthetic interface is of a fixed surface area and reducing the thickness of components will compromise mechanical and cushioning performance. Therefore, the only feasible way to achieve an increased level of heat transport at the prosthesis interface is to increase the thermal conductivity of the interface materials. As changes to interface materials could yield a solution to the problem that could be integrated into existing prostheses with relative ease, it made sense to test the hypothesis presented by Klute et al. before conducting any other research.

This chapter presents a research study which aimed to find out if changing interface materials to materials of higher thermal conductivities could be a practical, real-world solution to prosthesis thermal discomfort. Therefore, this chapter begins by finding materials that could be used at the prosthetic interface with higher thermal conductivities than currently used interface materials were found. As it was suggested that liners had a much larger effect on heat dissipation in comparison to the socket component, liner materials were the focus of this design exploration. These identified materials were thus used to create prototype liners. These prototypes were then evaluated under laboratory conditions with a novel protocol to assess their thermal dissipation potential. The data collected was then used to come to a conclusion of if the suggested solution would lead to a practical solution worth further development, or if further research was needed to further specify the problem space.

5.1 Method

5.1.1 Material Search

A material database search for commercially available elastomeric materials with a thermal conductivity above 0.266 W/m°C was carried out. This value was selected as it represented the highest thermal conductivity of liners currently on the market, as found by Klute et al. [128]. In addition, Shore hardness was used also used as a filter and materials with a Shore A hardness between 0-20 and a Shore 00 between 0-60 were included. This captures materials within a similar range to prosthetic liners, varying from ultra-soft gel liners (Shore 00, 0-30) to durable silicone and polyurethane liners (Shore A, 0-20). Both hardness scales were used as materials can be characterised using either the A or 00 scale to describe the same material softness. Figure 3 presents an overview of the typical materials that exist around these criteria and highlights the lack of materials that exist within these criteria.

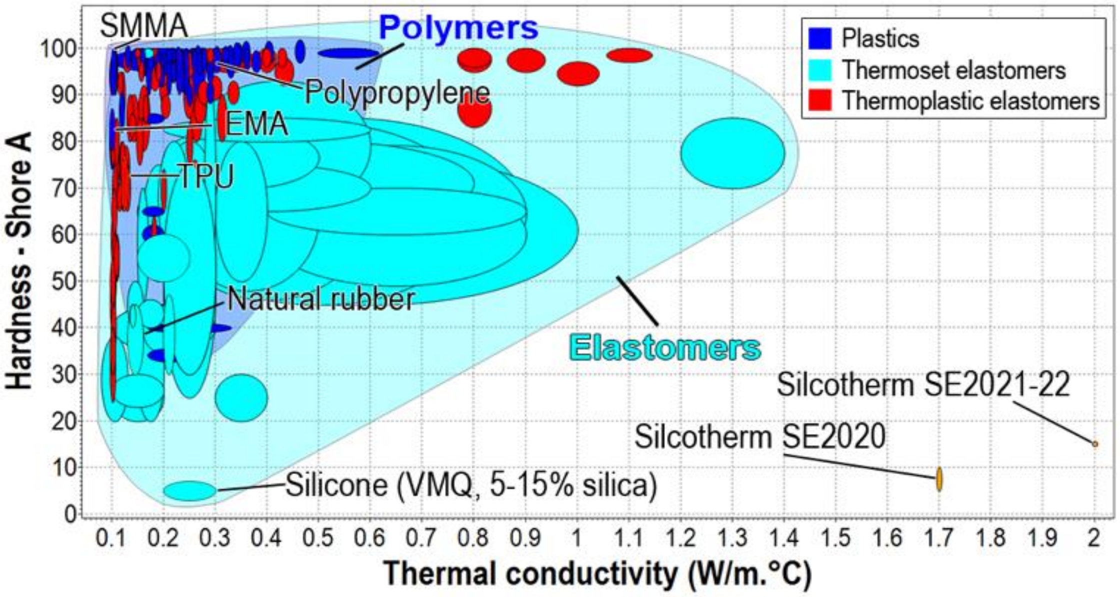


Figure 3: Bubble plot indicating currently available materials within ranges of Shore A hardness, and thermal conductivity.

The Silcotherm materials (ACC silicones, United Kingdom) were the only three materials that had potential to be used in this application (Table 4). These materials possess a thermal conductivity of between 1.7-2.0 W/m°C and a Shore A hardness between 5-15 and only liquid samples of the SE2010 material could be sourced. at a cost of nearly £70/50mL.

Table 4: Silcotherm materials are potential liner material candidates as they feature a high thermal conductivity and could be moulded. MTL: mini thermal liner; MHL: mini hybrid liner; MPL: mini plain liner; MOL: mini open liner.

Material	Thermal conductivity (W/m˚C)	Shore 00 Hardness	Liner scenario
Silcotherm SE2010	1.7	50	MTL and MHL
Silcotherm SE2020	2.0	62	-
Silcotherm SE2021	2.0	62	-
DragonSkin 10	Not provided	55	MPL, MOL and MHL

Only SE2010 was purchasable. Dragon Skin 10 was also used for any low-conductivity parts, though the thermal conductivity of this is unknown. It is likely to be between 0.14 and 0.35W/mC. Materials in bold were used in this study.

5.1.2 Design

The high cost meant that mini liner designs were preferred over full-sized prototypes, as this was not believed to significantly alter the underlying thermodynamics. In order to physically create these prototypes, digital models were made using computer aided design package, Rhinoceros Version 5.0 (Robert McNeel Associates, USA). A simplified conical surface that represented a residual limb was made, and ‘mini’ liners were designed to fit this shape. All liners were designed with a wall thickness of 3mm. This thickness represents some of the thinnest prosthetic liners that are commercially available. To create the more complex open and hybrid liners, an algorithm was created using Rhinoceros plugin Grasshopper that could auto-populate the surface with preselected geometries. Using this algorithm, it was possible to define the shape, size, position and number of geometric elements on the mini liner surface. Element density was used to quantify designs and was defined as the surface area of geometric elements, divided by the surface area of the external liner surface as a percentage. After experimenting with the algorithm, an elliptical element geometry and an element density of 30% was decided on (Figure 4). Densities exceeding this produced many overlapping elements. The algorithm could have been modified to include collision prevention, but it was thought that densities exceeding 30% would likely tear during de-moulding due to the decreasing amount of silicone between elements.

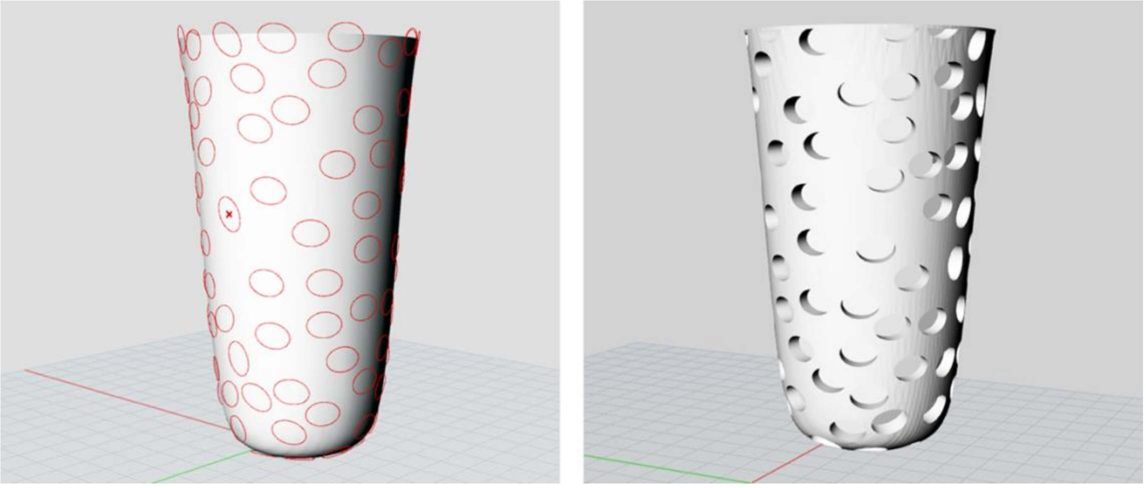


Figure 4: Using Rhino and Grasshopper, ellipses were programmatically placed onto the mock liner, and subtracted from a solid shape to create an open liner.

5.1.2.1 Fabrication

Master parts were 3D printed using a Form 1+ (Formlabs, USA) in a clear photopolymer. A conventional two-part mould was created, and the 4 mini liners were cast in DragonSkin 10 Fast (SmoothOn, USA) for the MPL and MOL, SE2010 for the MTL, and both silicones for the MHL. To cure, the SE2010 silicone was placed in an oven at 100°C for two minutes, and the liners using conventional silicone were cured for 75 minutes at room temperature. The parts were subsequently demoulded, and excess flashing was removed with a scalpel. SE2010 was difficult to mould, which meant that the MTL required minor surface repairs that added up to 1 mm to the thickness in those locations (Figure 5).

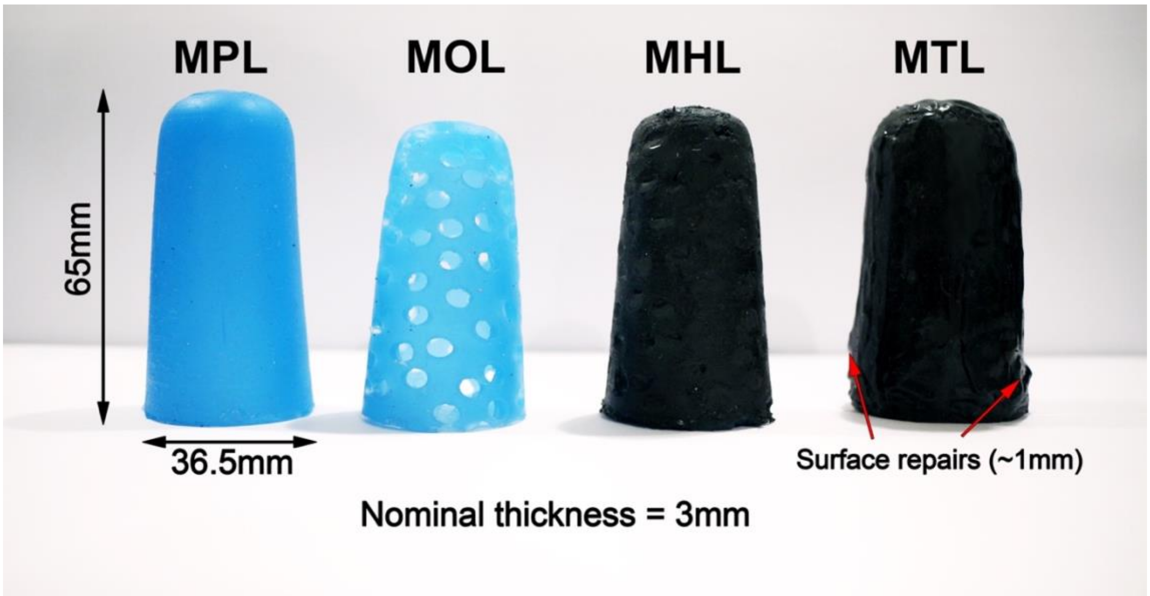


Figure 5: 4 prototype mini-liners were caste in various silicones and designs, coined the mini plain liner (MPL), mini open liner (MOL), mini hybrid liner (MHL), and mini thermal liner (MTL).

5.1.2.2 Tissue Phantom

Due to the early stage of this research, a controlled silicone limb phantom was used to test the effect of each liner scenario on heat decay, rather than an amputee’s residual limb. It was designed so that the base temperature profile of the interface due to the phantom would be the same in each experiment. This approach, although much more simplistic, removed physiologically related temperature variations [128] which would have been difficult to control. The homogeneity of the silicone phantom meant surface temperature was approximately the same over the entire surface. This differs from residual limbs, which have locational temperature differences due to anatomical features [182]. This extra layer of control meant that the average surface temperature data could be used in the analysis. Microwaving heating was used as it quickly heated the phantom volume, not just the surface and has been used previously to heat limb phantoms [104].

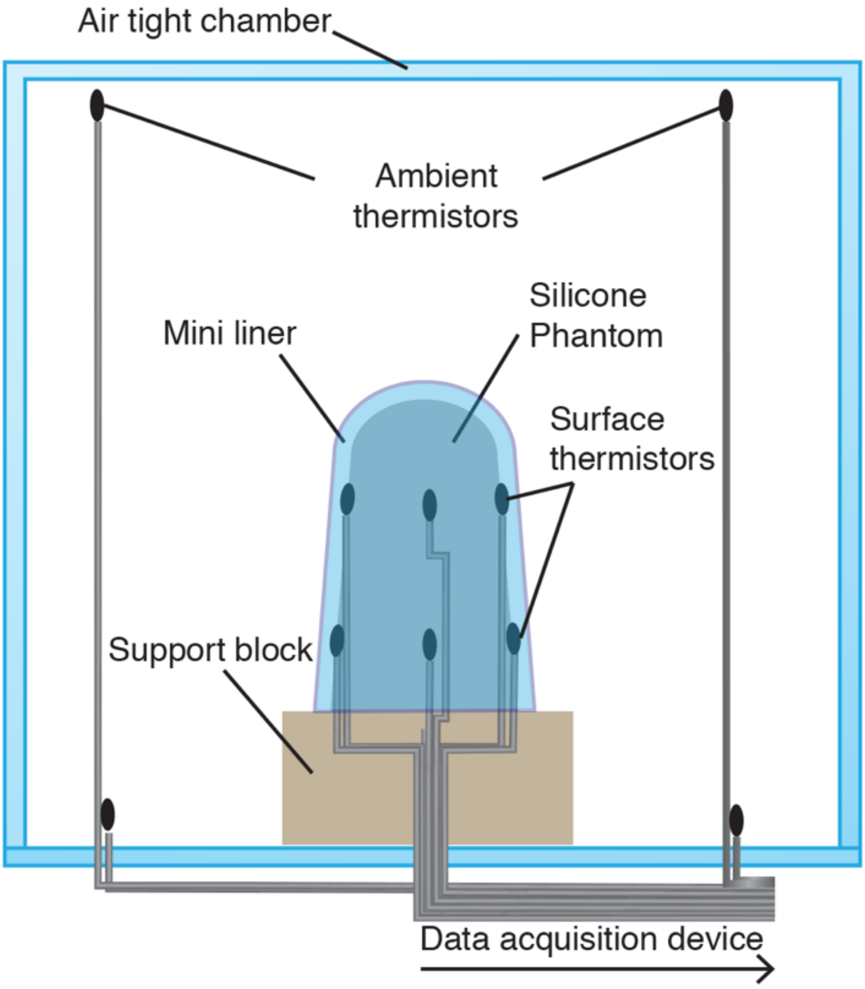


Figure 6: An air-tight chamber was created and instrumented with sensors to conduct the experiments in a controlled environment.

5.1.3 Experimental Procedure

Each test began by irradiating the phantom for 45 s in a category D 700-W microwave and attaching eight thermistors using Kapton tape (DuPont USA). Thermistors were evenly spaced around the perimeter of the phantom, with four on the upper and lower halves, respectively (Figure 6). Room temperature liners were rolled over the thermistors and phantom, and then placed into an acrylic box (Figure 6) and data were collected for 35 min. The time from removing the phantom, post-heating, to donning the liners was under 30s. Thermal grease was not applied to maintain similarity with the natural prosthesis interface. Eight thermistors recorded ambient conditions inside the box, and each scenario was repeated seven times to enable easy recognition of anomalous data, though the number of repetitions was arbitrary.

5.1.4 Data logging system

Data were collected with an Arduino Mega 2560 (Arduino, Italy), as it supported 16 analogue inputs, which were connected to sixteen 10-kΩ B57863S103F40 negative temperature coefficient (NTC) thermistors (Epcos, Germany). The Arduino was interfaced and programmed using LabVIEW 2015 (National Instruments, USA) and the LabVIEW LINX interface. Data were acquired at 2 Hz and stored on a connected laptop. This acquisition rate is above the thermoregulatory response time, which is an order of multiple seconds [198] and lies within the range of other prosthesis temperature studies (0.125–4Hz [110,130,183]). Thermistors were each connected to a potential divider, supplied by a 5-V direct current (DC) laboratory power supply and calibrated using the Steinhart–Hart equation, resulting in an accuracy of ±0.2°Cbetween 0°C and 70°C.

5.1.5 Analysis

After microwaving, the phantom was much hotter (>50°C) than skin. Thus, when the phantom registered 33.0 ± 0.1°C, the time was recoded as t = 0, to represent the highest temperature found post-exercise for transtibial amputees, in three studies [110,130,183] to the nearest integer. The average of phantom surface and ambient data was calculated (one ambient thermistor broke and was excluded).

Equation 6:

$$\boldsymbol{P} = \sum_{\boldsymbol{n}=\boldsymbol{0}}^{\boldsymbol{120}} (\boldsymbol{T}_{\boldsymbol{n}} - \boldsymbol{T}_{\boldsymbol{n}+\boldsymbol{1}})$$

Despite the airtight chamber, some coupling existed between ambient and phantom surface data. To remove this coupling, the difference between surface and ambient temperature data was calculated. Equation 6 was used to find the surface temperature decay, P, after a noise-reducing 60-second moving average filter was applied (filter window = 120 samples at a collection rate of 2Hz). This metric shows changes in phantom surface temperature in one minute during the experiment. This data was used to plot 1_{st}-

degree polynomial correlations using Matlab 2014a (Mathworks, USA) for each of the liner scenarios.

5.2 Results

The data collected was used to produce 1st-degree polynomial correlations after applying equation 2. Figure 6 displays these correlations. All fitted curves (figure 6) possess a high coefficient of determination (R_2) (Table 5) and evenly distributed residual plots. The real benefit of this analysis is it enabled all data collected both in repeat experiments and different liner scenarios to be compared. When the 35 data sets (7 experiments for the 5 liner scenarios) are combined and processed, a more general understanding of the effect each liner type has on the phantom temperature decay is provided. The no liner scenario demonstrated the greatest dissipation per minute, per ˚C of ambient-phantom temperature difference.

Table 5: The dissipation gradient for each scenario's correlation is presented. All fits possess a high coefficient of determination (R2) and evenly distributed residual plots.

	No Liner	MOL	MPL	MHL	MTL
Dissipation per minute, per ΔT	-0.07	-0.06	-0.05	-0.05	-0.05
R_2	0.97	0.97	0.99	0.98	0.98

With the effects of ambient temperature coupling removed and after visually inspection of Figure 7, the MHL appears to provide superior dissipation performance over the MPL scenario. The MTL, on the other hand, had approximately similar dissipative performance when compared to the MPL. However, when reviewing the dissipation gradients in Table 5, the performance difference between each liner, however, is minimal, and each scenario (excluding the no liner paradigm) performed similarly. It is not surprising that the correlations suffer from accumulated uncertainties that result in indistinguishable dissipation gradients between the hybrid, plain and thermal liner designs. It is possible to say however that the open liner scenario had a dissipation gradient that was closest to the no liner paradigm. To contextualise the data presented in Table 5 if the MOL was used in an ambient temperature of 20°C, with a phantom surface temperature of 30°C, the phantom surface will be able to decrease by 0.6°C per minute.

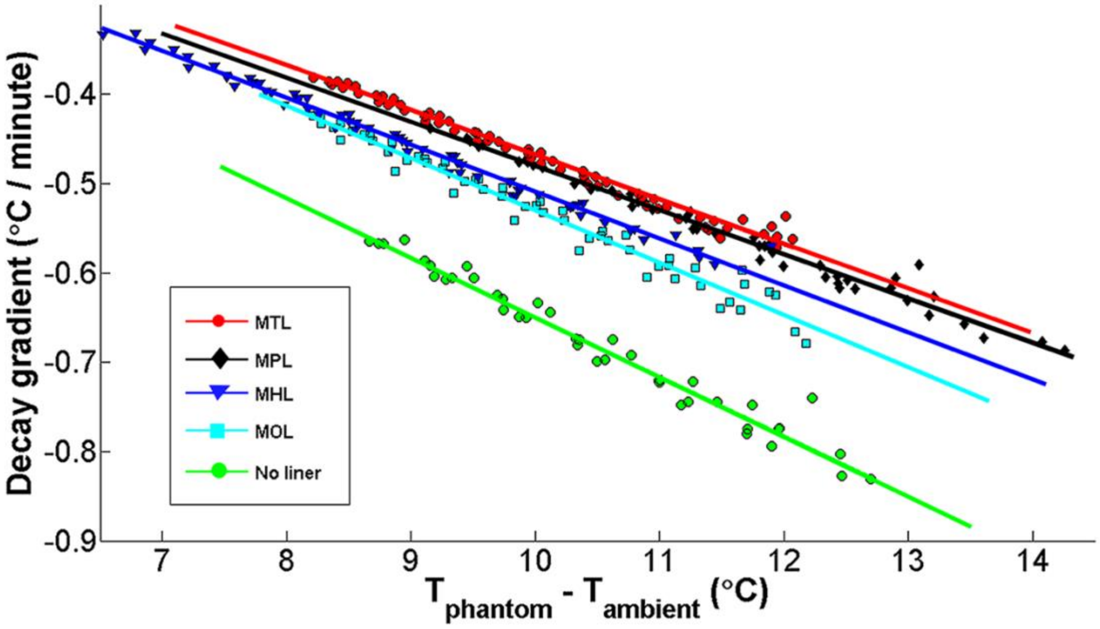


Figure 7: Temperature difference between phantom surface temperature and ambient temperature, vs the decay gradient was plotted to asses thermal performance of liners.

5.3 Discussion

Open elements were the most effective at increasing heat dissipation when compared to the other prototype liners. However, an open liner design with large open elements, such as those on the MOL, may be impractical in real-world use. The first concern is that open elements would likely lead a reduction in durability and also make donning difficult without stretching the liner and therefore introducing shear forces to the skin surface. When wearing a liner with open elements, skin could also bulge into the open elements under loading, causing high forces to be applied to the skin at the edges of the open elements.

Even if the MTL or MHL had provided significant increases in dissipation, by physically fabricating a prototype, it is possible to see that the material used would likely be inappropriate for a number of reasons. The first is that Silcotherm SE2010, although a silicone rubber, is mechanically different from most conventional silicones. It is much more prone to tearing under elongation (as demonstrated in demoulding of the MHL) than standard silicone. SE2010 also has a density which is nearly three times more than conventional silicones (2.7 kgm$_{-3}$ vs approximately 1.0kgm$_{-3}$). This difference in densities is fundamental to silicones with higher thermal conductivities, as higher thermal conductivities are achieved by filling the silicone with dense conductive metallic or ceramic powders. These filler materials therefore unavoidably add extra weight to the silicone mixture. In study 1, prosthesis wearers indicated that excessive weight of the prosthetic was a determinant of negative wearing experience. A prosthetic liner which utilised a filler material such as Silcotherm SE2010 could realistically increase the weight of the average TTA liner from 446.3g [217] to approximately 1.2kg. This would lead to a weight increase of approximately 48% of the entire prosthetic limb, as the *‘average’* TTA prosthetic has been found to be 1.59kg [12]. The use of a Silcotherm SE2010 based liner would result in a prosthetic device weighing approximately 2.35kg. Given the consequences that such additional weight would have on the prosthesis wearing experience and the relation between excessive weight and device abandonment, it is unlikely that this would be acceptable to prosthesis wearers. The argument remains that a thermally conductive silicone may exist or be created without material flaws exhibited by SE2010. However, even if a silicone were created with a lower density, comparable mechanical characteristics to conventional silicone and high thermal conductivity, the thermal conductivity may simply not be high enough to effectively dissipate enough heat away from the prosthesis interface to be a viable solution. Using simple thermodynamic equations, it is possible to infer that interface materials may require thermal conductivities of at least 7.4 W/m˚C, and as shown by Figure 3, this criterion exists outside of modern-day materials.

The experimental data presented here do have two important considerations and limitations. The first is that the experimental tissue phantom and liner combination deviate from a standard prosthetic by neglecting to include a simulated socket layer. This deviation, however, would not act to change the discussion, assessment and the conclusions of the presented solutions, but instead, strengthen them. The addition of a socket layer would act to increase the thermal resistance between the tissue phantom and the ambient environment. Therefore, from a whole prosthetic device perspective, the proposed liner solutions would have a lower dissipative impact than presented here. Even if the simulated socket layer were to be made out of materials with thermal conductivities above the materials which are used now to minimise the thermal barrier of the socket interface, the MTL and MHL dissipative characteristics would still be too low to be considered an improvement over a conventional liner.

Even with the limitations of this study considered, it is possible to deduce that increases to liner thermal conductivities seem to be an untenable solution to prosthesis thermal discomfort at the present day. This will likely be the status quo into the future unless there are significant and radical innovations in highly thermally conductive silicone.

There are two potential avenues for solution development. The first are passive solutions and the second are active solutions. Passive solutions aim to solve thermal discomfort by passively transporting excess heat away from the limb interface. The only other way in which passive materials could be implemented would be to adopt a similar approach to the Ohio WillioWood Smart Temp liner which implements phase change materials to store heat away from the skin. However, as has already been discussed, the efficacy of such a solution has yet to be proven. Additionally, this approach has the critical flaw that once the material reaches thermal storage capacity, the material will act as a heat source and return heat to the interface unless removed and cooled.

Prior active solutions have developed temperature regulation systems which utilise powered cooling elements such as thermoelectric cooling devices, heat sinking and fan-driven cooling. These types of systems require temperature regulation equipment to be retrofitted to prosthetic devices. This results in a bulkier and heavier prosthetic (prior active prototype solutions have weighed 415g [89] and 550g [83], excluding power supplies). However, the significant advantage compared to thermal storage solutions such is that interface heat is removed completely and transported away to the ambient environment. To be a viable real-world solution however, active solutions must be designed to minimise system weight.

Given that thermal discomfort amongst amputees was still underexplored in the prior literature, rather than continue with solution development, the research question central to this thesis was prioritised in the coming three studies (chapter 6, 7, and 8).

6 STUDY I: A QUALITATIVE EXPLORATION

> ***Parts of this chapter have been published in*** *Rhys James Williams, and Catherine Holloway. 2019. Prosthetics services: an opportunity for patient directed healthcare. In proceedings of Workshop on Unpacking the Infrastructuring Work of Patients and Caregivers around the World, CHI 2019.*

In the preceding chapters, comfort, skin health and thermal discomfort were discussed in detail to assess the impact that these factors can have on the prosthesis wearing experience as purported by literature. Specifically, a relationship between body overheating, excessive sweating, skin damage and reduced thermal comfort was identified. However, as this impact assessment has been constructed predominantly through large surveys, understanding the nuances and rich detail of *how* these factors arise or *how* they may interact with one another is not possible. With this in mind, a qualitative interview investigation would provide the required depth and richness to develop this knowledge gap.

In this coming chapter, research which explores the user experience (UX) of prosthetics and the impacts and ways in which factors of thermal discomfort interact with one another is presented. Crucially, by exploring the general everyday UX of prosthetic limbs, it was possible to focus on the second half of the research question; *what are the consequences* *of thermal discomfort for lower-limb prosthesis wearers?* More specifically, by collecting such a data set, there was an opportunity to deepen our understanding of the impact of thermal discomfort and to confirm that the literature narrative of thermal discomfort is supported by amputee experience.

To investigate the research question, this chapter presents a qualitative study comprised of data from 10 semi-structured interviews and textual data from blogs of 10 additional prosthesis wearers. However, rather than exclusively focus on thermal discomfort, the thesis examines life in general with a prosthesis to provide wider context to the issues discussed. This chapter begins by formally reporting the research method. Findings are then presented with two overarching themes which influence the prosthesis wearing experience being introduced. These two themes are subsequently broken down into further subthemes. Finally, findings are discussed by considering the implications of the prosthesis being identified as a negative factor to the wearing experience and also how technology could be used as a vehicle to foster positive experiences for prosthesis wearers. The chapter concludes with an in-depth discussion about thermal comfort. In conducting this research, the first half of the research question is addressed, by improving our understanding of life with a prosthesis and thermal discomfort, which is constructed from the perspective of prosthesis wearers. In doing so, the research community benefits from an impression of the realities of the consequences of thermal discomfort as prosthesis wearers go about their daily lives.

6.1 Method

6.1.1 Participants

Lower-limb prosthesis wearers who were aged 18-65, currently residing in the UK and receiving their prosthesis care from the National Health Service (NHS) were recruited. In theory, this ensured that all participants had the same access and standard of healthcare. Both transtibial amputees and transfemoral amputees were interviewed to provide variety to the data set, and recruitment was gender balanced. A wide range of reasons for amputation were included, however, diabetic amputees were excluded from this study. The reason for this exclusion is that, as mentioned earlier in this thesis, diabetic amputees are typically much older than other prosthesis wearer populations and will typically have multiple comorbidities which may result in complex prosthesis UX. All participants were also not undergoing any amputation related medical intervention at the time of the interviews, other than routine prosthesis maintenance. Finally, all participants were confirmed to be at least one-year post-amputation and using their prosthesis daily.

To conduct the study, departmental Ethics approval was obtained, and all participants provided informed consent. Participants were found through referrals from clinical contacts and via social media (Twitter). In total, ten lower-limb prosthesis wearers were recruited to the study. The participant sample (Table 6) was gender balanced to provide equal representation of experiences. Seven transtibial amputees and three transfemoral amputees participated. Amongst the participants, prosthesis wear was due to trauma (four participants), osteosarcoma (two participants), meningitis (two participants), congenital reasons (one participant) and complex regional pain syndrome (CRPS) (one participant). Participants ranged from 18- 65, with a mean age of 37.6. Time since amputation ranged from 13 months to 21 years, with a mean of 9.2 years. Additionally, based on the content of the interviews, participants were labelled as being either low, medium or high activity individuals. Low activity was regarded as individuals who wore their prostheses around the house and for short outside journeys. Medium activity corresponded to individuals who were able to wear their prosthesis for the majority of the day, complete activities such as commuting to work and shopping whilst wearing the prosthesis and light exercise. A high activity level corresponded to individuals who reported conducting normal everyday activities as well as intense and/or endurance exercise activities multiple times per week.

Table 6: Interview participants demographic and amputation information

Participant ID	Gender	Age	Amputation level	Aetiology	Time since amputation	Activity level
PT1	F	24	TTA	Trauma	2 Yrs	High
PT2	M	41	TFA	Meningitis	13 Mo	Medium
PT3	F	64	TTA	Osteosarcoma	17 Yrs	Medium
PT4	F	27	TFA	Osteosarcoma	14 Mo	Medium
PT5	F	18	TFA	Congenital	18 Yrs	Medium
PT6	M	24	TTA	Trauma	5 Yrs	Medium
PT7	M	44	TTA	Meningitis	21 Yrs	High
PT8	M	65	TTA	Trauma	14 Yrs	Medium
PT9	M	40	TTA	Trauma	10 Yrs	Medium
PT10	F	29	TTA	CRPS	3 Yrs	Medium

Table 7: Bloggers demographic and amputation information

Blogger ID	Gender	Amputation level	Aetiology	Activity level
BL1	F	TTA	CRPS	Medium
BL2	F	TTA	Meningitis	Medium
BL3	M	TFA	Osteosarcoma	Medium
BL4	M	TTA	Trauma	High
BL5	F	TFA	Trauma	Medium
BL6	M	TTA	Trauma	High
BL7	M	TTA	Trauma	High
BL8	M	TTA	Trauma	Medium
BL9	F	TFA	Trauma	Low
BL10	F	TTA	Trauma	High

Interview data were supplemented by written content from ten publicly available blogs that were independently written and curated by lower-limb prosthesis wearers. As with the interviews, the same inclusions criteria were used. The blogs were selected so that a gender balanced sample was collected (Table 7). The same ratio of transtibial amputees to transfemoral amputees (7:3) was obtained- though this was entirely coincidental. Aetiology was predominantly due to trauma, with one instance of CRPS, meningitis and osteosarcoma, respectively. Age was only explicitly reported in two blogs; therefore, it is not presented. Time since amputation was not consistently reported; therefore, it is also not presented. Participants ranged from low to high activity levels, but most were either medium or high, using the same perceived activity level as with the interviewed participants.

6.2 Materials

To conduct the semi-structured interviews, an interview guide was created to provide consistency to each interview. This interview guide started by asking participants basic questions relating to their prosthesis, the process of obtaining and maintaining a prosthesis, general issues experience, specific issues experienced and then ending with a *'day-in-the-life'* walkthrough. The interview guide was structured to enable participants to bring up issues that were important to them first, before being asked about specific issues such as thermal comfort, pistoning and skin issues. The full interview guide is shown in Appendix 1.

6.2.1 Procedure

Most interviews were conducted face to face (7 interviews), whereas the others were conducted via telephone. When arranging the interviews, participants were asked if they could easily get to UCL campus. For participants who could travel to UCL campus, interviews were conducted in private meeting rooms (PT2, PT3, PT4, PT6, PT8). For participants who could not travel to UCL campus but could travel to a mutually agreeable location across London, interviews were conducted in quiet cafés or restaurants chosen by the participant (PT1, PT7). In cases where a participant could not travel to London, the interview was conducted via telephone (PT5, PT9, PT10). All interviews were recorded using an audio recording device which was placed on the table in face-to-face interviews or announced to participants being interviewed by telephoned prior to commencing the interview.

Interviews started with a brief explanation of the interviewers' background and the general interest in exploring the UX of life with a prosthesis. The specific interest in thermal discomfort was not disclosed to interviewees prior to the start of the interview to prevent unintended fixation of the discussion on that specific issue. Participants were provided with the opportunity to ask the interviewer questions before commencing the interview, and informed consent was obtained from all participants. Once the main portion of the interview commenced, the interview guide was used to guide the conversation. However, if an interesting point was raised by the participant (as perceived by the interviewer), or a participant was particularly passionate about a topic, additional questions were asked. This strategy was employed to enable consistency between interviews, but flexibility to take advantage of unexpected opportunities to explore serendipitous topics in detail. The interview guide was constructed to touch on common issues known to the research team. However, rather than start by asking about specific issues, the interview guide was designed so that participants lead the discussion of issues that were seemingly important to them. This was achieved by initially broadly asking participants to share any issues that they experience. Participants were, therefore, free to start by discussing any issue of their choosing. Participant lead issue discussion was then followed by researcher lead discussion of issues from the interview guide which hadn't been mentioned. Once the interviews were almost finished, participants were provided another opportunity to ask the interviewer any questions they may have. To close the interviews, participants were thanked, and the value of their participation in the research was reiterated. Remuneration was not offered to participants in this study.

Blogs were found using the search engine Google, by searching on blogging platforms such as Tumblr and Blogger and from independently hosted blogs that were linked to

Twitter accounts. The first ten blogs found which had at least one year's worth of content were selected as part of the data corpus. To mine text data from the blogs, a Google Chrome extension called *'Save Webpage as Word Document'* (*https://www.chromeappsfactory.com)* was used. The entirety of each blog's content was extracted, regardless of relevance to the research aim (e.g. a persons' blog may include diverse topics ranging from cake recipes to experiences with a new prosthetic foot). Text data from the blogs were collated, and content reviewed once for relevance. This 'filtering' step was necessary, as some blogs were not exclusively about prosthesis wear and included other topics of interest to the blog writer. In these situations, when a blog post did not mention the prosthesis, amputation or life with a prosthesis explicitly, the blog post was removed from the data set. This reduced the number of blog entries from 443 to 202.

6.2.2 Analysis

Once data were collected, it was necessary to prepare the dataset prior to analysis. Audio recording files were verbatim transcribed first-hand and reviewed once for accuracy. Any discrepancies between the audio record and transcription were corrected. When conducting the transcription, excessive stuttering and 'umms' were removed to improve transcript readability. Slang terms and swearing were retained as removing, modifying or sanitizing the transcript could have removed personality, emphasis and emotion from the data. Analysis was conducted on the entire data corpus and after all data were collected. Data from interviews and blogs were analysed as a single combined data corpus. This approach was taken as although the data were collected in different ways, after data familiarisation, the content did not appear to be notably different. Coding and theme development were conducted using NVivo V11.0 for Mac. Braun and Clarke's thematic analysis [24] (see Section 4.2.2.3 for a detailed description) was used to structure analysis. Analysis was carried out by one person (the author) and was conducted as an inductive latent process. Coding was approached with the analytic questions of 'what influences the prosthesis wearing experience, how do these factors influence the wearing experience, and how do they arise?' Although the interview guide resulted in continuity of issues raised, influences which were serendipitously discussed were also of interest. Identified themes were iterated on 6 times by going back and forth between phases 3-5 of thematic analysis. Analysis was deemed to be *'complete'* when no more changes were made.

6.3 Findings

In total, the data corpus consisted of 10.5 hours of interview data and blog entries comprised of 149,000 words. Once analysed, two broad overarching themes were evident; termed simply as positive influences and negative influences on the wearing experience of lower-limb prosthetics (Figure 8). Subthemes which are presented can be thought of as potential influential factors that may lead to a positive or a negative experience when either fostered or encountered.

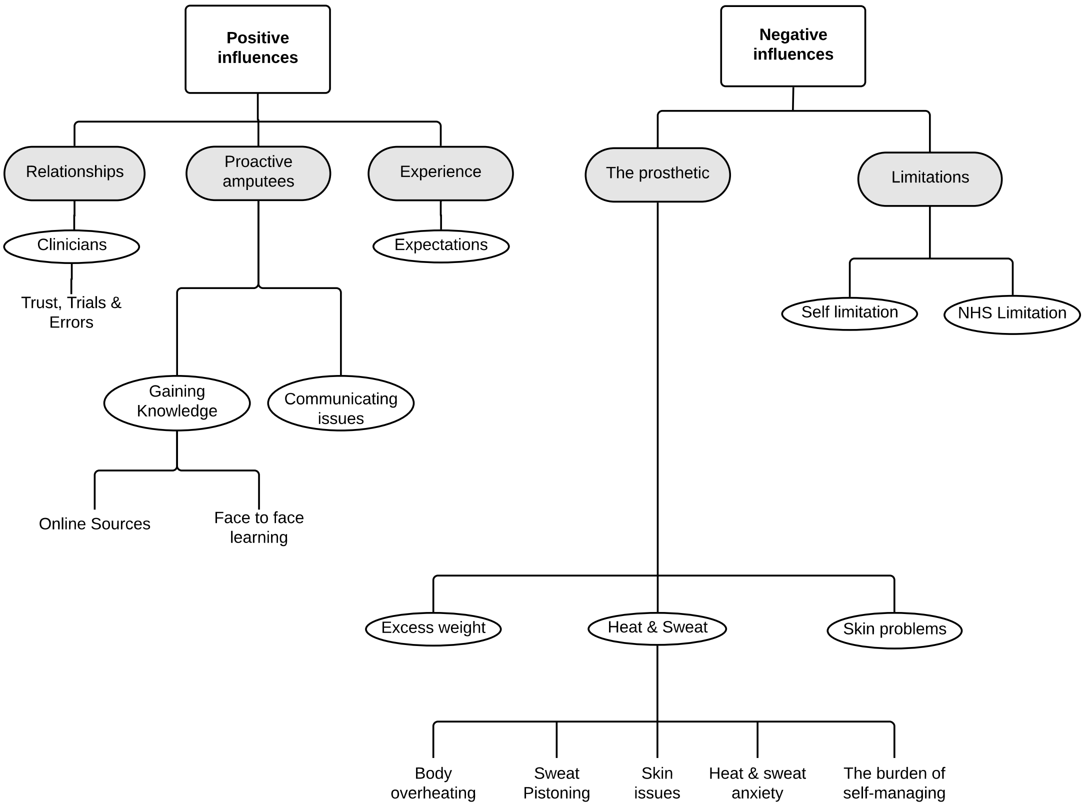


Figure 8: The themes which were identified from the data corpus were mapped out visually.

6.3.1 Positive influences

6.3.1.1 Relationships

6.3.1.1.1 Clinicians

When relationships are considered, almost all participants discussed the importance of the relationship with their prosthetist and how influential this relationship has been to their overall experience. One core element to the relationship, was a sense of trust with their clinical team.

6.3.1.1.1.1 Trust, Trial and Error

Many participants highlighted that the relationship with their prosthetist took time to evolve and develop into the current state and that they now have a clinical relationship with mutual trust and understanding.

"as time has passed, the relationship has improved and she understands that I'm gonna not accept stuff and I'm gonna be tinkering, basically. So it's like not "you cannot tinker with it" kind of now, so, I think yeah, she's actually been really good, she's taken stock of me as a person and knows that I'm not completely stupid and gonna hurt myself" PT6

Interestingly, participants and bloggers identified the importance of trial and error to improve their prosthesis wearing experience. Although viewed as a frustrating aspect of prosthetics (e.g. *"The problem with prostheses is that it's very much trial and error- so one thing that works for some people, may not work for another person" PT4),* a mutual willingness from prosthetists and prosthesis wearers to try new components appeared important to improving the prosthetic prescription. Trust in prosthetists aided this willingness to try, even if prosthesis wearers doubted the likelihood of new components efficacy was also evident (*"I'm willing to try almost anything on a short term basis even if I think it maybe a step backwards as sometimes it can be, but if you don't try you don't know." BL6).*

The end result of prosthetists that either encouraged or facilitated a trial and error approach and prosthesis wearers who trusted their prosthetists' suggestions was improved relationships (*"my prosthetist was like, yeah we'll order that and give it a go, and she'd be really good at trying things" PT1)* and improved wearing experience:

“there's other times that [my prosthetist] has said “oh I think this will work better for you.” But sometimes it's like I didn't realise how annoying the problem of my socket slipping- slipping in my socket was until the valve was put in and then we were like I don't know why we didn't do this all the time.” PT10

6.3.1.2 Proactive amputees

Some of the most positive prosthesis UXs were reported by prosthesis wearer, who demonstrated proactive behaviours.

6.3.1.2.1 Communicating issues

Prosthesis wearers who expressed that they were vocally communicative and actively led and directed clinical treatment (e.g. *“I don't hold back from saying anything, or you know voicing any concerns or anything like that” PT2)* reported interactions with clinicians generally as more positive, with better outcomes. The importance of proactive communication in order to receive improvements to the prosthesis was neatly demonstrated by PT10 as a result of finally discussing a recurrent issue of their prosthesis slipping whilst walking:

“So I think that kind of taught me to communicate kind of more about what... things were actually happening, because I think I'd just kind of assumed stuff was normal, when actually, a really simple fix could be done and it didn't happen again.”

6.3.1.2.2 Gaining Knowledge

The previous theme highlights that for prosthesis wearers to proactively engage with clinicians, there is a certain degree of knowledge that must be obtained. Knowledge can help prosthesis wearers identifying the difference between issue or annoyances which they can fix, and also empower them to effectively communicate their issue to the treatment team. However, there are many different pathways to gaining knowledge as a prosthesis wearer.

6.3.1.2.2.1 Online learning

As with almost all significant and chronic medical conditions, prosthesis wearers often find themselves using online resources to help them get to grips with wearing a prosthesis (e.g. *“having access to peoples tips and tricks and comments and whatever online, has really built up my understanding of this world, coz you know, I had no idea about it this time last year” PT4).* Additionally, *PT4* demonstrated that online resources helped not just as a passive source of information, but as an interactive resource via prosthesis wearer message boards: *“what I've seen online, is that when people have problems with their stumps and they can't get to their physio, they'll go onto like the amputee coalition of America, and they'll show a picture of what's happening to their stump and say, has anyone else experienced this, what should I do?”*

Online information also proved useful when prosthesis wearers wanted to actively direct and influence their prescriptions. However, prosthesis knowledge from online sources was used carefully and tactically to ensure that prescription suggestions were not simply dismissed by clinicians. For example, *PT6* discussed how they typically have to influence their prosthetist to prescribe components that they had researched beforehand, without specifically asking outright for them, potentially as a way of conforming to the typical patient-clinician system “*... basically what I've done is look stuff up and be really proactive online and research that things could be better and just really carefully have like, so not manipulative conversations, but you know what you're thinking of in your head and you just keep saying all the key words, because you can't just say “I saw this and I want it and it's on the internet” you have to let them [prosthetists] think it's their idea... but just eventually it works. Like with this leg I've specifically said, I've looked it up... and she was like "oh you know more than me!"... yeah… funny that.”*

6.3.1.2.2.2 Learning from others

Although for most participants, knowledge was gained from online exploration, there also appears to be a commonly experienced element of learning from other prosthesis wearers. Speaking with other prosthesis wearers or seeing other peoples’ prosthesis often acted as a curiosity driver or motivation to seek changes to their prosthesis. *“going [to the clinic], you do, chat to people around you, I'm always very fascinated about the other type of prosthesis's that I see, particularly from people who have been amputees for longer-”PT2.* Another participant discussed how seeing other prosthesis wearers prescriptions prompted her to discuss what she saw with her prosthetist: *“you see someone at the clinic and they have something different and you- like I'll maybe say oh is there a reason that they've got that? Or, you know... do I need that... kind of, it just... makes you think about it” –PT10.*

However, it is important to highlight that learning from others does predominantly seem to be constrained to visits to the clinic. PT8 shared an experience of finding a solution to mild skin irritations, and when asked how he discovered it, he stated that a fellow amputee shared the information: *"Somebody in the clinic. That's what I mean! That's where you get all your information."*

6.3.1.2.2.3 Experience

Although participants discussed various strategies that they employed to increase their knowledge of prosthetics and their prosthesis, simple time with their prosthesis and experience acted as a positive influence to general wearing UX. One major factor appeared to be reaching a level of experience which enabled prosthesis wearers to be able to self-manage issues as they occurred. PT7 stated that *"as I've got older and sort of more experienced, and certainly if I do start getting problems or I feel that there's an issues, there are a lot of things I can check myself with my legs, without actually getting the hospital involved. [...] early days I'd never of considered in any shape or form, I'd of gone straight to the hospital and got an appointment and got them to look at it so."* As shown in this quote, PT7 was keen to highlight that he was only able to self-manage thanks to his lived experiences; previously his immediate reaction would be to seek clinical assistance for almost all problems.

Some prosthesis wearers also presented themselves as reaching a level of near mastery of self-management. For example, PT8 commonly encountered skin issues. However, his experience led to him discovering a regime or self-care (e.g. topical creams, plasters or bandages) that could be deployed to prevent small skin irritations becoming skin damage requiring clinical intervention- *"I've got everything under control as far as- you know- originally you end up with things like blisters and sores and things like that, but I don't have things like that anymore because I know how to manage it. I tend to manage the situation, but it's only through experience."*

6.3.1.3 Expectations

Finally, an important factor in having a positive prosthesis wearing experience appeared to be managing ones' expectations. Although this may sound like an influential negative factor, prosthesis wearers who presented a pragmatic and realistic outlook on what their prosthesis could afford presented the UX as generally more positive. PT3 succinctly summed up her outlook on her prosthetic and the wearing experience: *"It's very complicated to get it perfect- I think it will never be perfect, you have to- not resign yourself- but accept that you can walk, that you can do loads of things, even if you have* *some, little discomfort- because one day you have the discomfort- the other day, you don't."*

However, it is likely important that expectations can be defined and managed by prosthesis wearers themselves and negotiated to an *'acceptable'* level of expected affordance from their prosthesis.

6.3.2 Negative influences

Although there were a great number of influential factors that positively affected the prosthesis wearing experience, it was abundantly clear that negative influential factors were more prevalent. The theme of negative influential factors has been broken down into sub-themes which will be presented individually.

6.3.2.1 The prosthetic

Possibly unsurprisingly, the prosthetic device itself appears as a central driver of a negative prosthesis UX. However, rather than the prosthetic device inherently reducing the prosthesis UX, issues encountered during normal prosthesis wear often lead to a reduced wearing experience.

6.3.2.1.1 Excess weight

One theme which was discussed by almost all participants was the importance of the weight of the prosthetic device. Predominantly it seemed that excessive weight interfered with the functional performance in terms of stability (e.g. *"I really struggled because of the weight, because of how you are supposed to operate it… and then I slowly got to grips with it but I just never really felt very stable on my prosthesis" –PT4*) and suspension (e.g. *"It's heavy, and if my socket isn't fitting correctly then it's just too heavy and any extra kind weight, it pulls it and the suction doesn't work" –PT1).* However, weight did not just appear to have a functional influence, but also a psychological influence. PT3 described how even small changes in prosthesis weight lead a noticeable perceived difference which required psychological adaption: *"I find the hydraulic foot in this one actually- I've got it on at the moment, is much heavier is much heavier- but even just 200 grams it makes a difference, I think it makes a difference because my brain has got to readapt again, and I think it's much heavier" –PT3.*

6.3.2.1.2 Skin problems stopping wear

A highly prevalent issue which appeared to be almost guaranteed during the prosthesis wear was skin issues. However, although pain and discomfort were implied consequences of skin issues such as blistering, the most important consequence to skin issues appeared to be that it prevented prosthesis wear and restricted mobility:

“These sores can be so painful and often I can’t wear my prosthesis for a while after suffering with them as they need a chance to heal.” –BL1 and “they're the bane, because as soon as there's a blister you're, you're stuffed. You can't do anything, so you've got to be able to recognise that you've got something happening” -PT8.

To add to the frustration, conventional topical creams that could either prevent issues or aid healing often lead to reduced suspension owing to a reduced level of friction and the skin-prosthesis interface: *“it's difficult coz like if I put cream on in the day time, then, it doesn't- my leg doesn't stay on at all. And, it's not enough at night-time just to... like it doesn't seem to fix the problem overnight” –PT10*

6.3.2.1.3 Heat and Sweat

Heat and sweat issues were raised by every prosthesis wearer during the interviews without prompting. Prosthesis wearers stated that it was their prosthesis which caused the heat and sweat discomfort and even minor bouts of exercise or activity lead to noticeable levels of sweat production which pooled in their socket:

“you know the material doesn't allow your skin to breathe- at all. On very hot summer days, I would come back home even after like an hour being out to the local shops, and I'd take the gel sock [liner] off and it was literally dripping” –PT2

“if I was to walk from the top of this street to the end of this street [approximately 250 metres], if I was to find a toilet, and I was to take off my prosthesis, I would check my socket and there would be like sweat, all moist in the bottom of the socket” –PT4

6.3.2.1.3.1 Body overheating

Prosthesis wear also did not just lead to localised thermal discomfort at the residual limb, but instead resulted in a reduction in whole-body thermal comfort. For example, PT6 noted that *“I'm- I'm always hot, I don't think I'm ever not hot”* and highlighted that he often will wear shorts and a t-shirt even in the wintertime. PT1 also experienced a similar frustration and rationalised the thermal discomfort due to reduced skin surface area: *“I'm always hot, and I would say like, oh it's, my body's changed, it's got less surface area now, but I'm always really hot, which is annoying.” –PT1.*

Interestingly, one participant highlighted that it wasn’t just hot weather that influenced his thermal comfort, but also his emotions- something that has not been highlighted in prior research: *“It's not just because of the actual hot weather- that certainly doesn't help- it's other things as well, like I said, also emotion” -PT2.*

6.3.2.1.3.2 Sweat pistoning

Body overheating and hyperhidrosis frequently caused prosthesis pistoning as a direct result of reduced friction at the skin-prosthesis interface. Sweat pistoning appeared to vary between participants in terms of levels of annoyance and also severity. For example, *PT5* found slipping to be a frequently experienced challenge (e.g. *“it's been good but apart from when I'm sweating and then they start to come off, or you lose suction and it's quite difficult” –PT5).* Of greater concern were participants who were able to notice pistoning manifesting itself as skin rubbing and perceived elevations in skin-prosthesis interface friction (e.g. *“if it was very hot, then it would be a struggle to do like 25-minute run, with [the prosthesis] still on coz it would get sweaty and then it moves, and then it rubs, and again where I'm really bony at the end of my tibia, where it's cut, that's kind of the issue I get with rubbing, and so as soon as I get sweaty, like it will just get loads of friction there.” –PT1).*

Many participants also experienced catastrophic failure of the skin-prosthesis interface, resulting in complete detachment of the limb. Although these instances had the potential to be extremely dangerous to the prosthesis wearers, participants were often more concerned with embarrassment and unwanted attention related to the detachment event. For example, *PT3’s* prosthesis detached whilst on holiday and a member of the public retrieved her leg for her: *“it was a holiday- and then I did not realise- I fell, and my leg just went, and I was so embarrassed. I didn't hurt myself or anything, but the leg went, and it went off the kerb and there was a man, who very kindly came up to me and gave me the leg.”* Another individual (*PT10*) recalled multiple instances of limb detachment caused by sweat in the gym whilst using the treadmill, however, although she was aware of other people noticing the limb detachment event, she viewed the instances comically:

"in the gym I have lost my leg on the treadmill I think about three times, it's just kind of slipped off and gone flying off the back so it always makes a huge clatter and I think I've nearly given people heart attacks twice."

6.3.2.1.3.3 Heat and sweat causing skin issues

Another consequence reported by prosthesis wearers was that sweat caused by overheating often lead to skin issues. For some individuals, skin issues were experienced every day; *PT4* described preventing skin issues as a daily battle- (*"it gets quite hot in the socket so it gets quite sweaty, it can get quite damp, it can get quite moist, that can cause like skin problems, I do - It's something that you do battle with daily" –PT4).* Other individuals found that although they often experienced sweat related skin issues, they found them to be more of an irritation rather than a battle (*"sometimes I get, well- it's almost like, red, red spots on my, on my, I guess just from sweating so much, which can get quite irritating, and yeah I can feel it, but I wouldn't say it hurts that much" –PT7).* The causative nature of sweat in sore and blister creation was also something that prosthesis wearers were keen to highlight when discussing the issue- *"if you sweat and it doesn't, you know, get absorbed, it creates sores. So, it's, it's the heat that's actually creating it." –PT8* and *'I had issues with blisters that we thought was down to the sockets or the liners not fitting properly, but what we found out was it was due to the stumps sweating.' –BL8.*

6.3.2.1.3.4 Heat and sweat causing social anxiety

For some participants, heat and sweat issues acted as a major frustration, with consequences such as sounds, smells and sweat leakage causing self-consciousness and anxieties in social situations:

"It sucks! Everything sucks about it. It always sucks and it's smelly, and the water [sweat] comes up out of the leg, and like squirts up your inner thigh- there's enough of it- and people think you've peed yourself because it's squirting right where you'd have peed yourself." –PT6

"…squelching like a welly boot- like it kind of, you can feel that happening, or, you can also hear it sometimes. Uhhh- wandering down the high street and you can hear a squelch. And then you panic that everyone else can hear it." –PT10

6.3.2.1.3.5 The burden of managing heat and sweat

The data corpus provides evidence that heat and sweat issues as a commonly experienced subtheme of a negative prosthesis wearing experience. However, to mitigate the impact of heat and sweat issues, prosthesis wearers often adopted similar strategies to self-manage thermal discomfort during normal everyday activities.

“I'll have to stop and take my leg off, and tip it [the sweat] out... like take the liner off- the liner when it's hot, you can just pull the liner off, it's not even gripping you anymore, because it's just got a layer of... sweat lubrication basically, you have to just pat it down... like wipe the smelly liner on your clothes and keep going.” –PT6

“I know if my sleeve is starting to slip then I need to take everything off and wash everything and dry it and give it a chance to cool down. And then just pop everything back on.” –PT9

Prosthesis wearers described resorting to thermal discomfort minimisation strategy multiple times per day in public toilets, at work or at school. This self-management routine represents a burdensome task to ensure that the prosthesis continues to be wearable throughout the day and the limb either does not slip, fall off, or skin issues do not manifest due to prolonged sweat exposure.

6.3.2.2 Limitations

The final theme that was identified as negatively impacting the prosthesis wearing experience was limitations. However, limitations could further be broken down into limitations imposed on ones’ self and limitations imposed by the National Health Service provision.

6.3.2.2.1 Self-limitation

PT6 also suggested a fascinating concept of self-limitation being a form of self-preservation via budgeting time wearing his prosthetic vs time not wearing his prosthetic. If he knew that he had an upcoming busy period requiring many hours of prosthesis wear, he preventatively limits his wear prior to a busy period:

“I always tell people- it's just, it's just budgeting, you budget time on and off the leg as to whether you've got stuff to do in your calendar or you've got things you need to be able to do... it's all about being concerned if you're gonna be able to do things” –PT6

Time budgeting once again indicates that prosthetic devices, whilst able to provide many affordances to the wearer, are not yet comfortable enough to be reliably worn on the demands of the prosthesis wearers. This is highlighted as at present; the wearer must adopt unique strategies to ensure daily wear can be maintained.

6.3.2.2.2 NHS limitation

The other significant side to limitations in prosthetics were limitations placed upon prosthesis wearers by a National Health Service provision. When prosthesis wearers discussed their prosthesis, almost all talked about how whilst they appreciated funding restrictions, systemic issues often resulted in them receiving prescriptions that did not meet their needs or were keeping them from receiving a prescription that did meet their needs.

One comment made by PT4 revealed that in her opinion, the NHS was overly focussed on function as opposed to appearance, despite aesthetics being an important component in her prosthesis needs.

“he [the prosthetist] is also restricted by like... NHS protocol. So, for me, I'm an above the knee amputee, and for me, I think an important part of my rehabilitation is how, my prosthesis looks, as well as how it functions. Whereas obviously the NHS has very restrained funds, so their primary concern is function- not how it looks.” –PT4

Additional frustrations came from a lack of information and awareness from clinicians. For example, PT5 had been awarded funding for a set of mechatronic prostheses. However, although the funding had been provided, she was not provided with any indication of timescales, and any attempts to clarify were met with a lack of information: *“I think NHS England said that they can give the funding, but they don't really know what's happening there so we're not sure how long it's going to take” –PT5.*

Another participant who had commented on a good relationship with their prosthetist was PT6. Although he had a good relationship, he noted that the prescription process and service delivery procedure was not, in his opinion, up to par. He justified his approach to always pushing to get more from the system as being a necessary step in improving future provisions. In his words, if budgets are not pushed by patient need, then there will be little reason for budgets and therefore, standards of care and prescription to be improved:

"I dunno, you just have to keep pushing and be aware... you can't accept the treatment that's given to you because it's... it's not good enough... if we don't push them to pay out, then their budgets won't be increased, because they won't be spending the money and stuff so... it's all... a nightmare." –PT6

One interviewee reported intense frustration and disillusionment with prosthetics services and the system in general as opposed to individual prosthetists or clinicians: *"I don't have a problem with my prosthetists as such as an individual. I have a problem with is the bullshit when you want to walk. All I want to do is walk." –PT9.* Given the perception of walking as being something fundamental to this individual, it is unsurprising that being limited by service protocols and restrictions would lead to such an intense reaction.

6.4 DISCUSSION

The work presented in this chapter has helped to gain an insight into the realities of life with a prosthesis from the perspective of prosthesis wearers. In doing so, it has also been possible to deconstruct how thermal discomfort arises and the real-world consequences of thermal discomfort. However, as well as understanding thermal discomfort, additional subthemes were evident from the data. Here themes of interest are discussed and situated in prior literature.

6.4.1 The prosthesis as a negative

It remains an interesting proposition that when the prosthetic limb is considered in isolation, it appeared as a negative factor for almost all prosthesis wearers. Probably, the most important factor that can give rise to negative feelings towards an amputee's prosthetic leg is excessive weight (e.g. PT1, PT3 and PT4).

This study, therefore, helps to provide insights into why excessive prosthesis weight is implicated as the cause for up to 43% of prosthesis abandonment [60]. Device weight, therefore, must remain an important consideration when formulating any design specification when developing new prosthetics for them to truly be practical in real-world contexts. This naturally introduces an additional engineering challenge to ensure new prosthetics which aim to improve the wearing experience are practical in real-world contexts.

Skin health was also demonstrated as being a key to mobility. However, skin issues were often discussed as an almost mandatory occurrence at some point when wearing a prosthesis. When skin issues were encountered, a typical healthcare product such as topical creams reduced prosthesis suspension and made wearing the prosthesis even more difficult. Therefore, prosthesis wearers who experience a skin issue are stuck in a contradictory situation where they must stop wearing the prosthesis in order to continue wearing their prosthesis. In this scenario, it is unsurprising that the prosthesis can be deemed as a negative factor given that simple wear can result in skin damage. As has already been mentioned, it was not necessarily the pain or discomfort which caused the greatest distress and frustration to prosthesis wearers, but instead, that skin issues meant that the prosthesis couldn’t be worn. This is unsurprising given that skin damage has been shown to take as long as 177.6 ± 113 days to heal [107], which would undoubtedly result in significant disruption to the lives of prosthesis wearers.

On a basic level, it is tempting to consider the UX of prosthetics to neatly conform to being exclusively ‘positive’ or ‘negative.’ Although here, these major themes have been identified, it is critically important to highlight that the UX of prosthetics is transitional- it is neither always *‘good’*, nor always *‘bad’*. When the theme of the prosthetic as a negative factor is given more thought, it would be an unfair assertion to state that prosthetic limbs were exclusively viewed as a driver of negative experiences.

It is probable that the prosthetic device could also be viewed by prosthesis wearer as a positive influential factor given that prosthetic limbs afford wearers mobility and freedom that they may not have if they did not use assistive technologies. The identification of the prosthesis as a negative influential factor is far more likely to be due to the design of the interview guide, which focussed on discussing issues with interview participants.

It is, however, interesting to note that the thematic analysis of the undirected blog dataset did not yield the identification of a similar antithetic theme. Once again, however, the absence of the prosthetic device as a positive influential factor in the undirected blog entries is not conclusive evidence that prosthetic devices cannot be positive factors in their own right. It may be likely that prosthesis wearers use blogs as a form of catharsis. Therefore, the blog content may be used as a way to 'vent' and could paint an overly negative portrayal of life with a prosthesis.

6.4.2 Fostering positivity

Prosthetic research and prosthesis development are a field of expertise that has naturally evolved out of medical necessity. With the additional input of scientists and engineers, prosthetics has been advanced under the prerogative of problem-solving to prevent further reductions in health and preserving as much quality of life as feasibly possible by providing limbs with 'good' enough function and comfort. When we consider how computing technology has been utilised to improve prosthetics, we have also almost exclusively seen technology being utilised to garner functional improvements via the likes of microprocessor empowered mechatronic limbs.

However, rather than improve prosthetics and the prosthesis wearing experience as an exercise in problem solving, a dual approach which also explores technologies which fosters positive experiences could be beneficial. In this regard, the sub-field of positive computing [34–36] could be used as a lens to create such technologies. For example, mobile computing technologies could act as a fertile technology space to develop software's which revolve around the core positive subthemes of relationships, proactivity and experience. In embracing both problem solving and a positivity fostering approach, prosthesis wearers may have a wearing experience which is not brought down or influenced by negative factors whilst also being lifted by positive technologies which delight the user and enhance their wellbeing to holistically improve the wearing experience.

6.4.3 Thermal discomfort

Prior investigations into heat and sweat discomfort have already been described in Chapter 4. However, up to now, prior heat and sweat research has almost all been constrained to questionnaires [82], laboratory studies [110,130,154,183,216], materials research [127,128,234] and solution development [83,84,89,90,235]. The only study to investigate heat and sweat in prosthetics from a qualitative perspective has been a small four participant research study [199]. Based on the prior literature, the impacts of body overheating appeared to be the onset of hyperhidrosis, skin issues and reduced quality of life. However, the study presented here builds upon our prior understanding of heat and sweat by providing additional depth and rigour and focusing deeply on thermal discomfort and delving deeper into why thermal discomfort reduces quality of life for prosthesis wearers.

6.4.3.1 Overheating:

The causes for body skin over-heating have already been identified as physical activity [130] and environmental conditions [154] with effects being amplified by low thermally conductive prosthetic liners and sockets [127,128,234]. In experiential terms, however, the data collected here suggests wearers will often feel a persistent sense of overheating during everyday life. This sentiment was noted by TTAs and TFAs alike, and as noted by PT1 and PT6, they have a near-constant feeling of being warm. In itself, this persistent feeling of overheating could lead to negatively impacting the wearing experience and leading to frustration and general discomfort. Of particular interest were descriptions of modifications in behaviours such as wearing the minimum amount of clothing possible to account for increased feelings of warmth. A particularly interesting point was raised by PT6 who would anticipate and almost have to resign himself to feeling thermally uncomfortable in situations where he was required to wear more formal layered attire.

6.4.3.2 Excess sweating:

As previously identified by literature analysis, sweating is triggered as a reactionary thermoregulatory response and rendered ineffective by impermeable prosthetic materials, leading to sweat pooling [85]. This impact was qualitatively reported by Ruiz et al. [199] who took the step to estimate the quantities of sweat seen by prosthesis wearers after doffing their limb. The findings from this study reaffirm how excess sweating is experienced by prosthesis wearers. *PT2* and *PT4* provided additional evidence, that not only is excessive sweating experienced when wearing a prosthesis (as expected), but only the slightest amount of physical activity or changes in ambient conditions can trigger excessive sweating. However, one unexpected cause of sweating was intense emotional experiences (PT2).

6.4.3.3 Sweat Pistoning:

Sweat pistoning can be thought of as a failure of prosthetic suspension, as the prosthesis begins to displace up and down as the wearer ambulates. A small amount of sweat can actually increase frictional forces between skin and the liner [54]. Increased friction would usually be regarded as a positive outcome, as it can improve suspension. However, based on the analysis presented in this study, past a fluid-friction boundary, the amount of sweat on the limb will lead to reduced friction, thus causing sweat pistoning. Initially, the effect would be to cause deviations in prosthesis function (i.e. causing abnormalities in gait and a feeling of the limb slipping). However, further reductions in suspension introduces the possibility of catastrophic failure and complete detachment of the prosthesis (as described by *PT3* and *PT10*). Though sweat pistoning to the point of limb detachment has inherent risks of injury, when participants recounted instances of limb detachment, it was not the injury, or risk of injury that they were most aware of. Instead, it was the embarrassment and the attention that was drawn to them by their limb detaching. Therefore, there is evidence of a dynamic of thermal discomfort leading to a reduction in quality of life via means of social mechanisms, as opposed to functional (i.e. gait distortion), or irritation and pain.

6.4.3.4 Skin Damage:

Skin issues and damage can be caused by one of two impact pathways. The first pathway is that sweat pooling and persistent skin contact can directly cause skin. In the case of sweat pistoning, basic skin tribology indicates that vertical motion will introduce high shear, tension and friction conditions which can rapidly lead to skin degradation [203]. In this study, analysis indicates that sweat pistoning is a reasonably prevalent issue amongst interviewees. Sweat pistoning would undoubtedly introduce damaging forces to the skin-prosthesis interface and therefore presents a risk of leading to skin damage. These consequences can be serious and must be prevented wherever possible.

6.4.3.5 Reduced Wearing Experience:

Prior work has identified that heat and sweat interfere with prosthesis wearers daily activities [93], causes odours that bother prosthesis wearers [14] and lead to social isolation [206]. In this study, the data corpus supports and reinforces the idea that heat, sweat and other factors are contributory to a negative wearing experience, with a reduced wearing experience acting as a consequence of phenomena such as overheating, sweat pistoning, skin damage and social anxiety. A reduced wearing experience can manifest itself as onerous “daily battles” to manage heat and sweat and social anxieties ranging from embarrassing sweat patches on trousers to squelching noises whilst in public. The heat and sweat-self management routine reported by participants in this study is also echoed by experiences of prosthesis wearers in the study conducted by Ruiz et al. [199]. When the combined influence of heat and sweat to the wearing experience is considered, it is not at all surprising that wearers feel frustrated and describe the wearing experience as negative (e.g. “*It sucks! Everything sucks about it. It always sucks…” –PT6).*

6.4.3.6 Generalisations, limitations and considerations

Qualitative research will always have direct and indirect influences inherent to the researcher who conducts it, the participant being interviewed, and the relationship and rapport between the two [19]. For example, prior to conducting this study, I had pre-existing knowledge of prosthetics, the related literature and the typical problems that are experienced by prosthesis wearers. This level of familiarity with the research topic made it possible to have an informed discussion. However, topic knowledge can also make it easy to inadvertently explore and discuss preconceived ideas and issues which are already known to the researcher, rather than pick up on subtler, rare or unexplored phenomena raised by participants [19]. For this reason, during interviews, particular effort was made to pay attention to the occurrence of topics, phenomena or experiences that were unknown to myself. The interview guide design also assisted by ensuring issues were initially discussed from a participant-directed perspective. During this phase of the research, participants were able to raise *any* issue that they deemed important.

In this research project, it was not possible to take a multi-coder approach due to pragmatic restrictions. However, as a compromise, themes were discussed with other researchers during the course of analysis and appropriately revised. The process of evidence-based discussion provided an important systematic check to increase the validity of the analysis. Participants in interview studies may also naturally respond to questions based on their perception of the researcher conducting the study, or even their own personal motives. For example, interviewees were aware that I was conducting the study with a broad aim to improve prosthetics. Therefore, they may have approached the interview with a mental focus of issues with their prosthesis. Give that most interviewees also enquired about my educational background (physics and engineering), they may also have consciously or subconsciously discussed topics that they perceived as being of interest to an ‘engineer’ or ‘scientist’.

Finally, it is important to highlight that the data presented exists within the context of the participants recruited. Although there was a reasonably large variation in age and amputation aetiology, almost all participants demonstrated medium to high levels of activity and independence. As was discussed in the introduction, the majority of amputees (who are not necessarily prosthesis wearers) are of advanced age with health conditions such as peripheral arterial disease and therefore much more likely to be more inactive. However, such limitations do not diminish the validity nor novelty of the findings presented here.

6.5 Summary

This chapter began by investigating if the literature narrative is supported by wearing experience. Based on the data collected here, the way in which thermal discomfort effects prosthesis wearers is reaffirmed. However, the research extends beyond confirmation by elucidating how thermal comfort arises and the consequences of thermal discomfort.

7 STUDY II: TOWARDS REAL-WORLD THERMAL DISCOMFORT RESEARCH

***Parts of this chapter have been published in** Rhys James Williams, Atsushi Takashima, Toru Ogata, and Catherine Holloway. 2019. A pilot study towards long-term thermal comfort research for lower-limb prosthesis wearers. Prosthetics and Orthotics International 43, 1: 47–54.* https://doi.org/10.1177/0309364618791604

In the previous chapter, the research question was investigated using semi-structured interviews to try and understand some of the consequences of thermal discomfort for prosthesis wearers. Additionally, the general prosthesis wearing experience was also captured, to provide additional context to the findings. However, as discussed in Chapter 3.5, prosthesis thermal comfort studies have been exploratory and collected residual limb temperature data from either one [110,154], five [183] or nine [130] male transtibial amputees in a laboratory setting [110,130,154,182,183] using a 'rest-exercise-rest' protocol. Rest has ranged from 15 – 60 minutes and treadmill ambulation has ranged from 10 – 30 minutes. A notable exception to this protocol was published in November 2016 by Segal and Klute, who adopted a 'rest-exercise-rest-exercise-rest' approach (rest = 5 minutes, exercise = 30 minutes), whilst manually recording PTC and heart rate. Reported changes in mean residual limb temperature between the beginning and end of experiments have ranged from 1.7 – 3.9 ˚C [110,130,154,183]. The findings from these studies also show that wearing a prosthesis increases mean residual skin temperature and physical activity increases mean residual skin temperature. Additionally, Segal and Klute found that PTC changes were significantly associated with rest and activity.

In light of the literature, this chapter presents two studies. The first adopts a conventional controlled laboratory ‘rest-exercise-rest’ protocol, representing the status quo of research. The second study adopts a multi-hour research protocol conducted in real-world environment, with full participant autonomy. This second study represents the first step to beginning to deconstruct how thermal discomfort arises in naturalistic environments, using a multi-parameter sensing strategy that facilitates participant autonomy. Research from this chapter was conducted in Japan as part of a 10-week Japan Society for the Promotion of Science summer fellowship, hosted by the National Rehabilitation Centre for Persons with Disabilities, Tokorozawa. All experiments were conducted during August 2016, where ambient temperatures were on average 30 ± 3 ˚C [245]. Transfemoral amputees were predominantly recruited to provide insights from a previously untested participant group [236].

7.1 Study 2a: The status quo

The majority of prosthesis thermal discomfort studies to date have been conducted in highly controlled laboratory environments. With protocols comprising of a ‘rest-exercise-rest’ format as a standard structure for this specific type of research, it made sense to conduct a study which was in keeping with the status quo of research. The primary advantage of such an approach was to collect a primary data set which could be situated within prior research. Additionally, prior to this study, I did not have experience conducting an in-situ sensing study with prosthesis wearers. Therefore, this first study provided a useful opportunity to learn practical experimental skills such as sensor placement in a controlled environment with minimal risks, whilst also collecting a standardised data set.

7.1.1 Methods

7.1.1.1 Participants

Ethical approval was obtained from UCL’s board of ethics and the ethics committees of the National Rehabilitation Centre for Persons with Disabilities research centre and hospital. Recruitment criteria were male lower-limb amputees who wore a prosthesis daily and were at least 6 months’ post-amputation. Both TTAs and TFAs were recruited, as previous studies have exclusively recruited TTAs, meaning that TFA thermal discomfort is unexplored. Thermal discomfort research has also failed to include female perspectives to date. However, as the research team was all male, females were not recruited to reduce potential embarrassment while participants were in a state of undress while sensors were applied. Diabetic amputees were not recruited due to perceived additional skin-damage risks and condition related complications. Due to the fixed timescale of this project, the projects clinical supervisor consulted colleagues within the NRCD to recruit suitable participants, rather than using recruitment strategies such as poster advertising.

Participants were required to take part in all studies of the project, though were free to withdraw from the study at any point without reason or consequence. In total, five male participants were recruited and completed all studies, with an average age ± standard deviation of 30 ± 9 years. The time since amputation varied from 11 months to 37 years (congenital amputee). Table 8 describes basic participant characteristics. PTJ2 was the only bilateral amputee and also used a walking aid. In his case, sensors were applied only to the transfemoral residual limb.

Table 8: Demographic and amputation information of the five participants that were recruited.

	Gender	Amputation level	Cause	Time since amputation	Prosthesis interface type	Age	Height	Weight
PTJ1	M	Left leg (TFA*)	Trauma	11 mo.	Suction socket Össur ICEROSS TF seal in liner	19	168cm	87kg
PTJ2	M	Left arm (SDi†) Right leg (TFA*) Left leg (TTA‡)	Trauma	18 mo.	Suction socket Össur ICEROSS X5 suction liner	28	175cm	-
PTJ3	M	Left leg (TTA‡)	Congenital	37 yrs.	PTB socket Ohio Willow Wood Alpha classic Alpha hybrid flex sleeve	37	172cm	54kg
PTJ4	M	Right leg (TFA*)	Trauma	6 yrs.	Suction socket No liner	42	168cm	80kg
PTJ5	M	Right leg (TFA*)	Trauma	4 yrs. 6 mo.	Suction socket Ottobock 3R80	25	175cm	57kg

* TFA = Transfemoral amputee, † SDi = Shoulder Disarticulation, ‡ TTA = Transtibial

7.1.1.2 Data collection system

To collect temperature data, an Arduino MEGA 2560 microcontroller (Arduino, Italy) was connected to a DS1307 real-time clock (Maxim Integrated, USA) and an SD card reader. Sixteen B57863S103F40 NTC thermistors (Epcos, Germany) were connected to a linear potential divider (10 kΩ ±1% tolerance resistors). The system was powered by six AA 1.5V batteries, and new batteries were used for each study. The microcontroller was programmed using Arduino’s integrated development environment (IDE) to acquire and save data at 1Hz. Thermistors were calibrated using the Steinhart-Hart equation (Appendix 2) and provided an absolute measurement accuracy of ±0.2˚C in a range between 0-70˚C. The data logger was placed into a waist bag, and standard 1-meter 28 AWG ribbon cables were routed under the participants clothing so as to not be visible. Four thermistors positioned on the outside of the waist bag also recorded ambient temperature.

7.1.1.3 Procedure

Once participants were recruited, participants visited the temperature-controlled laboratory. Participants were asked to remove their prosthesis and twelve thermistors were attached to their residual limb using Hypafix medical tape (BSN Medical, Germany). Thermistors were placed within the lower, middle and top third of the residual limb, excluding the knee joint for transtibial amputees (Figure 9). Thermistors were placed on fleshy parts of the residuum, as determined by palpation, and bony prominences were avoided. Sensor attachment typically took 3-5 minutes with two researchers attaching the sensors, and at most, 10 minutes.

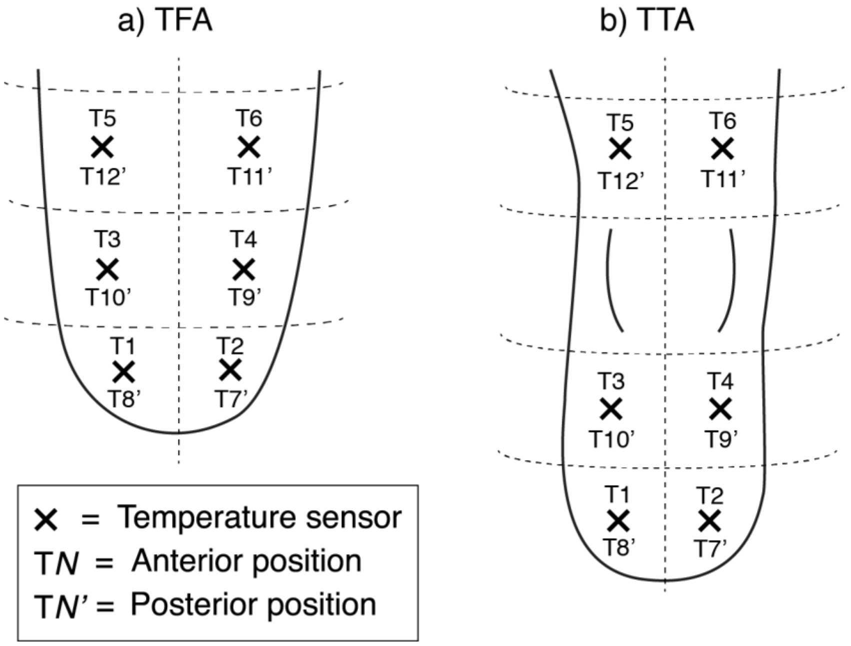


Figure 9: Thermistors positioning across participants' limbs was kept consistent, allowing for anatomical differences.

After attaching the sensors, participants were asked to don their prosthesis and take a few supervised steps around the laboratory. At this point, participants were asked if they noticed any discomfort, pain, or reductions in suspension. If these issues were present, participants were asked to sit down, remove their prosthesis, and the offending thermistor was repositioned. This process was repeated until no issues were present. At this point, the data logging system was initiated.

Once instrumented, participants were asked to sit and rest for 15 minutes. The first rest period allowed participants to relax and reduced limb heating effects that could have been caused by movement during sensor attachment. Once this first rest segment was complete, participants were asked to walk for 10 minutes on a flat treadmill at a self-selected pace. Finally, participants were asked to sit and rest for a further 30-minute period. This rest-activity-rest protocol mirrored prior amputee thermal comfort research studies.

7.1.1.4 Analysis

Matlab 2016a (Mathworks, USA) was used to conduct data analysis. Mean limb temperature over all thermistor locations provided a descriptive summary of the residuum temperature behaviour. Data were collected as participants switched between rest and activity segments of the protocol; however, to standardise timings, intermediate switching data was removed. However, for all participants switching took no more than 30 seconds and was therefore removed from the data corpus. During the study, some thermistors broke (see Table 9)- in these instances, data from these thermistors were discarded.

7.1.2 Results

At the start of phase one, PTJ3's mean limb temperature was hottest, with a temperature of 31.8 ˚C, followed by PTJ5; 31.6 ˚C, PTJ2; 31.0 ˚C, PTJ1; 30.9 ˚C and PTJ4; 30.4 ˚C. During the first rest phase, participants experienced increases in limb temperature ranging between 0.4-1.8 ˚C. In the exercise phase, participants experienced changes in limb temperature ranging from -0.1-+1.7 ˚C. The final rest phase resulted in further increases in the limb temperature of between 0.3-1.1 ˚C.

At the end of the study, PTJ1's residual limb was the hottest at 34.5 ˚C, followed by PTJ3; 34.5 ˚C, PTJ5; 33.2 ˚C, PTJ2; 32.7 ˚C and PTJ4; 32.3 ˚C. Some thermistor wires broke during the experiments (Table 9). The mean laboratory temperature was 26.7 ˚C. Segment-by-segment limb temperature changes are presented in Table 9, and limb temperature data is presented as a time-series in Figure 10.

Table 9: Mean temperature data from Study 2a are shown ± SD. Changes in temperature (Δ) are calculated as the difference between the average of the last and first ten-seconds of temperature data in a segment of interest.

	Start Temp' (˚C)	R1Δ Temp' (˚C)	EXCΔ Temp' (˚C)	R2Δ Temp' (˚C)	End Temp' (˚C)	Mean Temp' (˚C)	Start-End Δ Temp' (˚C)	Sensor breakage
PTJ1	30.9 ± 0.8	1.8 ± 0.005	1.3 ± 0.01	0.5 ± 0.01	34.5 ± 0.9	33.5 ± 1.1	3.7 ± 0.4	T7
PTJ2	31.0 ± 0.6	0.6 ± 0.006	0.6 ± 0.02	0.5 ± 0.01	32.7 ± 0.8	32.1 ± 0.5	1.7 ±0.3	T1, T3
PTJ3	31.8 ± 0.8	0.4 ± 0.003	1.7 ± 0.002	0.3 ± 0.01	34.5 ± 0.7	33.5 ± 1.1	2.8 ± 0.3	T1, T7
PTJ4	30.4 ± 0.7	0.8 ± 0.001	-0.1 ± 0.004	1.1 ± 0.008	32.3 ± 0.7	31.4 ± 0.5	2.0 ± 0.3	T6
PTJ5	31.6 ± 0.5	0.9 ± 0.002	0.3 ± 0.001	0.4 ±0.01	33.2 ± 1.2	33.0 ± 0.5	1.6 ± 0.4	T5

Temp' = Temperature, R1 = Rest segment 1, EXC = Exercise segment, R2 = Rest segment 2, T# = Thermistor number

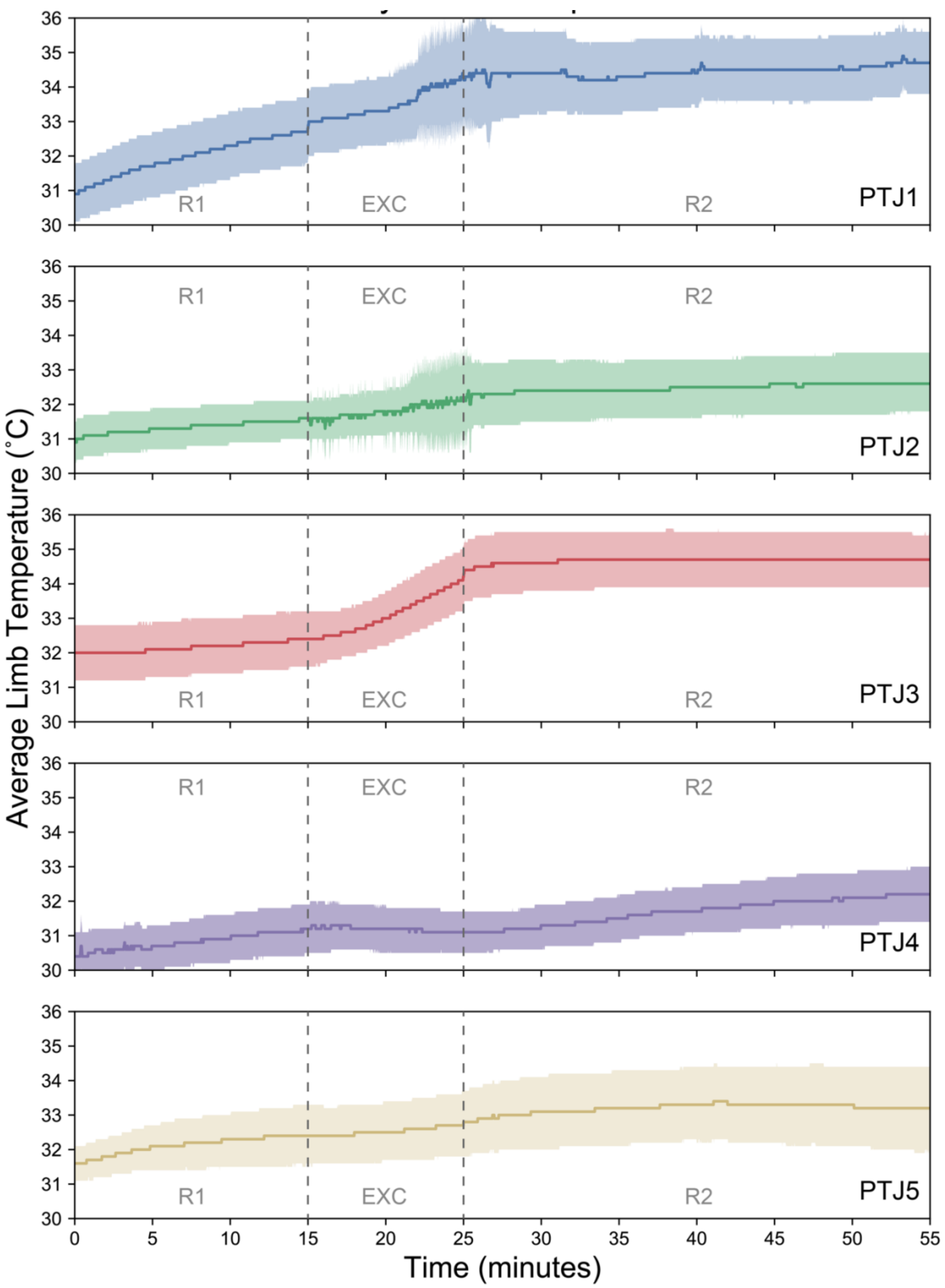


Figure 10: Residual limb temperature for each participant during phase one is shown as a time-series. The shaded region of each graph encapsulates the average limb temperature ± SD over sensing sites. Each section of the protocol is labelled as rest 1 (R1), exercise (EXC) and rest 2 (R2).

7.2 Study 2b: Towards real-world research

7.2.1 Methods

7.2.1.1 Participants

Participants from study 2a were required to also participate in study 2b. Therefore, the same recruitment strategy and participant demographics presented in the previous study apply to this study.

7.2.1.2 Data collection systems:

To collect ambient and residual limb temperature data, the same data collection system was used as in study 2a. However, as well as limb temperature and ambient temperature, perceived thermal comfort was also autonomously collected using dedicated self-reporting devices (Figure 11).

Figure 11: The PTC recording system was made to be small enough to be handheld and simple to operate and record data points. The electronics were secured in a 3D printed plastic case.

7.2.1.3 Perceived thermal comfort recording system

The PTC self-reporting devices contained an Adafruit Feather 32u4 ‘proto-board’ (Adafruit, USA) which was connected to a data logger shield containing a PCF8523 real-time clock (NXP, Netherlands) and micro-SD adapter. These devices facilitated the recording of PTC via a 1-5 Likert scale, which was represented by five LEDs which acted as a visual reference. This scale represented perceived thermal comfort as opposed to perceived thermal sensation of the residuum [61], where 1 = very comfortable, 3 = neutral, and 5 = very uncomfortable. This one-sided scale represented PTC with respect to warmth due to the hot climate. To record data, participants rotated an analogue potentiometer to the appropriate value and pressed a button to timestamp and save the PTC value.

7.2.1.4 Procedure

On a different day to study 2a, participants returned to the laboratory to begin study 2b. Upon arrival, participants were instrumented with thermistors, using the same procedure as in study 2a. Once the sensor system was attached, participants were shown the PTC recording system and instructed how to operate it. The meaning attached to the Likert scale was also explained by a native Japanese speaker, and participants were told to record PTC only when they wanted to. The decision to collect data as and when the participants wanted, as opposed to a regularised or reminder-based reporting strategy was taken to reduce the invasiveness of the study. At this point, participants were free to leave the laboratory and could return whenever they liked before the end of the day. Once participants left the laboratory, no contact was made with the participants until they returned. Participants were not given any direct instructions of what activities to do, and were therefore free to conduct activities of their choosing. Although researchers did not contact the participants, researchers were contactable if needed, and it was made clear that the sensors should be removed if they caused pain or discomfort. This autonomous study was designed to empower participants to take part in an experiment whilst going about natural activities, in real-world environments with minimal interruption.

7.2.1.5 Analysis

The data analysis procedure for study 2b was mostly the same as with study 2a. Matlab 2016a (Mathworks, USA) was used for the analysis, and mean limb temperature was calculated over all thermistor sites. Additionally, mean ambient temperature was calculated. As with study 2a, some thermistors broke during the course of the experiment. In these situations, data from the broken thermistors were excluded. To analyse PTC, PTC values were summarised by calculating the modal PTC value for each participant.

Finally, as two datasets had been collected (study 2a and study 2b), residual limb temperature differences between in lab and out of lab experiments were evaluated using a Wilcoxon Signed-Rank test, with a two-tailed p-value being reported and 95% CI, with significance determined when $p < 0.05$. This step was taken to examine if residual limb temperature behaviour was significantly different outside of a controlled laboratory environment.

7.2.2 Results

Due to differences in participant schedules, the length of time that each participant took part in the study varied, ranging from 2h 22m (PTJ2) to 5h 21m (PTJ3), with an average experiment length of 4h 7m. At the start of the second study, PTJ1's residual limb was the hottest at 32.9 ˚C, followed by PTJ3 at 32.3 ˚C, PTJ5 at 32.1 ˚C, PTJ4 at 31.7 ˚C and PTJ2's limb was the coolest at 31.1 ˚C. At the end of the experiment, PTJ5's residual limb was the hottest at 37.3 ˚C, followed by PTJ3 at 37.2 ˚C, PTJ1 at 36.1 ˚C, PTJ2 at 35.2 ˚C and PTJ4 at a temperature of 33.5 ˚C. The smallest change in limb temperature from the start-to-end of the experiment was PTJ4, with a change of only 1.8 ˚C, and PTJ5 presented the largest change in limb temperature at 5.1 ˚C. Temperature data from this phase are presented in Table 10. Again, some thermistor wires broke during the experiments (Table 10).

Table 10: Residual limb temperature and ambient temperature data were recorded for each participant during study 2b. To calculate the start and end temperature, the first and last ten seconds of limb temperature data were averaged.

	Start limb temp' (˚C)	Mean limb temp' (˚C)	End limb temp' (˚C)	Temp' difference (˚C)	Mean ambient temp' (˚C)	Duration	Sensor breakage
PTJ1	32.9 ± 0.8	35.9 ± 0.8	36.1 ± 0.6	3.2 ± 0.3	30.8 ± 2.2	4h 27m	T12
PTJ2	31.1 ± 0.6	33.9 ± 1.2	35.2 ± 0.8	4.1 ± 0.3	30.4 ± 2.9	2h 22m	-
PTJ3	32.3 ± 0.4	34.6 ± 1.3	37.2 ± 0.2	4.9 ± 0.1	28.5 ± 1.8	5h 21m	T1, T7, T8, T10
PTJ4	31.7 ± 0.7	33.1 ± 0.7	33.6 ± 0.7	1.8 ± 0.3	27.6 ± 2.3	4h 12m	T5, T7
PTJ5	32.1 ± 0.5	35.4 ± 1.1	37.3 ± 0.8	5.1 ± 0.3	33.0 ± 2.7	4h 17m	T5

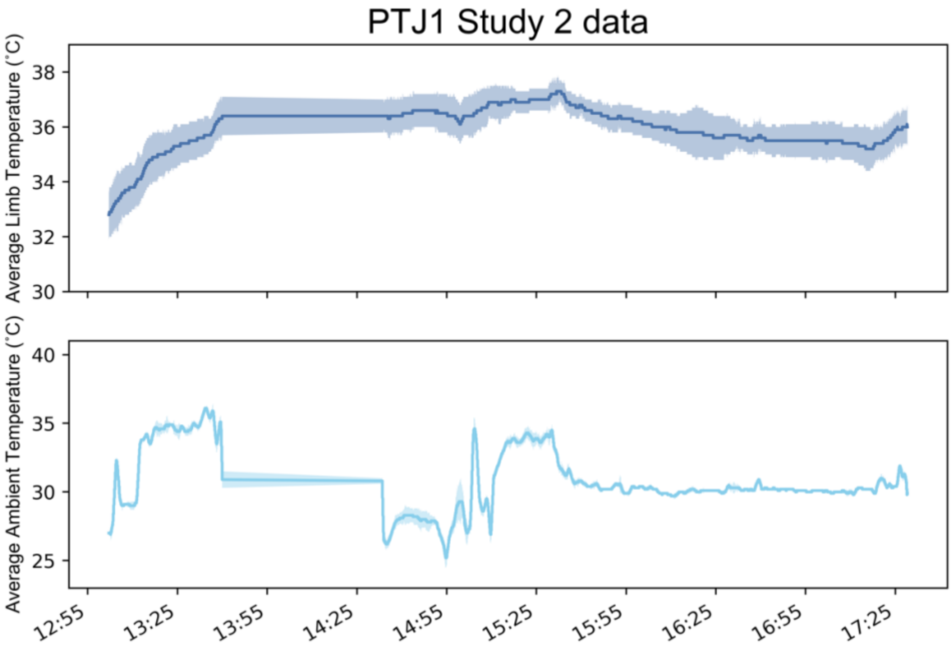


Figure 12: Average limb and average ambient temperature data for PTJ1 during study 2b

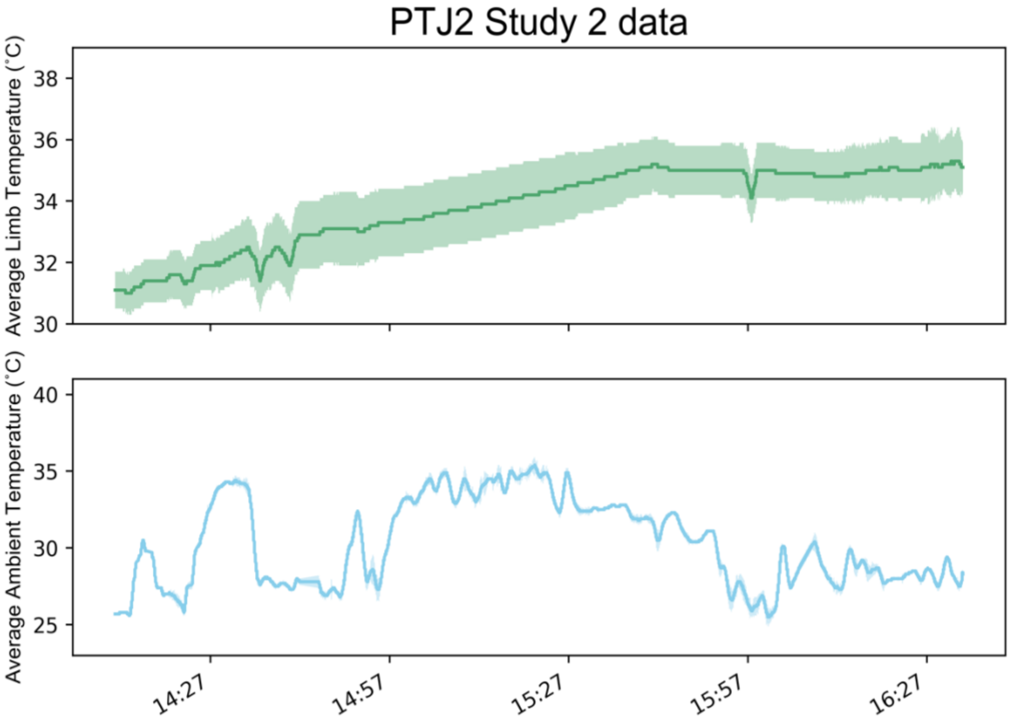


Figure 13: Average limb and average ambient temperature data for PTJ2 during study 2b

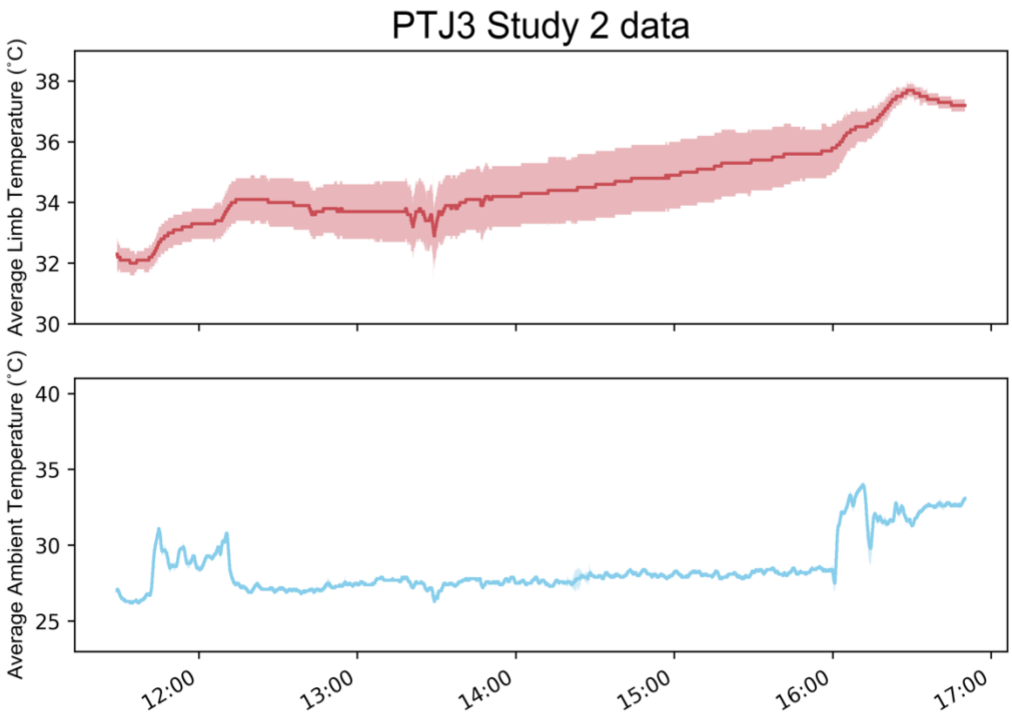


Figure 15: Average limb and average ambient temperature data for PTJ3 during study 2b

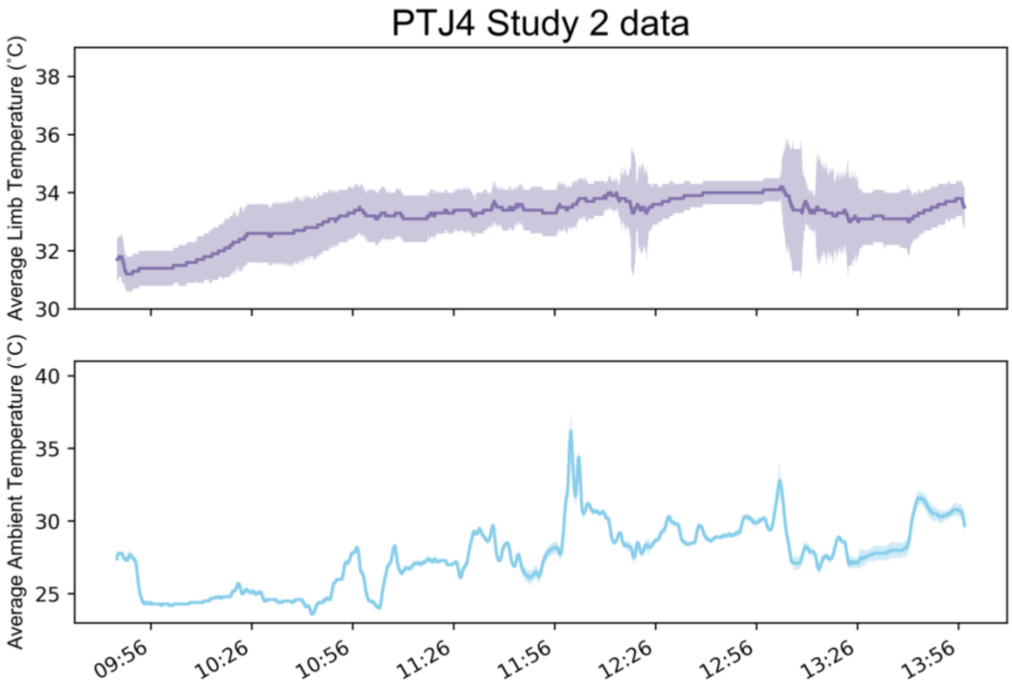


Figure 14: Average limb and average ambient temperature data for PTJ4 during study 2b

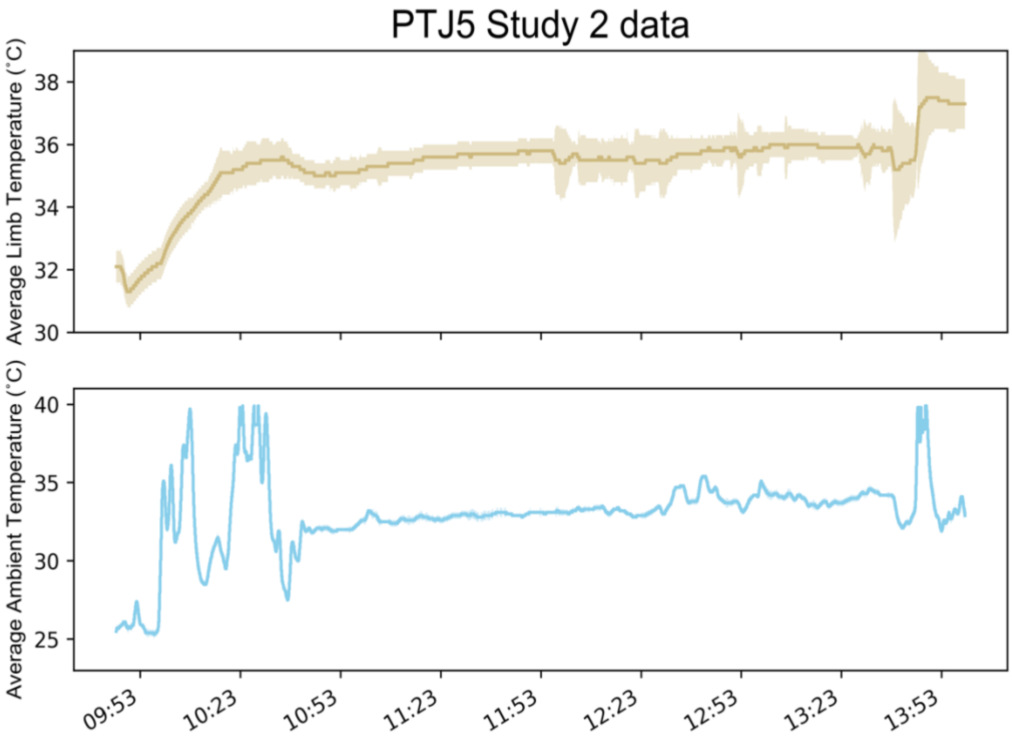


Figure 16: Average limb and average ambient temperature data for PTJ5 during study 2b

Time-series plots were made for each of the participants and display both the average limb temperature and the average ambient temperature throughout the course of the second experiment (Figure 12- Figure 16). Both parameters are shown as a solid line representing the average temperature, encapsulated by a shaded region representing the average ± SD over all thermistor sensing sites.

In study 2b, PTJ1 recorded PTC twelve times, with a modal PTC of 4 (uncomfortable). PTJ2 only recorded two PTC data points (one neutral and one extremely comfortable). PTJ3 recorded five PTC values, with a modal value of 2 (comfortable). PTJ4 recorded eighteen PTC data points with a modal value of 2 (comfortable). Unfortunately, PTC data for PTJ5 corrupted and could not be retrieved. To try to untangle any relationships between PTC and limb or ambient temperatures, average limb and ambient temperature over a 5-minute period prior to PTC recordings were calculated.

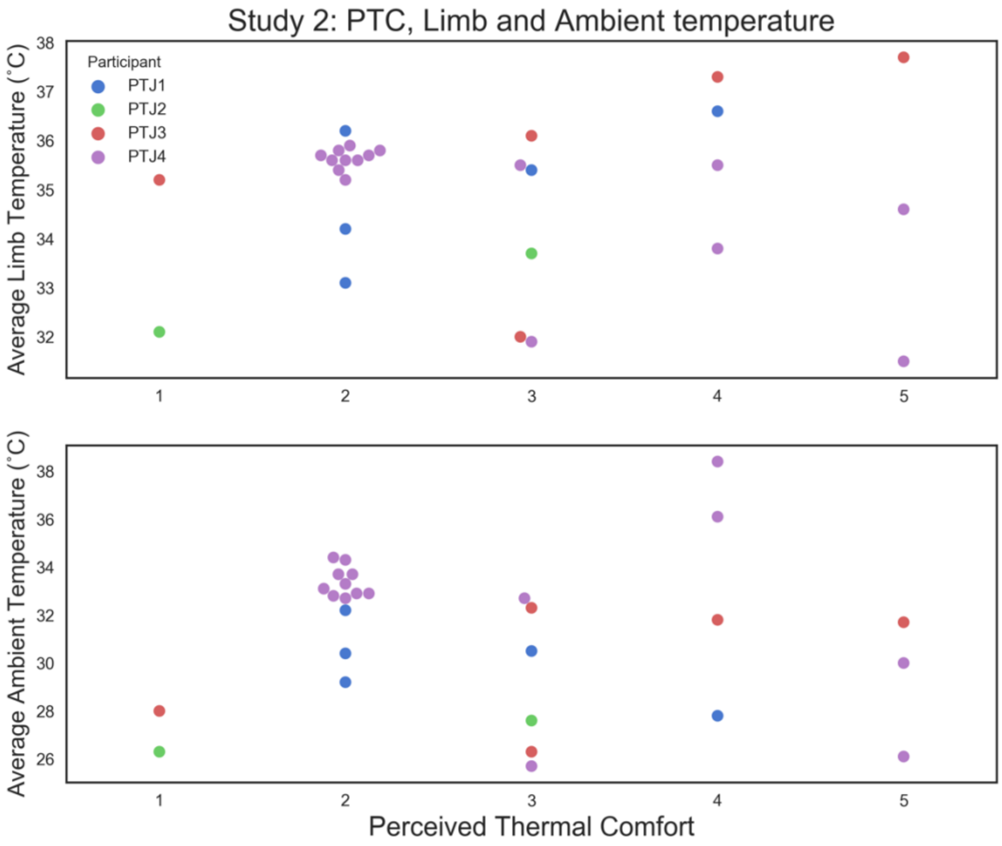


Figure 17: Swarm plot consisting of PTC vs average limb temperature and PTC vs average ambient temperature during study 2b. 1 = very comfortable, 2 = comfortable, 3 = neutral, 4 = uncomfortable, and 5 = very uncomfortable.

These values (PTC and 5-minute limb and ambient temperatures) were then plotted as swarm plots (Figure 17) for visual inspection. A Wilcoxon Signed-ranks test revealed that experiments conducted away from the lab yielded significantly hotter mean residual limb temperatures than in lab tests (Z = -2.023 p = 0.043), with an increase of 1.9 ˚C (95% CI = 1.2 – 2.6 ˚C).

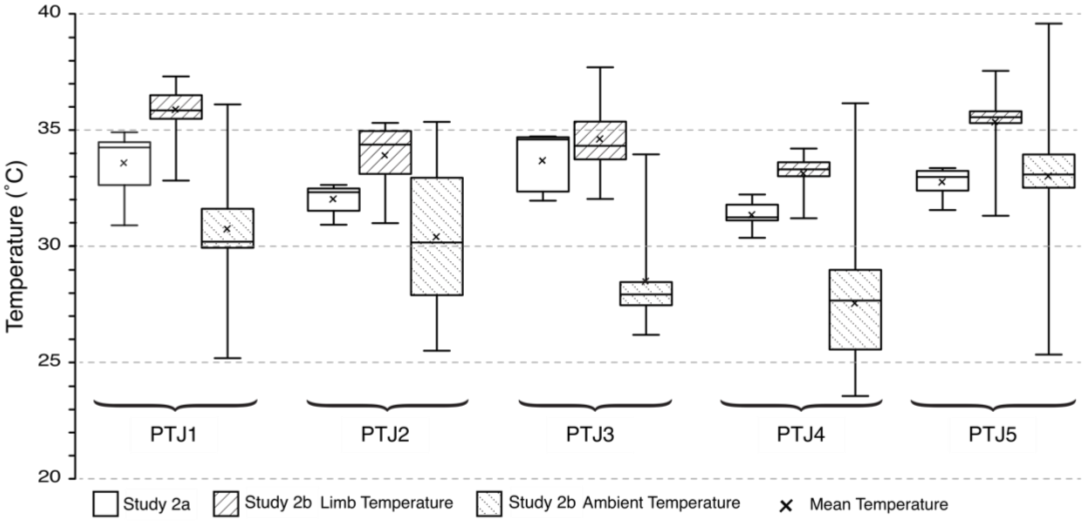


Figure 18: The residual limb temperature data from study 2a and 2b, and ambient temperature data from 2b are displayed as a boxplot distribution for all participant datasets.

7.3 Discussion

The studies presented in this chapter collected data in a laboratory-based research scenario and an out of lab scenario and proves that it is possible to conduct multiple hour autonomous studies away from the lab and generate unique insights. In-lab data were collected over a 55-minute period according to a structured research protocol and out of laboratory data were collected between 2 hours and 22 minutes, to 5 hours and 21 minutes- dependent on participant schedules.

Thermal discomfort studies have previously provided insights into the types of temperature changes seen in transtibial prosthesis wearers in laboratory settings whilst performing controlled activities. A notable exception was the study by Segal and Klute, who investigated residual limb temperature in a cold non-laboratory environment [216].

When reviewing data from study 2a, increases in residuum temperature are noticeable after donning the prosthesis – an observation first reported by Peery et al. [183]. Most participants also displayed an increase in temperature during the exercise phase – something that was clearly demonstrated in PTJ1 and PTJ3. PTJ4 did not display a clear change in limb temperature; however, this unique behaviour could be due to the lack of a liner. In the final rest phase, all participants demonstrated a further increase in limb temperature with PTJ1, PTJ2, PTJ3 and PTJ5 approaching a plateau. Only PTJ4 appeared as though their limb would continue increasing in temperature if the rest period continued. None of the participants' residual limbs returned to pre-exercise temperatures which clearly demonstrates that heat is retained at the prosthesis-skin interface. Previous studies observed residual limb temperature changes ranging from 1.7-3.1˚C in controlled laboratory settings [110,130,183]. However, here, in similar conditions, the largest temperature change in the lab was 3.7 ˚C (PTJ1).

When inspecting the time-series plots (Figure 12- Figure 16), participant-by-participant trends are apparent. For example, PTJ1 (Figure 12) experienced an initial rise in ambient temperature, which was mirrored with a steady rise in limb temp up until 13:40. Unfortunately, the data collection system malfunctioned and did not record data for a 50-minute period. Decreases in ambient temperature also appeared to be associated with temperature at some points- for example, ambient temperature markedly decreased from 34.4 ˚C at 15:33 to 29.8 ˚C by 16:25. Limb temperature also diminished from 37.3 ˚C to 35.9 ˚C, during this time period. When PTJ5 participated, it was a particularly hot day, and as such, when the participant was outside experiencing temperatures approaching 40 ˚C, limb temperature also correspondingly increased. This is behaviour is evident at both the first 45 minutes and the last 15 minutes of the experiment.

The collected data also suggests that ambient temperature is not the sole predictor of limb temperature, something best demonstrated by a portion of temperature data collected from PTJ3 (Figure 15). Between 12:15 and 16:00, ambient temperature remained relatively stable. Initially, limb temperature decayed from 34.1 ˚C at 12:15 to a low of 32.7 ˚C at 13:29. However, despite the stable ambient temperature, limb temperature visibly continues to increase up to 35.6 ˚C by 15:59. The increase in limb temperature could have been due to physical activity during this time interval; however, it could also have resulted in changes in ambient parameters such as humidity.

Some participants' data was seemingly less interesting. For example, PTJ2 (Figure 13) experienced a gradual increase in limb temperature from 31.0 ˚C at 14:10, to 35.1 ˚C by 15:40, eventually reaching an apparent plateau. However, there are few remarkable features to discuss. Additionally, when reviewing the time-series plot of PTJ4s data

(Figure 14) there are also no clear nor obvious trends which are observable. In future studies, unremarkable datasets such as these may prove to be more interesting, when additional sensing modalities are also considered.

When we consider PTC data, PTJ1 who had the hottest mean residual limb temperature of 35.9 ˚C also recorded being thermally uncomfortable the most (PTC = 4). PTJ4, who had the coolest mean residual limb temperature of the participants at 33.1 ˚C recorded being thermally more comfortable than any other participants (PTC = 2). The notion that a warmer limb may result in higher instances of being thermally uncomfortable appears logical. However, after inspecting (Figure 17), it is possible to see data which both confirms and conflicts this. For example, PTJ1 recorded a PTC of 4 when their limb was warmer (36.6 ˚C) compared to other comfortable or neutral recordings (PTC = 2-3, limb temperature = 33.1-36.2 ˚C). However, in this uncomfortable instance, PTJ1 was in a cooler ambient environment (27.8 ˚C) compared to PTC recordings that were lower (PTC = 2-3, ambient temperature = 29.2 – 32.2˚C). PTJ3 also recorded uncomfortable PTC values of 4 and 5 when their limb was warmer (37.3 ˚C and 37.7 ˚C respectively) than other neutral or comfortable PTC recordings. These uncomfortable PTC recordings were also experienced mostly at warmer ambient temperatures (31.8 ˚C and 31.7˚C respectively) compared to neutral or comfortable recordings. In contrast, PTJ4 recorded two PTC = 5 instances with a limb temperature of 31.5 ˚C and 34.6 ˚C (ambient temperature = 26.1 ˚C and 30.0 ˚C respectively) and two PTC = 4 instances with a limb temperature of 33.8 ˚C and 35.5 ˚C (ambient temperature = 33.8 ˚C and 35.8 ˚C respectively). The three PTC = 3 (neutral) recordings occurred when the limb was between 31.9 – 35.5 ˚C and at an ambient temperature of between 25.7 – 32.7 ˚C. The other ten PTC = 2 (comfortable) recordings occurred when the limb was between 35.2 – 35.9 ˚C and ambient temperatures were between 32.7 – 34.4 ˚C. The implication of PTJ4s data is that this participant felt thermally comfortable even when his limb was relatively warm and in a warm environment. Given the complexities to the data and the implication that more data sources may be required, it is not possible to convincingly identify a relationship between PTC, ambient and limb temperature using the data collected in this study.

Figure 18 shows that all participant’s residual limbs were, on average, hotter in the out of lab phase than in the in-lab lab phase. This is confirmed by a significant increase of 1.9

˚C (95% CI = 1.2 – 2.6 ˚C, p = 0.043). Differences in ambient temperatures between phases make this a relatively unsurprising finding, however, it subtly highlights the value of out-of-lab studies which have natural variety to prosthetic thermal comfort research. Additionally, during phase two, PTJ5's residual limb changed temperature the most, at 5.1 ˚C. This appears higher than increases found by Segal and Klute [216], who found a mean residual limb temperature change of 3.9 ˚C. However, as only the mean residual limb temperature changes between subjects were reported and not the range, it is difficult to compare. This difference may indicate that any thermal discomfort solutions designed using an engineering specification derived from prior thermal discomfort work, could under specify the required cooling capacity.

7.3.1 Changes to future work

The two studies that were conducted for this chapter provide meaningful and worthy contributions to our general understanding of thermal discomfort by opening up recruitment criteria to individuals with higher levels of amputation, extending protocol length beyond the status quo and by collecting data in naturalistic contexts. However, although this chapter is a step forward in thermal discomfort research, the data provides minimal assistance in truly understanding how thermal discomfort arises for prosthesis wearers in their daily activities.

Firstly, small participant size (n=5) means that generalizations about the wider amputee population cannot be made. It is important to also highlight that participants were all relatively active, and therefore, our findings may not translate to lower activity prosthesis wearers. One additional limitation which is inherent to most prosthetics research is that prosthesis prescription was not consistent between participants, as it would have made recruitment prohibitively difficult. However, prescription differences do not reduce the validity of the presented analysis nor findings.

One of the most obvious limitations to the data analysis was simply the lack of PTC data quantity, which makes it unwise to attempt any more sophisticated analysis beyond visual inspection. During the design process of the PTC reporting devices, the conscious decision was made to not include any form of reminders or notifications to record data to minimise annoyance and interruption to participants' activities.

As notifications were not used, PTC was recorded via dedicated physical objects as I perceived that during the experiments, participants might naturally be reminded to report their PTC levels by simply seeing the physical embodiment of the PTC reporting device. If an alternative smartphone-based PTC strategy were used (without notifications), the PTC reporting mechanism would likely be in competition for attention with other phone features. For example, if an app-based reporting strategy were used, the PTC reporting app would be competing for attention with a participants' phone calls, text messages, entertainment and social networking applications. However, despite these concerns, a digital PTC reporting tool may offer increased robustness of data collection and events such as the loss of PTJ5's PTC data (due to an issue with the SD card hardware) may be avoided. Moving to a digital PTC reporting tool would, therefore, be a welcome methodological progression, with the additional use of notifications.

When examining the PTC data in combination with ambient and limb temperatures, no clear trends are evident. This leads to a number of potential avenues for PTC investigation in the coming chapters. The first consideration is that PTC could be related to other parameters that were not observed. For example, when we consider ambient conditions, it may be that factors such as ambient relative humidity also need to be considered, as has been done in thermal comfort research in non-prosthesis wearers. Physical activity is also an identified trigger which should be considered and tracked either in terms of metrics such as heart rate or step count. Therefore, attempting to track additional physiological and environmental information would make a welcome addition in trying to understand the characteristics of thermal discomfort.

7.4 Summary and next steps

Upon reflection of the processes and methods used in this chapter, some important lessons were learnt which were taken forward. The first lesson is that PTC data should be collected using the assistance of some form of notification system. Although the use of notifications would not guarantee uniformity in quantities of PTC data collected between participants, it would at least provide a uniform sampling approach between participants. To mitigate the concern of oversampling, leading to onerousness and annoyance, exploring appropriate sampling frequencies for self-reporting would be a necessary step.

It is clear that to understand thermal discomfort amongst prosthesis wearers, a much more ambitious approach is needed than demonstrated here, and multi-day studies may be required. Long-term, multi-day out of lab research, however, have numerous challenges. The first relates to designing an easy to use and reliable PTC reporting system, which samples at an appropriate frequency. Such a system would face a tension between collecting ‘enough’ data to satisfy the research goal, without oversampling, which could interrupt daily activities, or lead to annoyance and frustration resulting in participant withdrawal from the study. As recruiting prosthesis wearers is an activity which requires sustained time, effort and expense, it is important that such an extensive study is designed to minimise participant attrition due to an overly onerous protocol.

The second challenge relates to sourcing or designing and creating a sensor system which can track ambient conditions (including temperature and humidity), physical activity (including heart rate, step count or other physical activity indicators) and residual limb temperature. Such a sensing system must be necessarily robust to minimise failures in data collection. Thermistors are prone to wire breakages, as demonstrated here and in other studies. Therefore, robust wiring or ideally wireless systems should be explored. The sensor system must also be feasible to wear during normal daily activities, as well as easy to attach and remove as deemed necessary by participants. In both study 2a and 2b, application of the limb temperature sensors was laborious, requiring researcher assistance. Finally, a sensor system must either require no charging or be easily charged by participants and data collection and storage should be autonomous or at least easy and quick enough to require minimal participant intervention. As these considerations represent an essential and significant investigation in their own right, chapter 8 explores aspects of such a sensor system in detail.

8 STUDY III: REAL-WORLD THERMAL DISCOMFORT RESEARCH

The previous chapter aimed to explore if a sensor-based strategy could be used to identify triggers for thermal discomfort. As discussed, in the previous study, it was not possible to find any convincing evidence of a relationship between PTC and residual limb temperature or ambient temperature. However, due to the small amount of PTC data, which was collected, it could be that there simply was not enough data to identify a relationship.

To appropriately investigate the research question and to begin to inform what conditions cause thermal discomfort, it was necessary to collect a larger multivariate dataset, centred around PTC data. However, to collect a *‘large’* dataset, multiple approaches could be taken when designing the protocol. The first approach would be to recruit many more participants. However, amputees represent a small proportion of the general population, and individuals who regularly wear a prosthesis are an even smaller minority of the wider amputee population. Therefore, recruitment at scale is a non-trivial challenge. Often in these types of research studies, one aims to recruit as many individuals as is practical with respect to pragmatic boundaries such as time and money. Instead, a more realistic approach to collecting more data is to extend the duration of a thermal comfort research study to a multi-day or even multi-week longitudinal study. In recognition of these options, a two-week longitudinal study was designed to collect a data set which could be used to interrogate the research question.

In this chapter, the protocol used for the final situated study is presented in detail. The many facets of a multivariate study required significant design and research effort to be devoted to crafting sensor strategies that were not only safe and reliable but also compatible with everyday activities of participants. The protocol is introduced and explained, and each sensing aspect of the study are presented, in combination with supporting research. Finally, the data processing and analysis strategy which was used is illustrated, preceding presentation of the collected data and discussions in the subsequent chapter.

8.1 Method

8.1.1 Participants

Institutional ethical approval was obtained (reference: UCLIC/1617/010/Staff Holloway/Williams) and prospective participants were recruited via social media and clinical contacts, with recruitment criteria being individuals aged between 18-65 years. Participants were required to wear a prosthesis daily and to be at least two years post-amputation. Recruitment criteria with regards to amputation aetiology and level were flexible, with unilateral and bilateral amputees considered, as well as TTA, TKA and TFA amputees. Individuals with diabetes were once again excluded. However, for this study, participants with additional arm amputations were not recruited, as I perceived that the sensors would likely be difficult to apply independently. Once participants were recruited, prospective participants were asked if they currently had any skin irritation on their residual limb or had experienced any skin issues within the last 30 days. If participants were currently experiencing skin issues, they were not recruited until they were at least one-month post healing. Upon passing this screening step, arrangements were made to setup the participant with equipment. Once participants had completed the study, each participant was emailed a £100 Amazon voucher as remuneration for their time commitment.

8.1.2 Procedure

Once participants were recruited, arrangements were made for the participant to come to the research institute, or to meet in a mutually agreeable location (e.g. a participants' workplace). The initial set up of the study took approximately 60 minutes and began by obtaining informed consent. Whilst obtaining consent, I was available to answer any

questions or to provide clarifications. Once consent was obtained, participants were asked to provide some demographic information and to discuss their experience with thermal discomfort (a mini interview guide can be seen in Appendix 3). This initial entrance interview was captured using an audio recorder and took no more than 20 minutes.
Following the entrance interview, the sensor system was described to the participants, showing them how to charge each sensor, maintain them, and how to wear them. Both the Fitbit and ambient sensor required minimal explanation. Participants were shown where to wear the Fitbit, how to charge it, how to upload data, and how to review data if they were interested. The ambient sensor simply required participants to wear the sensor and required no charging or participant interaction. However, all participants were informed that the ambient sensor had to be worn external to all clothing, including coats or jackets.

The PTC sampling system was then introduced to the participants. For the duration of the study, individuals were provided with a smartphone to receive and reply to PTC sampling requests. Participants were informed that throughout the study, they would receive multiple SMS text messages throughout the day asking them to report their current perceived level of thermal comfort, what activity they were doing at that instance and where they were. To ensure that participants clearly understood the meaning of thermal comfort, a pre-defined definition of thermal comfort was read out:

“Thermal comfort is the state of mind where you are comfortable within your thermal environment”

In some cases, additional explanation was provided that the thermal environment relates to how hot or cold the environment is, or even how humid it feels. To provide standardised responses, a standardised 1-5 Likert scale was used. All participants were informed to reply to the sampling request with a value that represents *“how thermally comfortable your residual limb makes you feel”.* Additionally, I explained that when reporting their activity and location, a brief description of what they were doing at that moment was all that was required. Finally, if participants were otherwise occupied when they received a sampling request, they were free to reply when convenient but should try to reply as close to the original request as possible.

Setting up participants with the skin temperature sensor required more explanation and intervention. Firstly, though the sensor system was simple, participants were shown how to turn the sensors on and off, how to charge the sensor, and how to connect temperature sensors to the main data logger box. Participants were then advised that throughout the study, they must pay particular attention to their limb and if they began to feel intense itching at the location of the sensors, pain rather than discomfort or a burning sensation, they should remove the sensor immediately and contact the research team. Additionally, when removing the sensors each day, participants were asked to monitor for any signs of skin damage where the sensors were or any indentations that persisted for more than 45-60 minutes, post-sensor removal. In all circumstances, participants were advised to err on the side of caution and if in doubt to remove the sensors and to contact the research team. This comprehensive description of what to look out for when wearing the sensors helped to ensure the study had reasonable and sensible precautions whilst participants independently wore the sensors.

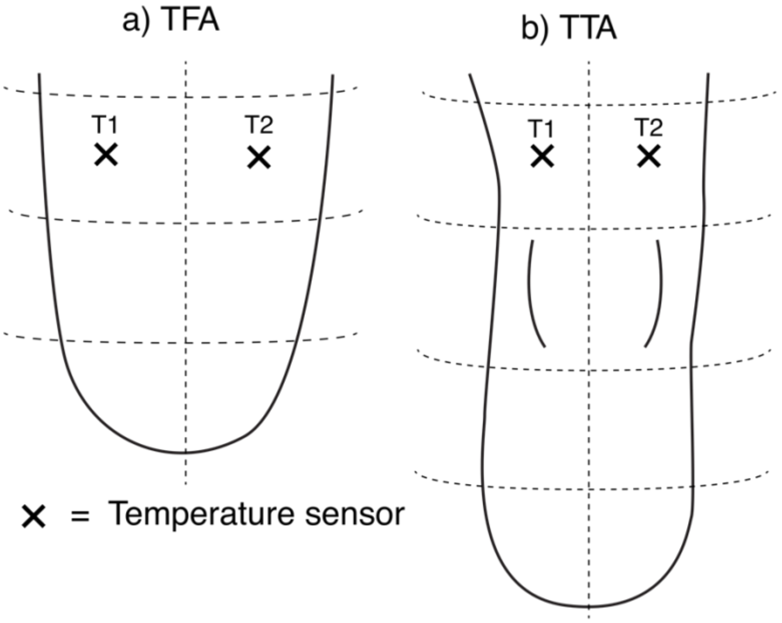


Figure 19: Thermistors positioning across participants' limbs was kept consistent, allowing for anatomical differences. Fewer thermistors were used compared to Study 2.

To appropriately advise on where to place the skin temperature sensors on the limb, participants were asked to remove their prosthesis. At this point, the residual limb was inspected for any signs of skin irritation, bony prominences, invaginations and scar tissue. If any of these areas were present, participants were warned that the sensor and wiring must be placed away from these limb features. After obtaining permission from the participant, the residual limb was also palpated to find compliant areas on the anterior medial and anterior lateral areas. Upon finding a suitable position, sensors were applied using Hypafix medical tape, and wiring was tracked underneath clothing. The two temperature sensors were placed in approximately the same location for each participant (Figure 19), and a photo of the recommended position was taken on the supplied smartphone to act as a reference for when the participants applied the sensors independently. Once limb temperature sensors were applied, participants were asked to don their prosthesis, ensuring that cabling laid flat underneath their liner. If required, participants were advised to use tape to keep the cabling flat. Once their prosthesis was donned, participants took a few supervised steps around an office room and asked if they noticed any pain and to check that suspension was maintained. If pain or lack of suspension was present, the sensors were repositioned until comfortable. If suspension could not be maintained even after sensor repositioning, the prospective participant was advised against participation. This was only encountered for one prospective participant, who had an active elevated vacuum prosthesis. After a few successful steps in an office room, participants were then supervised to walk up and down a 15m corridor and asked if they experienced pain or discomfort. If this procedure was successful without issues, participants were free to leave the lab whilst wearing the equipment. As this contact with participants was in the afternoon or evening, the remainder of the setup day was used as a trial run of wearing the sensors, with the first day of the study commencing on the following morning.

Over the next 14-days, participants continued their daily activities whilst wearing the sensors and replying to the PTC sampling requests. At the end of each day, participants were asked to charge the iPhone, Fitbit and skin sensors. In some instances, participants informed me that they needed a day off the study (e.g. to compete in an all-day triathlon) but would complete an extra day of the study at the end of the original two-week period. Over the 14 days, participants were telephoned at the end of day 1, 4, 7 and 10 and asked to answer a pre-defined safety checklist. If participants passed the checklist, I asked them to continue the study if they were happy to do so.

Upon completing the experimental aspect of the study, participants were contacted to arrange return of the sensor equipment and to conduct a brief exit interview. Each exit interview lasted approximately 15-20 minutes and predominantly centred on the participants' experience of the study, a review of what each level of thermal comfort meant to them and some in-depth exploration of their provided PTC reports, which was reviewed prior to the meeting with the participant.

8.1.3 Materials

This study intended to create a holistic data set that could be used to reconstruct an amputee's experience of thermal discomfort and to identify conditions that cause discomfort to arise. However, to collect a data corpus such as this, it is tempting as researchers to burden our participants with *'just-one-more'* sensor or question. Whilst this approach ensures the maximum amount of data is collected from participants, overly burdensome research protocols can come at the cost of disruption to a participants' life. Therefore, in recognition of this tension, each facet of the sensing system was designed with the mantra of *sensing-minimalism*, wherein the aim was for the sensing system to disrupt participants at a practical minimum, and only be required if there was a logical need.

8.1.3.1 Entrance interview

To provide some initial context to each participants' data, the study began by conducting a semi-structured interview, using an interview guide (Appendix 3). Participants were first asked to describe any experiences of skin irritation. The causes and situations relating to the skin irritation arising were developed further. Participants were asked if they experience thermal discomfort whilst wearing a prosthesis, how frequently they experienced this discomfort and under what situations. Finally, the interview ended by investigating the consequences of thermal discomfort for the participant.

8.1.3.2 Skin temperature sensing

8.1.3.2.1 Requirements

The previous skin temperature sensing system was developed in the previous chapter was capable of tracking 16 thermistors. However, as has been discussed, this number of sensors required the assistance of two researchers to attach all of the sensors, taking approximately 5 minutes to apply. During a study completely away from the lab, participants had to be able to apply sensors independently and ideally without adding undue amounts of time to prosthesis donning. Therefore, an approach used in prior research [154] of sensing limb temperature at only two points was used. The sensor nodes and data logger also had to be comfortable, robust, small and unobtrusive to be able to be worn for multiple hours, across multiple days. Finally, the device needed to be able to collect data for 14 days continuously, therefore requiring large enough data storage and battery capacity.

8.1.3.2.2 Technical specification

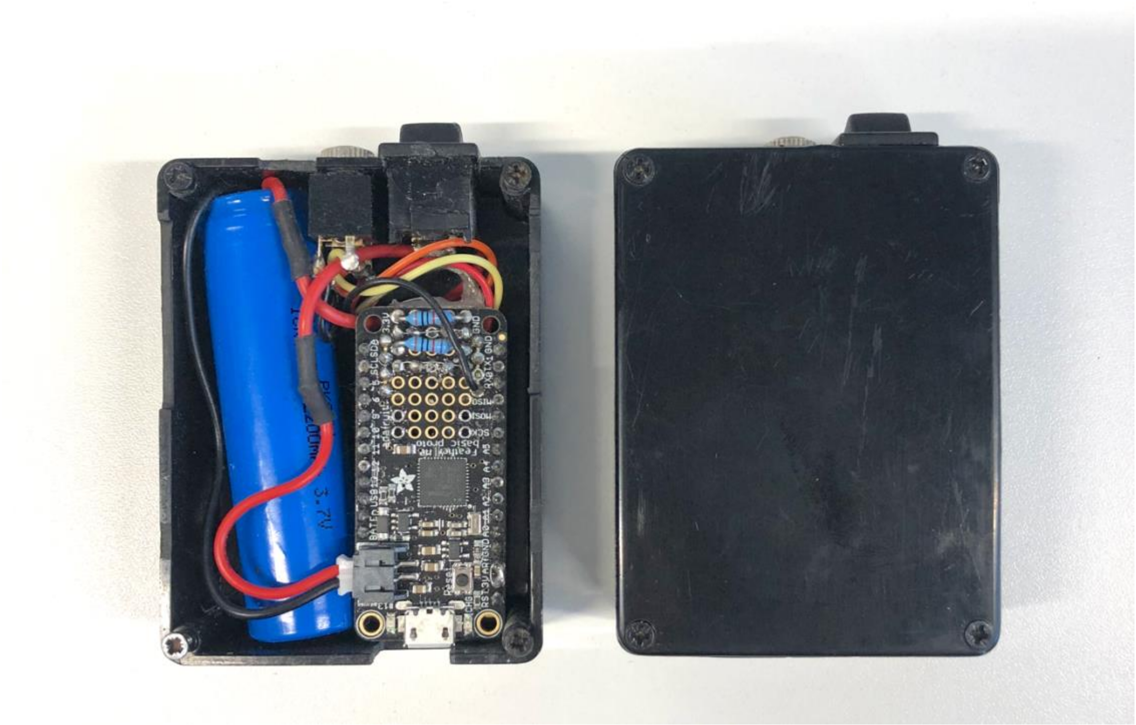


Figure 20: A temperature data logging sensor was constructed in a small waist mounted plastic enclosure, comprising of a microcontroller, battery and connection ports.

The data logging system was based on an Adafruit M0 Basic proto board (Adafruit, USA), which supported a 32-bit ATSAMD21G18 ARM Cortex M0 processor (Figure 20). This micro-processor also contained a 12-bit analogue-to-digital converter. To enable timestamping of the data, the microcontroller was connected to a data-logging shield which contained a PCF8523 Real Time Clock (NXP, Netherlands) and a micro SD card reader. Two B57863S103F40 NTC thermistors (Epcos, Germany) were connected to a linear potential divider (10 kΩ ±0.1% tolerance resistors). Thermistors were Lineman splice soldered to standardised 1 m lengths of 28 AWG ribbon cable. The Steinhart-Hart equation (Appendix 2) was used to calibrate the sensors to an absolute measurement accuracy of ±0.2 ˚C, in a 0-70 ˚C range. The system was powered using a 2200 mAh lithium-ion battery, which was capable of providing 16-days of continuous monitoring.

All hardware was contained in a waist-mounted enclosure, measuring 75 x 55 x 25 mm (LxWxH) and mounted to a waist belt which could be discretely positioned underneath clothing. To obtain the data, the Arduino IDE was used to create custom software. Data were collected at a frequency of 1 Hz. Improvements in battery life, in comparison to the previously developed temperature sensing system, were possible by storing 60 seconds of data in FLASH memory, before writing to the data to the SD card.

8.1.3.2.3 Testing and iterations

To test the real-world practicality of the sensing system, I undertook a mock deployment of the sensing system, attaching it to the medial and lateral anterior of my non-amputated tibia. For 14-days, I wore the system whilst continuing my normal activities, ranging from commuting through a busy city, working in an office building and socialising with friends and family. This first self-test phase, whilst not a true replication of applying temperature sensors to a residual limb interface, still provided a useful opportunity to test the usability of the system and to identify system issues. As well as self-testing, however, the first participant of the study volunteered to also relay design suggestions during their study. As the participant lived close to the research lab, it was possible for the participant to raise an issue and a new system iteration to be provided before the next day of the study commenced.

Based on these tests, a number of changes were made to the limb temperature sensing system. When self-testing the sensors system, the majority of changes were made to the belt system. The first development of the system used an elasticated waist belt; however, this either felt overly constrictive when tight or as if the system was falling down my waist when slightly looser. Additionally, the plastic clip mechanism which tightened the strap occasionally ‘slipped’ when moving due to the elastic in the strapping. To solve these issues, a non-elasticated waist strap was used instead.

When the sensor system was tested by the prosthesis wearer, initially, thermistors were connected using flexible flat cable (FFC). Although in the previous chapter, ribbon cable was not highlighted by participants as being uncomfortable, over a long-term experiment, I imagined that ‘thick’ ribbon wiring could become uncomfortable. Therefore, FFC was thought to be the most unobtrusive wiring possible whilst also having high toughness and durability. However, whilst unobtrusive, the participant noted that completely flat cabling had sharp and uncompliant edges which occasionally caused pain. Therefore, another approach was immediately trialled. The second iteration of wiring was to use single core 30 AWG wire. As this wire was thin, it was thought to provide the same features as FFC, however, pain would be mitigated due to the circular wire profile. However, after one day of testing this new cabling, the participant stated that the fine wiring caused intense pressure at the interface, which made the wiring feel sharp and harsh on the participants' skin. In recognition of this, the final wiring iteration of wiring was developed, whereby the original 28 AWG two-wire ribbon cable was used. Upon trialling this iteration of sensor wiring, the participant almost immediately noted that it was significantly more comfortable than the previous versions. Though wiring may seem like an afterthought in sensor development, this experience of sensor wiring iteration highlights the importance and difficulty of ensuring technologies are developed with the insight, input and experience of the intended wearer of sensors. Participant involvement with system development revealed that my design preconceptions were false.

One of the final changes to the system was that even with the new wiring, it became clear that thermistors needed to be replaceable by participants. Wired thermistors have been shown previously to have a high probability of failure. Therefore, rather than be directly soldered to the sensing system, thermistors were instead connected to di-pole 3.5mm jack connectors to enable hot-swapping. Participants were asked to inspect thermistors at the end of each day to identify breakages, and if they were noticeably broken, they should be swapped out. This meant that participants could continue with the study with minimal researcher intervention, even in the event of sensor breakage.

8.1.4 Activity monitoring

To monitor physical activity, Fitbit Charge HR (Fitbit Inc., USA) devices were used (Figure 21). These wrist-worn activity sensors are capable of detecting a wearers step count (via an accelerometer) and heart rate (via a photoplethysmography sensor), as well as a number of other inferred measures. The Fitbit Charge HR has been found to have mean absolute percentage accuracies ranging between 1-9% compared to 'gold' standard electrocardiograph sensors [231]. Application of ECG sensors can be inconvenient, owing to a conventional three-wire lead set up or a chest-worn strap setup and can also be uncomfortable when worn for more than a few hours. Therefore, wrist-worn HR sensors are a convenient alternative with reasonable accuracy, given their comfortable form factor and ease of application. Fitbit devices have also recently been shown to have a mean absolute percentage error below 10% when worn by prosthesis wearers [8], a value which is within the norm of other commonly used and experimentally validated step counters [138].

Although there are alternative wrist-worn activity sensors that could have been used (e.g. Empatica E4 or Apple Watch), many of these devices are at least ten times more expensive than Fitbit Charge HR devices, which can be purchased for approximately £45. Given that any out of lab deployment of sensing equipment has the inherent risk of equipment being lost, the cheaper Fitbit option was most suitable.

Figure 21: Fitbit sensors were provided to participants to be worn on their wrists during the duration of the study as activity monitors.

To collect and retrieve the data, the manufacturer smartphone application was installed on the provided smartphone, configured to an anonymous user account, and set to continuously synchronise the data from the watch to the phone. Data were then extracted using the Fitbit Application Programming Interface (API), with a custom Python 3.7 script used to collect timestamped HR data (collected once per second) and step-rate (collected once per minute).

8.1.5 Ambient condition monitoring

To sense the local ambient conditions experienced by participants throughout the study, a separate ambient monitoring sensor was needed. This would provide an insight into the conditions around the participants at any one time and indicate transitions between different thermal environments. To collect this data, Tempo Disc (BlueMaestro, UK) Bluetooth sensors were used to continuously log ambient temperature and relative humidity (RH). Temperature measurement accuracy is reported as ±0.3 ˚C, and RH accuracy is reported as ±3%. The sensors were set with a sensing interval of once every 20 seconds; however, data were only logged once every 5-minutes. During the experiment, sensors were mounted in a sensor holder and attached to a lanyard which was worn by participants external to all clothing (Figure 22). Data were downloaded at the end of the study using the companion smartphone application.

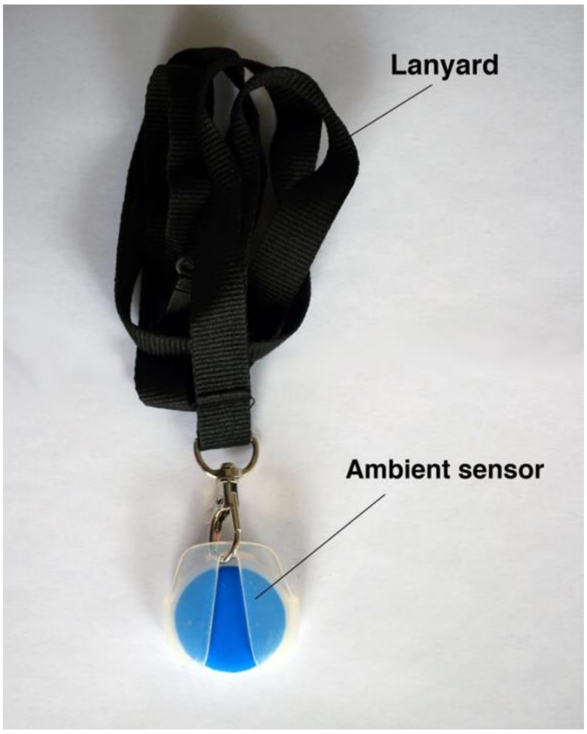


Figure 22: Ambient temperature and humidity sensors were mounted in a lanyard.

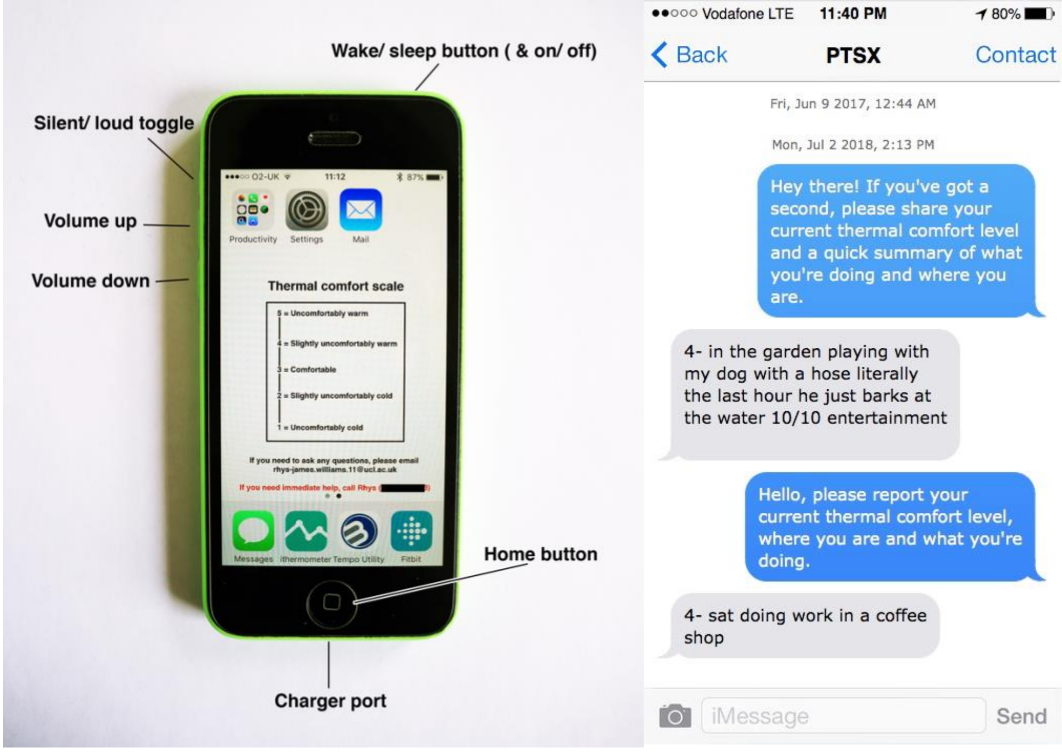
8.1.6 Experience sampling: Perceived thermal comfort

8.1.6.1 Purpose

The final dimension of the sensor system was to devise a technology which could reliably and regularly collect PTC data. As was intended in the previous chapter, PTC data would ensure that data were analysed from the perspective of participant experience and perception of the phenomenon, rather than based on the researcher’s interpretation. Upon combining PTC data with other sensor data, it would be possible to explore if certain physiological, environmental or experiential conditions can be attributed to states of thermal comfort, therein aiming to investigate conditions which can be attributed to thermal discomfort.

8.1.6.2 Design and implementation

The first change to the PTC sampling system in comparison to the previously developed hardware devices was to implement a digital sampling approach. This design decision was taken to minimise the chance of loss of data due to hardware failure. In the previous chapter, participants reported PTC as and when they wanted. Whilst this introduced minimal interruptions to the participants, this design decision came at the cost of data regularity and introduced a large variability in the amount of data collected for each participant. Therefore, an interval-based approach which utilised reminders for PTC sampling in the final study was implemented. However, it was important to ensure a reminder schedule appropriate sampled a participants’ day, without sampling too frequently to cause annoyance of onerousness. To decide on an appropriate PTC sampling frequency, guidance from prior research [222] was used. Therefore, a sampling frequency of 12-messages per day, spaced at approximately hourly intervals was selected. Additionally, in comparison to the previous chapter, the system which was developed for the situated study extended beyond simple self-reporting of PTC by also requesting participants to record their current activity and also their location. In doing so, the developed PTC reporting system represents a full implementation of the ESM.



Thermal comfort scale

5 = Uncomfortably warm
4 = Slightly uncomfortably warm
3 = Comfortable
2 = Slightly uncomfortably cold
1 = Uncomfortably cold

If you need to ask any questions, please email rhys-james.williams.11@ucl.ac.uk

If you need immediate help, call Rhys ([redacted])

Fri, Jun 9 2017, 12:44 AM

Mon, Jul 2 2018, 2:13 PM

Hey there! If you've got a second, please share your current thermal comfort level and a quick summary of what you're doing and where you are.

4- in the garden playing with my dog with a hose literally the last hour he just barks at the water 10/10 entertainment

Hello, please report your current thermal comfort level, where you are and what you're doing.

4- sat doing work in a coffee shop

Figure 23: iPhone 5C (Apple) were used to coordinate sensors, and to collect ESM data. An example ESM SMS exchange is shown to the right.

The first message that participants received each day was a reminder asking participants to begin wearing the sensors and to reply with a ‘Yes’ once sensors were attached. This message was scheduled to arrive 10 minutes before the first sampling message of the day. Participants then received 12 PTC sampling messages requesting them to record their PTC level, what they are doing and where they are. To standardise PTC responses, a pre-defined 1-5 Likert scale was used. To help participants’ to remember the meaning of the scale, the provided iPhones’ lock screen and home screen displayed the definition of the scale intervals (Figure 23). The Likert scale had the options of ‘uncomfortably warm’ (5), ‘slightly uncomfortably warm’ (4), ‘comfortable’ (3), ‘slightly uncomfortably cold’ (2), and ‘uncomfortably cold’ (1). Participants’ were also advised to report their activities and locations generally rather than specifically (e.g. *‘I’m in a meeting at my office’* was sufficient, as opposed to *‘I’m in a meeting with person x and y, discussing z and I’m at 66-72 Gower st, WC1E 6BT.’*) A typical PTC sampling message and response pair are shown in Figure 23.

The twelve sampling messages per day were restricted to a 12-hour sampling window. However, participants were given the option to change the sampling window to their own specified sampling windows for weekdays and at the weekend. Despite this option for customisation, all participants requested a sampling window from 9 am -9 pm. Messages were sent approximately every hour, with a randomised 15-minute delay added to reduce participant expectation for sampling messages to arrive at specific times. Finally, at the end of each day, participants were sent a reminder text message requesting that they placed the iPhone, skin temperature sensor and Fitbit on charge and to synch data from the Fitbit.

The messages sent by the PTC sampling system were textual and written to convey friendliness, informality, and approachability (Figure 23). To convey this tone, informal language like *"hey"* and *"see ya",* and PTC sample requests such as *"Hey, it's thermal comfort reporting time!"* were used, as opposed to a more neutral *"Hello, report your current thermal comfort levels".* This design decision was made so that interactions with the sampling system would seem less like a survey and more conversational. Additionally, rather than ask participants to self-report PTC levels the same way each time, PTC request messages were varied so that participants would not receive the same sampling message more than once per day. Over the 14 days, participants also received unique morning and end of day messages as I imagined these would be more memorable, and a lack of variability would be noticeable.

8.1.6.3 Architecture

To create the PTC ESM system, the Twilio (https://www.twilio.com) API was used. The API provided an easy way of implementing an internet connected experience sampling service; however, to define the message content, recipient and sender, a script was written in Python 3.7. Twilio only provided the base messaging mechanism though, and not message scheduling. To automate scheduled messages, 'Cron' (a time-based job scheduler, native to Unix systems) was used.

8.1.6.4 Reliability

To test the reliability of the new system, a trial experiment was set up to automatically send 12 sampling messages per day to 20 artificial recipients. Artificial participants were made by purchasing programmable mobile numbers, with each mobile number representing an artificial participant. The newly designed system was also used to automatically generate replies to each sampling request from each recipient. This automated 'back-and-forth' system was tested for 14 consecutive days. Of the 3,360 sampling requests which were scheduled to be sent, all sampling requests were sent as expected. Additionally, all sampling request responses were replied to without failure. This test indicated that the newly designed sampling system would be reliable over a long-term deployment with multiple simultaneous participants.

8.1.7 Exit interview

Upon finishing the study, participants were invited back to the lab to return the equipment, or I travelled to a mutually agreeable location to collect the sensor equipment. However, rather than simply exchange the research equipment, participants were invited to end the study by engaging in a reflective exit interview. Exit interviews were conducted as short (>30 minutes) semi-structured interviews, with the assistance of an interview guide (Appendix 4). The interviews were audio recorded and transcribed first-hand. During the interview, participants were initially asked to reflect on their experience of the experiment. Individuals were then asked to retrace their experience of thermal discomfort and the consequences and to discuss if they noticed any situations where thermal discomfort arose more often. Participants were then asked to discuss the PTC 1-5 scale, by translating what each level of the scale meant in terms of how they experienced thermal discomfort. Finally, print outs of the collected PTC data were used to scaffold the discussion with the participant about general trends in their data, and specific PTC data points that I perceived to be interesting.

8.1.8 Data handling and analysis

8.1.8.1 Qualitative data

Qualitative data were collected during the entrance and exit interview, as well as in each PTC report. Given the qualitative data was collected to provide supplementary context to the quantitative data collected by the sensors, rather than be a qualitative study in its own right, thematic analysis was not used to analyse the data. However, entrance and exit interviews were still transcribed in-house and reviewed once for accuracy. Quotes which are presented are done so to reflect the views, and experiences of participants to provide an additional layer of depth and contextual understanding to otherwise abstract quantitative data.

8.1.8.2 Data preparation and collation

In situations where the skin temperature sensors were not worn, but data was still collected, this data needed to be filtered out of the main data corpus or it would negatively bias summary statistics. To remove the unneeded data, a two-step process was used. Firstly, a simple threshold was used to remove temperature data which was below 20 ºC. This threshold was selected as skin temperature would be highly unlikely to be below this value, given the seasonally warm weather during the experiment. The threshold removed most of the irrelevant data. However, sections of the data which reflected sensors being applied or removed demonstrated sharp turning points in the data. To filter out turning points, the time-series plots were inspected, and turning point data preceding a filtered-out data plateau were manually removed (Figure 24). Data from both thermistor sensing sites were then averaged between each reading. Corresponding ambient temperature, humidity, HR and step rate data which was collected during these periods of non-wear of the skin temperature sensors were also removed from datasets as required.

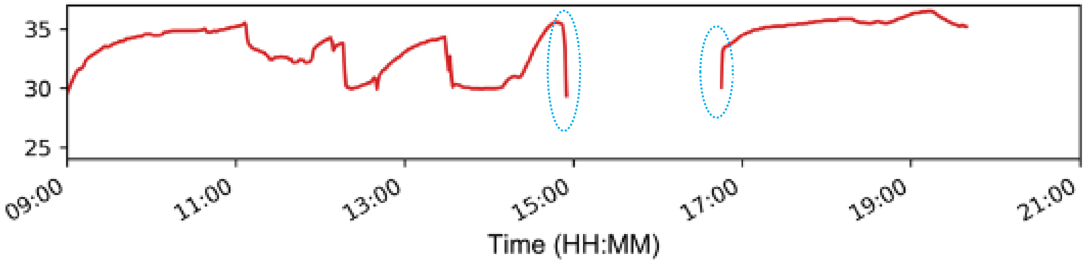


Figure 24: An example of data which required manual removal, where sensors had been removed and turning point artefacts remained.

One of the main challenges when processing multi-dimensional datasets collected from disparate sources is that data are rarely collected at the same sampling frequency. Here, sampling frequency varied from once per second (Skin temperature and HR), once per minute (step-rate), once per 5-minutes (Ambient temperature and humidity) and approximately once per hour (PTC). Higher frequency data were downsampled using a mean filtering approach to represent minute-by-minute data. Step rate data were downsampled to reflect the number of steps taken in 5-minute periods. With the dataset appropriately resampled and filtered, the time index of each PTC data point was used to synchronise matching skin temperature, ambient temperature and humidity, HR and step rate data. Two versions of the dataset were preserved; one which contained complete data and one which contained data where one or more of the data sources were missing at that specific PTC recording.

8.1.9 Protocol limitations

8.1.9.1 Restrictions to sensor wearing

Although the experiment hoped to capture a reflection of normal daily life, some restrictions were placed on when the sensors should be worn. For example, the sensors were only to be worn during waking hours, were not to be submerged in water (therefore prohibiting bathing and swimming) and were not to be worn during exercise. Data collected during exercise would have undoubtedly been interesting, as it would have captured situations where skin temperature, and possibly thermal discomfort, would have likely reached an absolute maximum. However, though the Fitbit sensor would be suitable for wear during exercise, the neck worn ambient sensor could have been both unsafe and disruptive to participants while exercising. Additionally, during impact exercise (e.g. running or ball games), the skin interface would experience forces far above those experienced during everyday ambulation. The introduction of a rigid sensor under these conditions was perceived to introduce undue risk of skin irritation and breakage of the sensor equipment. For these reasons, participants were asked to remove the sensors before exercising and to re-apply them once they had finished exercising.

8.2 Results

In total, five participants (2 females, 3 males) were recruited, with a variety of different levels of amputations and aetiology. Experiments took place between the end of May and the end of July 2018. During this period, the UK experienced a number of heatwaves. Due to the large amount of data collected for each participant, each participants’ data are individually presented in detail in the coming sections.

8.2.1 Participant 1

The first participant (PTS1) was a male amputee in his early forties. He had become an amputee 2.5 years prior to participating after contracting meningococcal meningitis, requiring bilateral transtibial amputations. Although he was a bilateral prosthesis wearer, data was only collected from his right leg as he noted that although he was in perfect health at the time of participation, he had historically experienced more issues with his left leg. His right prosthesis utilised a polycarbonate pin-lock socket, in tandem with a Silcare Breathe liner (Blatchford, UK). His left prosthesis was also polycarbonate with the same liner; however, the suspension was suction as opposed to pin lock, with an additional 6-mm thick suction sleeve.

PTS1 worked part-time (3-days per week) as an office worker in London. When asked about their general day-to-day routine, they reported an active lifestyle. When working, PTS1 typically started work at 10 am, so would awake at 8 am, have breakfast, leave the house and commute via bus for 20 minutes. Whilst at work, their work activities mainly involved sitting at a desk or going to meetings. However, PTS1 would often walk to buy lunch or eat their lunch in a park or back at the office. Their working day typically finished by 5 pm and upon returning home via the same mode of transport, they would occasionally meet up and socialise with friends. However, it was more common for him to prepare food upon returning home, eat and then relax by watching television and occasionally *“pottering”* around the house. Non-workdays typically differed as PTS1 would visit the gym in the morning and possibly also go swimming. They often tried to meet up with friends on their non-working days, although that typically was in the evening. Generally, this lifestyle can be considered highly active. However, although they wore their prostheses for long periods of time, PTS1 reported frequently removing their prostheses when home, in favour of using a wheelchair, except for certain chores or activities which were more convenient with legs:

> *“I don't use a wheelchair all the time at home- especially if I’m doing- if I have to do things like washing my clothes- from the washing- or folding bedsheets, doing that from seated is not really practical”*

8.2.1.1 Experience of thermal discomfort

When PTS1 was asked to talk about their experience of thermal discomfort prior to the experiment, they stated that they experience heat and sweat discomfort on a daily basis throughout the year:

> *“not only on hot days like today, you know like even on, even during the winter I have problems with heat and sweat”*

When asked to describe how PTS1 experienced thermal discomfort, they stated that it occurred usually when doing activities, but described discomfort primarily due to the sweating.

> *“The sweat... well, say when I'm walking, mainly when I'm active, whether it's walking or if it's exercise, but even with a stroll down to the bus stop I will already feel the effects, […] and you just feel it.”*

However, the feeling of overheating- not sweating- often lead to feelings of irritability and tiredness:

> *"I usually feel slightly irritated, irritated because you know, it's not the sort of like body... temperature that you want."*

Moreover, when thermal discomfort was experienced, particularly in situations where PTS1 could not intervene and alleviate the discomfort, the discomfort increased the longer that it was endured.

> *"you know it's going to stay for a little while and it's not going to go, especially if you've got a long journey or you have to be somewhere for a long time where you know you won't be able to easily take your legs off and have a rest, it's so- you know it's sort of like, it sort of builds up psychologically"*

8.2.1.2 Overall data summary and interday data

Data were collected successfully for 13 days in total. When the data from PTS1s study are examined, it is possible to summarise that he was thermally comfortable (PTC = 3) most of the time; however, he was also slightly uncomfortably warm (PTC = 4) for a large proportion of the study. Being slightly uncomfortably cool (PTC = 2) or extremely uncomfortably warm (PTC = 5) was relatively infrequent, however, PTS1 recorded no instances of being extremely uncomfortably cold (PTC = 1). A summary of the collected data can be found in Table 11, Figure 25, and Figure 26.

Table 11: Total and intraday modes for PTC and averages for limb temperature, ambient temperature, ambient humidity, and heart rate, as well as total steps per day for PTS1 are presented.

	PTC	Limb Temp ± SD (˚C)	Ambient Temp ± SD (˚C)	Ambient RH ± SD (%)	HR ± SD	Steps per day
All Data	3	30.4 ± 2.0	24.7 ± 2.6	44 ± 7	78 ± 11	-
Day 1	3	29.4 ± 2.1	22.5 ± 1.7	48 ± 3	75 ± 12	6000
Day 2	2	29.1 ± 0.8	21.9 ± 0.9	50 ± 7	80 ± 12	8735
Day 3	3	28.3 ± 1.1	23.8 ± 3.1	41 ± 5	79 ± 10	3528
Day 4	3	30.0 ± 1.6	23.0 ± 2.5	51 ± 8	75 ± 11	8575
Day 5	3	28.6 ± 1.2	24.2 ± 2.4	44 ± 5	78 ± 11	10454
Day 6	3	30.8 ± 1.5	24.5 ± 1.8	47 ± 6	74 ± 11	7266
Day 7	3 & 4	31.4 ± 1.6	24.4 ± 1.5	40 ± 5	80 ± 12	8154
Day 8	3	32.3 ± 1.9	24.7 ± 0.8	43 ± 2	79 ± 10	6177
Day 9	4	31.0 ± 1.5	25.2 ± 0.9	43 ± 3	84 ± 11	11785
Day 10	-	-	-	-	-	-
Day 11	4	32.5 ± 0.6	27.5 ± 2.3	42 ± 4	77 ± 9	6001
Day 12	4	31.7 ± 1.1	26.3 ± 0.6	38 ± 0	75 ± 9	6802

Day 13	3	31.9 ± 0.8	26.8 ± 2.2	34 ± 5	70 ± 9	5134
Day 14	3	30.1 ± 0.9	24.1 ± 1.1	41 ± 4	82 ± 11	942

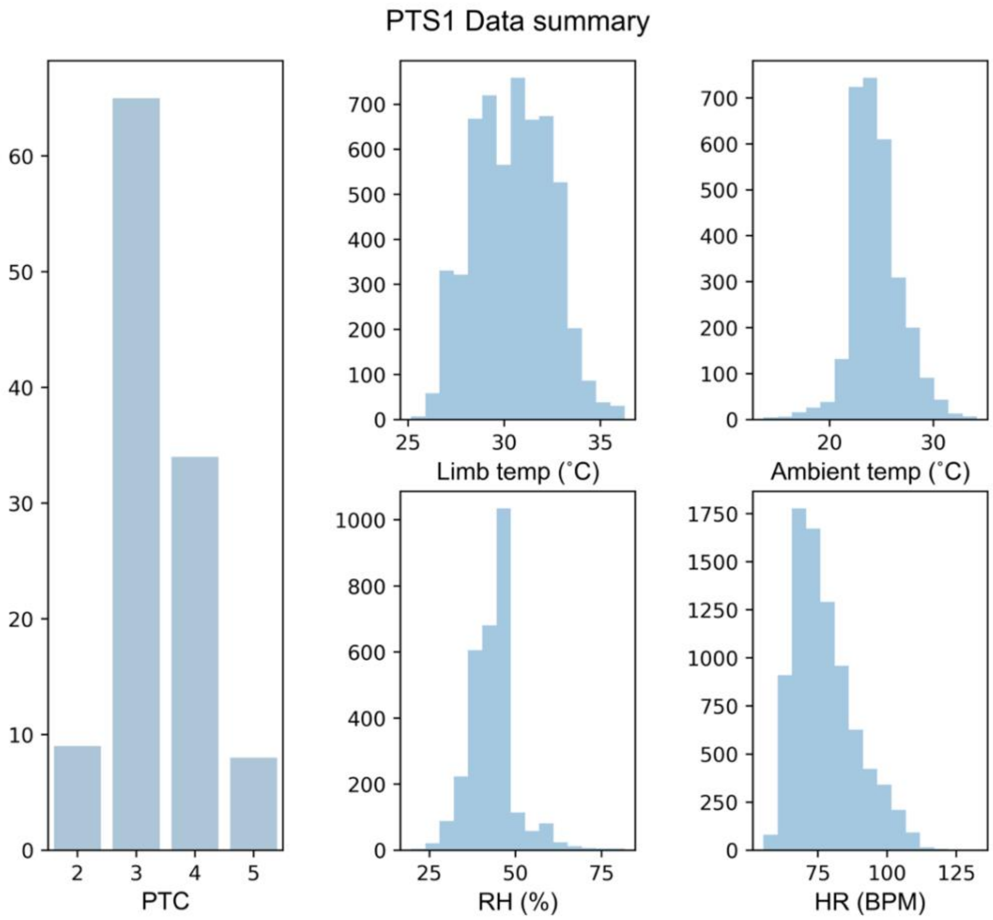


Figure 25: Histograms for PTC, limb temperature, ambient temperature, ambient humidity, and heart rate for PTS1 are displayed. The y-axis on all plots corresponds to numeric 'count'.

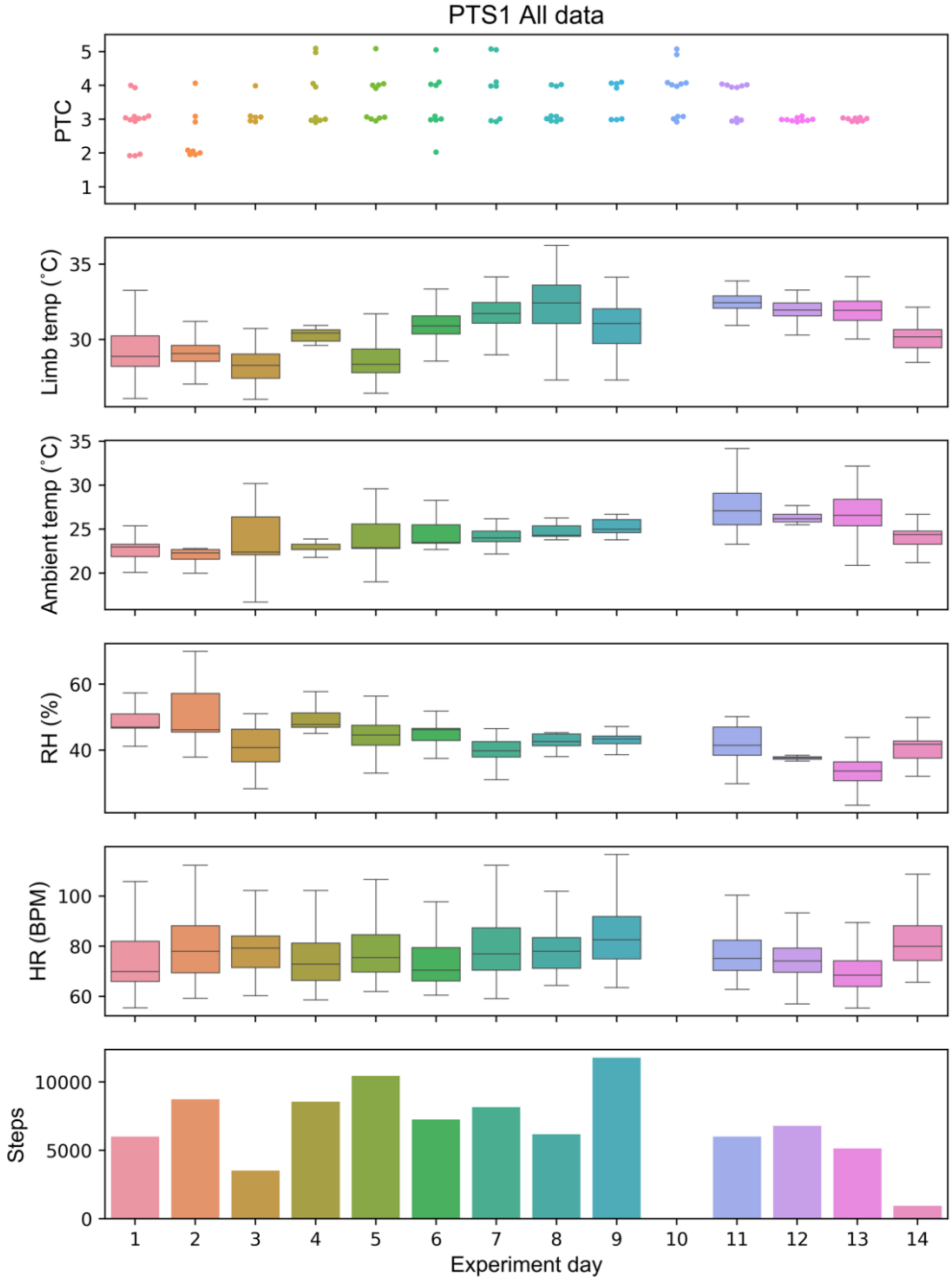


Figure 26: Intraday swarm plots of PTC, box plots of limb temperature, ambient temperature, ambient humidity and heart rate, and a bar chart of total step count are displayed for PTS1.

8.2.1.3 PTC Level trends

To begin to disentangle and interpret trends between levels of PTC and each of the recorded parameters, PTC values were temporally collated to each parameter to create a multivariate dataset. During the experiment, PTS1 did not record any PTC values of 1. Descriptive statistics for each PTC level are presented in Table 12.

Table 12: PTC data for PTS1 is presented alongside the average limb temperature, ambient temperature, ambient humidity, heart rate, and step rate.

	PTC1	PTC2	PTC3	PTC4	PTC5
Count	-	8	64	34	8
Limb Temp (˚C)	-	29.1	30.9	30.6	30.6
Ambient Temp (˚C)	-	22.6	24.6	24.5	26.4
Ambient Humidity (%)	-	48	42	44	44
HR (BPM)	-	71	75	79	76
Step rate	-	14	24	61	57

PTS1 experienced eight PTC instances of 2 (slightly uncomfortably cold). Upon further examination, it was possible to see that for five of the PTC=2 recordings, PTS1 was at a cinema screening event. Limb temperature ranged from 28.1 – 29.5 ˚C, with an ambient temperature between 21.7 – 22.3 ˚C. On average, Day 2 had the coldest mean temperature in comparison to other days at 21.9 ˚C; however, the previous days mean ambient temperature was not much warmer at 22.5 ˚C. When PTS1 was asked to recount the experience, he stated that:

> *"I remember that afternoon, it was just crazy- it was like going back into November, you know like all of a sudden, it was just freezing"*

It was not just the external weather conditions that influenced his PTC level, but also the venue and the lack of activity:

> *"it's a very old and like most buildings like heating is often subpar, and of course, you have to sit through a screening so you you're not moving so your body tends to get cold"*

The other three PTC=2 recordings were all over a three-hour period, where for two of them PTS1 was working from home with his prosthesis off and then had just got on a bus. When working from home, his limb was on average 28.6 ˚C, at an ambient temperature of 23.3 ˚C. However, on the bus, his limb was much colder, at 26.9 ˚C, even though the ambient temperature and humidity- were the same as prior recordings (23.3 ˚C, 47%). The only difference was a decreased heart rate (65 BPM vs 74 and 70 BPM whilst working inside).

The most common PTC value for PTC was a comfortable rating (PTC = 3). When investigating the ESM data, it is possible to see that the most frequent combination of activity and location for PTS1 to be comfortable was when he was relaxing at home. PTS1 was comfortable when his limb temperature ranged between 26.9 – 35.2 ˚C, an ambient temperature between 18.7-32.2 ˚C, an ambient humidity between 23-62 % and finally a heart rate between 60-106 BPM. Activities included relaxing (21 entries), working (11 entries), self-care (8 entries), eating (8 entries), commuting (6 entries), walking (4 entries), food preparation (3 entries) and socialising (3 entries). Locations included home (41 entries), work (11 entries), public transport (6 entries), clinics (3 entries) and outside or at restaurants/ bars/ pubs/ cafés (2 entries respectively). When the comfortable data was discussed, he described being at home as being most comfortable as he could do things in his own time to manage discomfort:

> *"when you're in the comfort of your own home and you can do things in your own time, whether you've got your prostheses on or they're off […] I can do it in my own time"*

The next most common PTC value for PTS1 was when PTC = 4 (slightly uncomfortably warm) as there were 34 recorded instances. In this state, PTS1s limb temperature ranged between 27.3 – 33.1 ˚C, the ambient temperature was between 20.55 – 29.6 ˚C, the ambient humidity was between 23 – 51 % and PTS1s heart rate were between 63 – 98 BPM. Activities included commuting (12 instances), working (8 instances), relaxing (5 instances), walking (3 instances), socialising (3 instances), housework (2 instances) and self-care, eating, food preparation and exercise (1 instance respectively). The most common activity and location for PTS1 to feel slightly uncomfortably warm was whilst commuting on public transport.

The most extreme feeling of thermal discomfort (PTC = 5) was only experienced by PTS1 on eight occasions throughout the study. Generally, PTS1 described a PTC of 5 as:

> *"[I'd feel] a more intense feeling or irritability and also a more intense and sort of like the worry that you know, the worry that it you know, maybe the pain will have lasted for longer"*

Additionally, PTS1 suspected that in his opinion, these extreme PTC values were on days which were much warmer:

> *"similar to the ones that I've described for the slightly uncomfortably warm, but maybe on the hotter days… on the very warm days"*

PTS1s extremely uncomfortably hot recordings captured a limb temperature ranging from 28.6 – 33.0 ˚C, an ambient temperature between 22.6 – 32.3 ˚C, an ambient humidity between 40 – 55 % and a heart rate ranging between 70 – 102 BPM. Two instances of work, commuting and walking were recorded as being extremely uncomfortably warm (whilst at work, on public transport and outside). One instance of working was measured as occurring when the ambient environment was warm at 27.1 ˚C, with the participant writing in the ESM entry:

> *"Still seated at my desk, it's a very warm work environment. TC 5"*

The other working entry had no notably high parameters, however, the participant stated that he was:

> *"Still at work. Thermal comfort currently 5. I will remove my right prosthetic to cool off"*

When commuting data is examined, the first recording found PTS1 on a bus journey lasting over an hour:

> *"On the bus on my way to [rehabilitation clinic]. It's quite a long and uncomfortable journey, it takes me an hour to get there. TC 5"*

At the point of recording, the sensors did not detect elevations in physiological or ambient conditions, however. The second extremely uncomfortably warm experience of commuting was a standard commute back home from the participants' workplace. However, although skin temperature, ambient temperature and ambient humidity were all at relatively standard levels, in this instance, PTS1s HR was 102 BPM. This is considerably higher than heart rates for other PTC = 5 instances.

When walking is examined, both of these instances were outside. On one occasion, PTS1 found himself outside for lunch, walking in the park:

> *"Went for a walk, had lunch in a park with colleagues. Now back at work. My stumps feel swollen with the heat. I struggle to put them [the legs] on and take them off. TC 5"*

His perception of being extremely uncomfortably warm was matched with a limb temperature of 33.0 ˚C, in a warm work environment which was 32.0 ˚C, 40% and an HR of 70 BPM. With a limb and ambient environment as warm as this, it was unsurprising that the participant had issues. On the second occasion, the participant was waiting for a bus, and whilst skin data was not recorded, ambient temperature was sensed as 30.2 ˚C, with an ambient humidity of 41% and an HR of 80 BPM.

Of the remaining two PTC = 5 recordings, one was at home, post-exercise. The participant described that they were briefly at home before going out to meet friends. This recording did not have associated skin temperature data, and ambient conditions and heart rate were relatively low (23.5 ˚C, 40% 67 BPM). The final PTC = 5 instance was surprising, as the participant was at home relaxing. However, upon further investigation, it appears that this feeling was unlikely due to measured variables, but instead due to pain:

> *"Just got home from work. I feel stump pain from sitting in the same position through a two-hour meeting. The pain makes me feel hot. TC 5"*

8.2.2 Participant 2

The second participant (PTS2) was a female amputee in her late twenties. She became an amputee 2 years and 4 months ago at time of participation, due to osteosarcoma and required a transfemoral amputation on her left leg. PTS2 used a polycarbonate suction socket, with an Iceross Seal-In X5 liner (Össur, Iceland). Generally, she preferred to continuously wear their prosthesis for the whole day without removing it until bedtime.

PTS2 worked as an office worker in central London but was often able to work from home unless she had a meeting. Generally, PTS2 would wake at 7:30 am and then get dressed, eat breakfast and read the news. If she was travelling into the office, she would alternatively leave the house by 7:30 am and commute for about 30 minutes to work via public transport. PTS2's job typically involved desk work, though she tried to make an effort to get up and walk around at least once an hour, even when working from home. At the time of the experiment, the participant had recently experienced warmer weather and therefore tried to either spend approximately 10 minutes of their lunch break outside or to end their day with an equally short walk. Three times a week after work, PTS2 went to yoga classes or to a swimming pool. After exercising, PTS2 would prepare and eat a late dinner and then watch television. Towards the end of the week, PTS2 often socialised with friends in pubs, bars or restaurants. Based on the description of PTS2s daily routines, her lifestyle can also be considered as active.

8.2.2.1 Experience of thermal discomfort

PTS2s experience of thermal discomfort appeared to have multiple impacts to her prosthesis wearing experience. Firstly, thermal discomfort led to sweating and pistoning, causing functional difficulties:

> *“When it's not thermally comfortable, it slips and it slides and it pistons, and it moves out of place and that makes it harder for me to stand, to sit and to walk. [...] it's like your shoe coming off and you've kind of got it on- you've still gotta walk. And you're trying, but you just use much more energy to do it”*

The functional deviations and extra effort required to continue normal activities made PTS2 feel generally tired and annoyed:

> *“It makes me tired, it makes me annoyed, it makes me alert that there's a problem”*

Additionally, as was found in Chapter 6, the general feeling of thermal discomfort was not just localised to the residual limb, but had a knock-on effect on the whole body:

> *“I, I become, it just, it starts to irritate the rest of my body but I'm often in places where I can't just stop take my leg off, and then get back in.”*

The feeling of being warmer post-amputation was also persistent:

> *“I feel that my- I’m much warmer now wearing a prosthesis, than if I didn’t have a prosthesis. I don’t need to wrap up as much as I used to, because just to walk, the energy that I’m using keeps me warm”*

Another aspect of thermal discomfort experienced by PTS2 was the smell aspect- particularly in hotter weather:

> *“when it gets really hot, like the smell- coz it's not open to the air- it's disgusting”*

As discussed in Chapter 6, a foul-smelling limb can have greater consequences, with the smell leading to social anxieties.

Aside from functional difficulties, impact to mood and energy, body-wide overheating and social consequences, for PTS2, thermal discomfort also often resulted in pain.

Therefore, thermal discomfort lead to a complete failure in prosthesis fit and comfort, resulting in an unpleasant wearing experience:

> *“Like the whole set up of the prosthesis when they're making it is trying to eliminate spots where it can hurt you, and as soon as you get thermal discomfort, it does hurt you”*

Finally, for PTS2 thermal discomfort appeared to be a ‘disillusioning’ phenomenon which highlighted a fundamental problem in that prosthetics are designed based on unrealistic scenarios and situations:

> *“that is the world of prosthetics, they, you know- let's model this fake world which does not exist.”*

8.2.2.2 Overall data summary and interday data

Data were collected for 14 days in total. Unfortunately, the ambient sensor malfunctioned and intermittently collected data before finally corrupting the dataset upon retrieval. Therefore, there were no ambient temperature or humidity data collected for this study. Over the last four days of the study, the skin temperature sensors also malfunctioned and did not collect any data. Data collected during the study is summarised in Table 13, Figure 27, and Figure 28.

Table 13: Total and intraday modes for PTC and averages for limb temperature, ambient temperature, ambient humidity, and heart rate, as well as total steps per day for PTS2 are presented.

	PTC	Limb Temp ± SD (˚C)	Ambient Temp ± SD (˚C)	Ambient RH ± SD (%)	HR ± SD	Steps per day
All Data	3	32.4 ± 2.6	-	-	90 ± 12	-
Day 1	3	32.3 ± 1.6	-	-	86 ± 11	5997
Day2	3	33.8 ± 1.2	-	-	80 ± 11	4232
Day3	4	32.8 ± 2.0	-	-	86 ± 11	4178
Day4	4	34.3 ± 1.5	-	-	89 ± 10	5045
Day5	3	33.2 ± 2.5	-	-	94 ± 9	5625
Day6	3	32.5 ± 2.6	-	-	90 ± 10	8159
Day7	3	32.0 ± 0.03	-	-	91 ± 12	5269
Day8	3	29.5 ± 1.3	-	-	91 ± 14	8425
Day9	4	30.5 ± 3.0	-	-	89 ± 12	6730
Day10	4	31.7 ± 2.3	-	-	92 ± 9	6120
Day11	3	-	-	-	93 ± 11	9686
Day12	3, 4	-	-	-	94 ± 12	8243
Day13	3	-	-	-	96 ± 10	6813
Day14	3	-	-	-	92 ± 10	5420

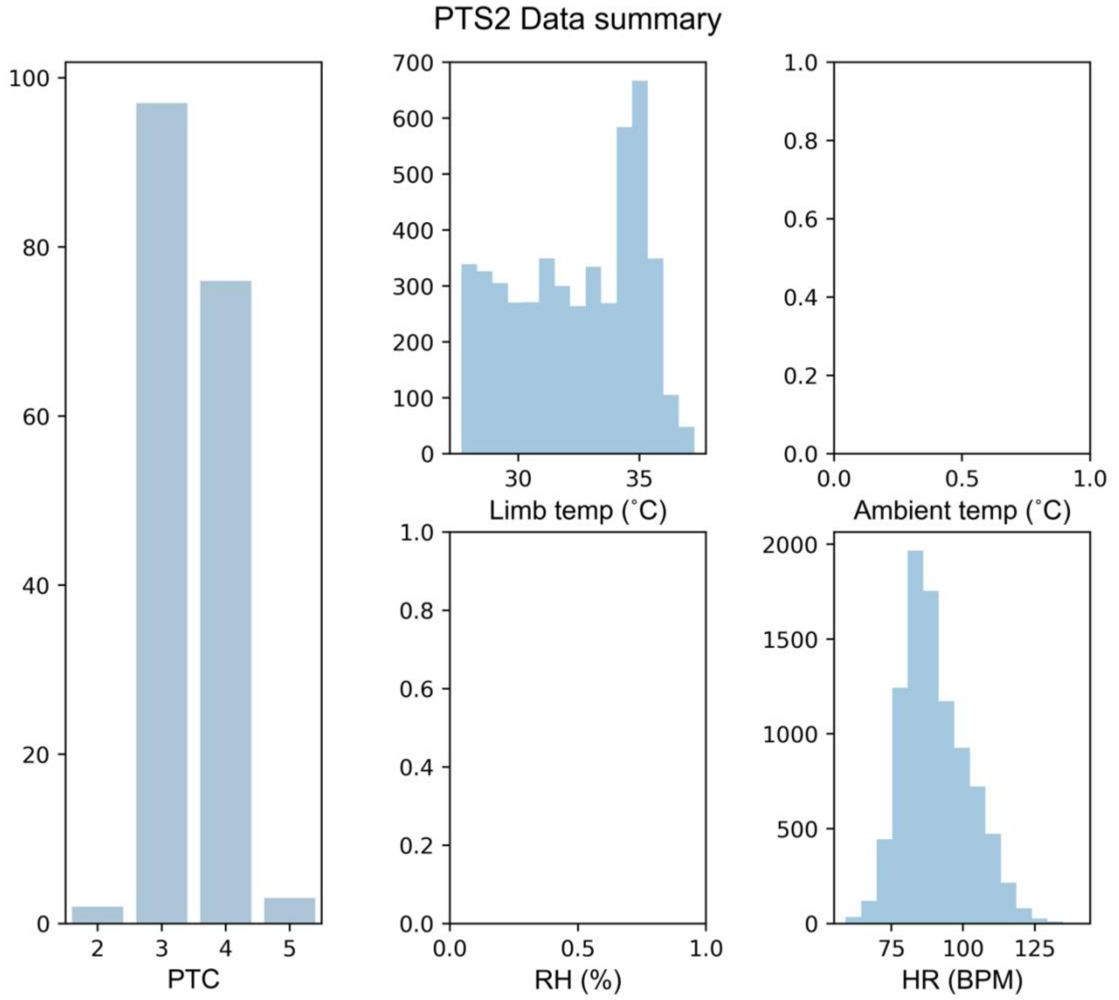


Figure 27: Histograms for PTC, limb temperature, ambient temperature, ambient humidity, and heart rate for PTS2 are displayed. The y-axis on all plots corresponds to numeric 'count'.

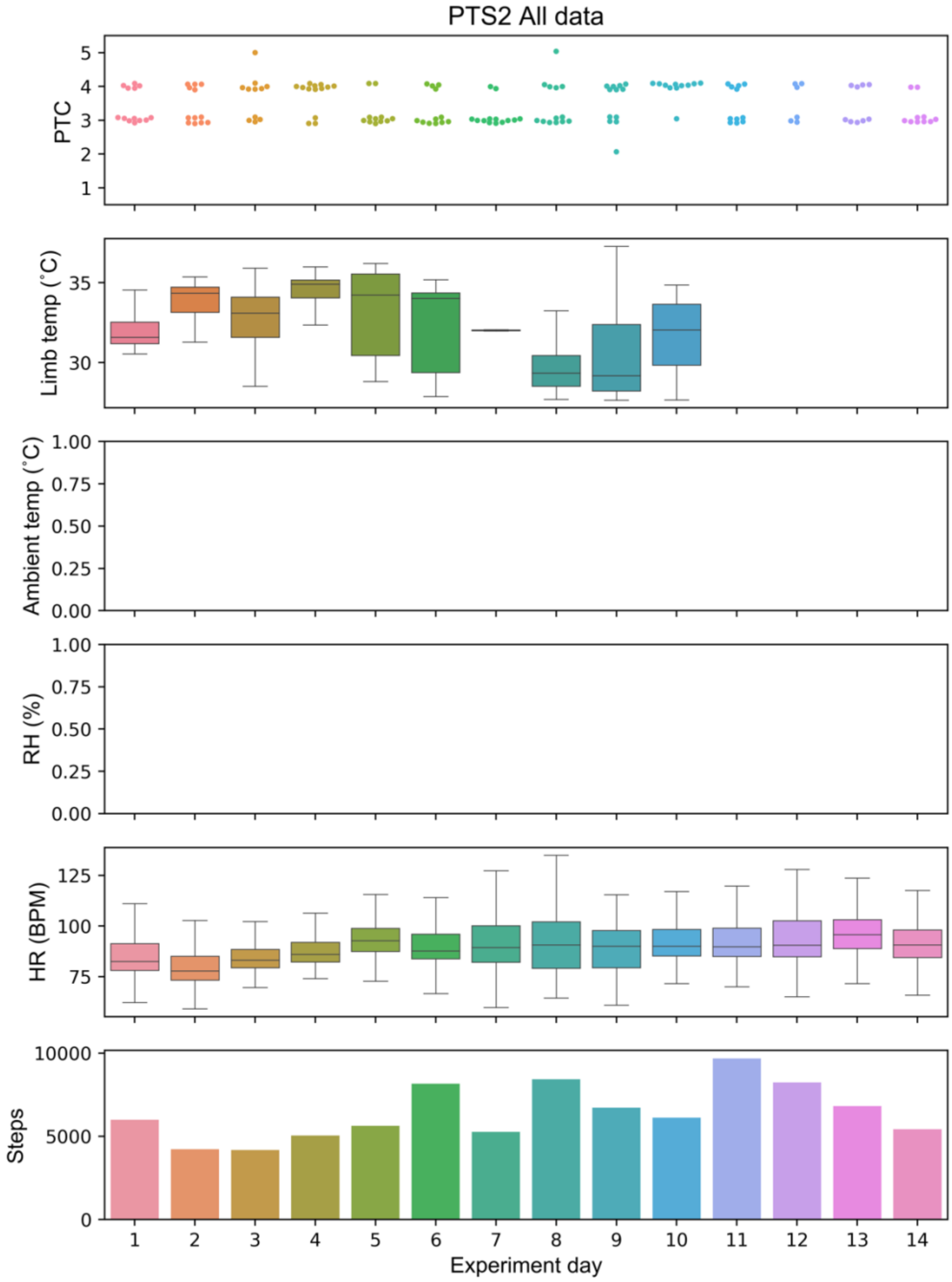


Figure 28: Intraday swarm plots of PTC, box plots of limb temperature, ambient temperature, ambient humidity and heart rate, and a bar chart of total step count are displayed for PTS2.

8.2.2.3 PTC Level Trends

When reviewing PTC data (Table 14), PTS2 was thermally comfortable most frequently (PTC = 3), but a large number of recordings were also slightly thermally uncomfortable (PTC = 4). Instances of being either extremely uncomfortably warm (PTC = 5) or slightly uncomfortably cold (PTC = 2) were scarce. There were no recorded instances of PTS2 being extremely uncomfortably cold (PTC = 1). Unfortunately, due to the failure of the ambient condition sensors, ambient temperature and ambient humidity are not available for analysis.

Table 14: PTC data for PTS2 is presented alongside the average limb temperature, ambient temperature, ambient humidity, heart rate, and step rate.

	PTC1	PTC2	PTC3	PTC4	PTC5
Count	-	2	97	76	3
Limb Temp (˚C)	-	28.6	32.2	32.7	30.0
Ambient Temp (˚C)	-	-	-	-	-
Ambient Humidity (%)	-	-	-	-	-
HR (BPM)	-	93	90	90	90
Step rate	-	25	45	47	88

When investigating instances of PTC = 2, PTS2 only reported two instances of being slightly uncomfortably cold. The first instance was while PTS2 was relaxing at home, and when sensor data is investigated, her limb was at a temperature of 28.6 ˚C. At that point in time, PTS2's HR was 93 BPM- within one standard deviation of the mean experimental HR value. However, her residual limb was 3.8 ˚C cooler than the mean limb temperature throughout the entire study- possibly explaining why she felt slightly uncomfortably cold. In the second instance, no sensors were worn, however, the participants' ESM data showed that she was sitting in church. When discussed in the exit interview, she explained that on that occasion, she felt cold because:

> *"It looked warm outside coz I thought that by the time I did the steps [up to the church] I would have been sweaty so I'll be warm, but I was a little bit, I was a bit cold, so maybe I didn't rush up the steps as quickly as I thought I would."*

When asked to describe what a general PTC of 2 would feel like, she described a similar situation:

> *"It does mean maybe it's cold outside and maybe it's colder than I anticipated it to be, it means that maybe I didn't take a cardigan because I assumed my body would work up a sweat and it didn't"*

The most common state of thermal comfort for PTS2 was to be thermally comfortably (97 instances). Upon reviewing sensor data, thermal comfort was reported when limb temperature was between 27.7 – 36.9 ˚C and HR was between 65 – 116 BPM. The most common comfortable activity was working from home (35 instances), followed by relaxing at home (17 instances). PTS2 walked outside (8 instances) at home (3 instances) and at work (1 instance) whilst maintaining thermal comfort. PTS2 also recorded activities such as housework and self-care (7 instances respectively), eating (6 instances), napping (5 instances), food preparation and socialising (4 instances respectively), driving (3 instances), exercising (2 instances), and shopping and commuting (1 instance respectively) whilst thermally comfortable. When locations are considered isolated from activities, PTS2 was most comfortable at home (61 instances), followed by at work (14 instances), outside (8 instances), in public spaces, restaurants/ bars/ cafes and in private transport (4 instances), and in a clinic (2 instances). PTS2 explained that when at a 3, she felt that:

> *"I think 3, 3 was like my baseline, I feel like I'm neither hot nor cold and comfortable"*

A PTC score of 4 (slightly uncomfortably warm) was also a frequent state for PTS2, with 76 ESM recordings being at this level. Sensor data revealed that PTS2s limb temperature ranged between 27.9 – 36.2 ˚C and heart rate between 72 – 119 BPM whilst slightly thermally uncomfortable. Most frequently, PTS2 was working (21 instances), walking (14 instances), relaxing (12) instances), doing housework or self-care activities (7 instances), driving (6 instances), socialising (5 instances), eating (4 instances), commuting or preparing food (3 instances), and napping (1 instance). These activities were mostly conducted at home (42 instances), at work or outside (8 instances), in private transport (6 instances), in a restaurant/ bar/ café (5 instances), in a clinic (4 instances) or on public transport (3 instances). Qualitatively, PTS2 described that a PTC of 4 to her meant that:

> *"4…4- I've probably done something that exerted a lot of energy- that took up a lot of energy, but I'm recovering. I'm not quite at my baseline, but I'm*

> *heading towards that, or I'm still doing that thing, but I feel like I could still be hotter"*

She also stated that at a PTC of 4, she managed the situation using breathing techniques:

> *"At a 4, I'd try to make sure I'm properly breathing so that I'm using my energy efficiently I think"*

In contrast, PTS2 felt that that *"5 is extreme. It's completely out of my control I guess."* There were only 3 instances which were listed as being a 5. The first was when PTS2 was commuting on the underground. Though her limb was relatively cool (27.7 ˚C), her heart rate was elevated (106 BPM). The second instance occurred after whilst the participant was at the gym- though she was not wearing any sensors as advised. Given the physical strenuousness of exercise, elevated thermal discomfort is unsurprising. In the final instance, PTS2s limb was at nearly an average temperature (32.3 ˚C), and her heart rate was lower than average (75 BPM). However, when this instance was discussed, PTS2 explained that:

> *"so I was walking with my fiancé and he's got two legs and I'm trying to keep up and he's obviously slowing down, but I'm also trying to keep pace [...] I'm always nervous that I'm not gonna be able to keep up. But I do keep up, but it does then have the knock-on!"*

8.2.3 Participant 3

Participant 3 (PTS3) was a male amputee in his mid-forties. At the point of participation, he had worn prostheses for 21 years and was a bilateral transtibial amputee as a result of meningococcal meningitis. Over the course of the study, data were only collected from his left leg, though this choice was arbitrary. His prostheses consisted of polycarbonate suction sockets, with a 6mm thick Extreme Cushion Liner (ALPS, Russia). He also placed thin cotton socks directly underneath the liner to absorb sweat and wore three cotton socks outside the liner to maintain socket fit. Finally, suction was maintained with a 3mm thick silicone suction sleeve. On both weekdays and weekends, PTS3 wore his prostheses for the entire day and only occasionally removed them briefly to cool down his limbs.

PTS3 also worked as an office worker in central London. After waking at 5 am, the participant would get ready for work leaving the house by 6 am, followed by a commute via car, national rail, London underground and foot, with a commute time of over an hour. Once at work, PTS3 switched between seated desk work and meetings and frequently walked around the office. He made an effort to take lunch outside, involving about 45-minutes of walking around a public park near his workplace. His workday typically finished by 5 pm, followed by a commute home. In the evenings, PTS3 would run when it was cooler; else he'd eat dinner, spend time with his family, and then sit and watch television before sleeping. At weekends, his day would start at 7 am, followed by an hour running on both Saturday and Sunday. The majority of his weekends typically revolved around family members' hobbies, playing with his children and chores. Evenings were typically spent in a similar way to in the week. PTS2s lifestyle was extremely active, involving commuting activities, large amounts of walking, and running 5-10km, up to five times per week.

8.2.3.1 Experience of thermal discomfort

When discussing thermal discomfort with PTS3, he noted that thermal discomfort was rarely an issue during cooler seasons:

> *"through the winter and spring when it's sort of standard temperatures, there'd be no reason for me to take my legs off except from going to bed to be honest"*

However, as with PTS1 and PTS2, thermal discomfort did become an issue in summertime:

> *"it's only really when the temperature rises, a lot more that obviously that the sweating becomes more"*

To manage the thermal discomfort, PTS3 would frequently opt to remove his limbs in private, finding that a minute or two without his legs felt like enough time for his limbs to cool off and to regain thermal comfort:

> *"if I do feel quite warm, at work for example, I'd go into the toilet, take it [the prostheses] off, and put it back on again just to give it a quick airing and that just releases the heat"*

However, when PTS3 was away from home or his office environment, he tended to not use the same intervention routine due to cleanliness of public toilets:

> *"I wouldn't go into a public toilet and do that because it's not particularly pleasant to do that."*

Instead, PTS3 would alternatively choose to either walk at a slower pace or simply take a rest altogether to relieve the discomfort:

> *"If it's getting too warm, it's almost just yeah, slowing down, perhaps having a sit down- going for a coffee, that sort of thing just sort of relieves the heat that way."*

8.2.3.2 Overall data summary and interday data

PTS3 completed all 14 days of the experiment. However, over the 14 days, the skin sensor and ambient sensors at times malfunctioned. Therefore, there are missing skin temperature data for days 4-5 and days 7-14 and missing ambient data for the first 4 days. Data summaries and interday data are presented in Table 15, Figure 29, and Figure 30.

Table 15: Total and intraday modes for PTC and averages for limb temperature, ambient temperature, ambient humidity, and heart rate, as well as total steps per day for PTS3 are presented.

	PTC	Limb Temp ± SD (˚C)	Ambient Temp ± SD (˚C)	Ambient RH ± SD (%)	HR ± SD	Steps per day
All Data	3	35.8 ± 0.8	24.4 ± 1.5	43 ± 8	80 ± 11	-
Day 1	3	35.9 ± 0.6	-	-	80 ± 8	2354
Day 2	3	35.9 ± 0.7	-	-	87 ± 10	5730
Day 3	3	35.5 ± 0.7	-	-	80 ± 12	11115
Day 4	3	-	24.2 ± 0.6	55 ± 2	80 ± 12	10798
Day 5	3	-	24.2 ± 0.3	55 ± 1	80 ± 11	9876
Day 6	3	35.7 ± 1.0	24.1 ± 0.3	41 ± 3	76 ± 10	11390
Day 7	3	-	23.9 ± 1.3	36 ± 1	78 ± 11	7788
Day 8	3	-	25.7 ± 0.5	33 ± 2	83 ± 10	9027
Day 9	3	-	26.9 ± 1.0	32 ± 0	83 ± 10	6730
Day 10	3	-	24.8 ± 1.6	37 ± 1	79 ± 13	13650
Day 11	3	-	22.9 ± 1.2	44 ± 2	80 ± 11	9787
Day 12	3	-	24.7 ± 1.4	44 ± 2	79 ± 11	10859
Day 13	3	-	24.0 ± 0.5	48 ± 2	78 ± 11	11021
Day 14	3	-	22.7 ± 0.6	49 ± 1	76 ± 12	11032

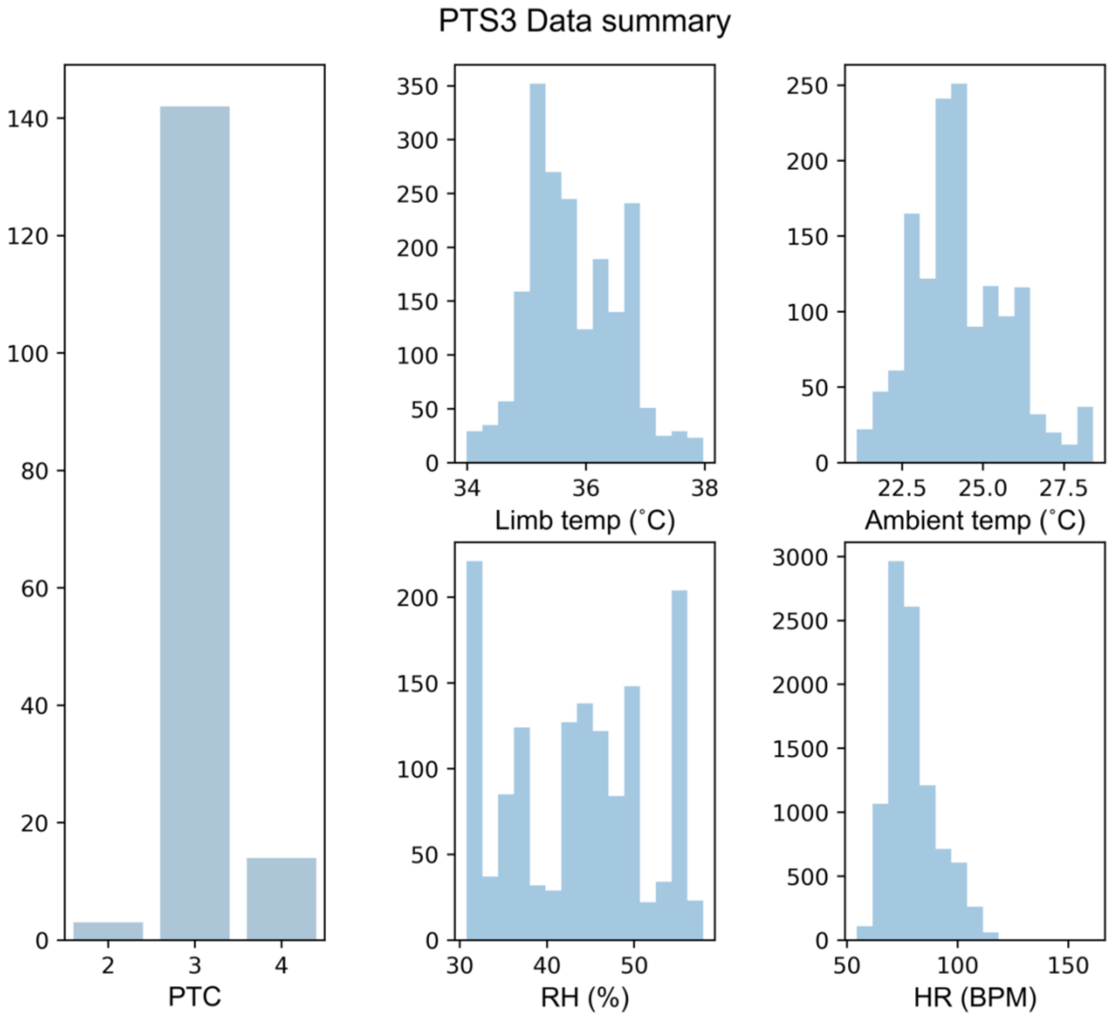


Figure 29: Histograms for PTC, limb temperature, ambient temperature, ambient humidity, and heart rate for PTS3 are displayed. The y-axis on all plots corresponds to numeric 'count'.

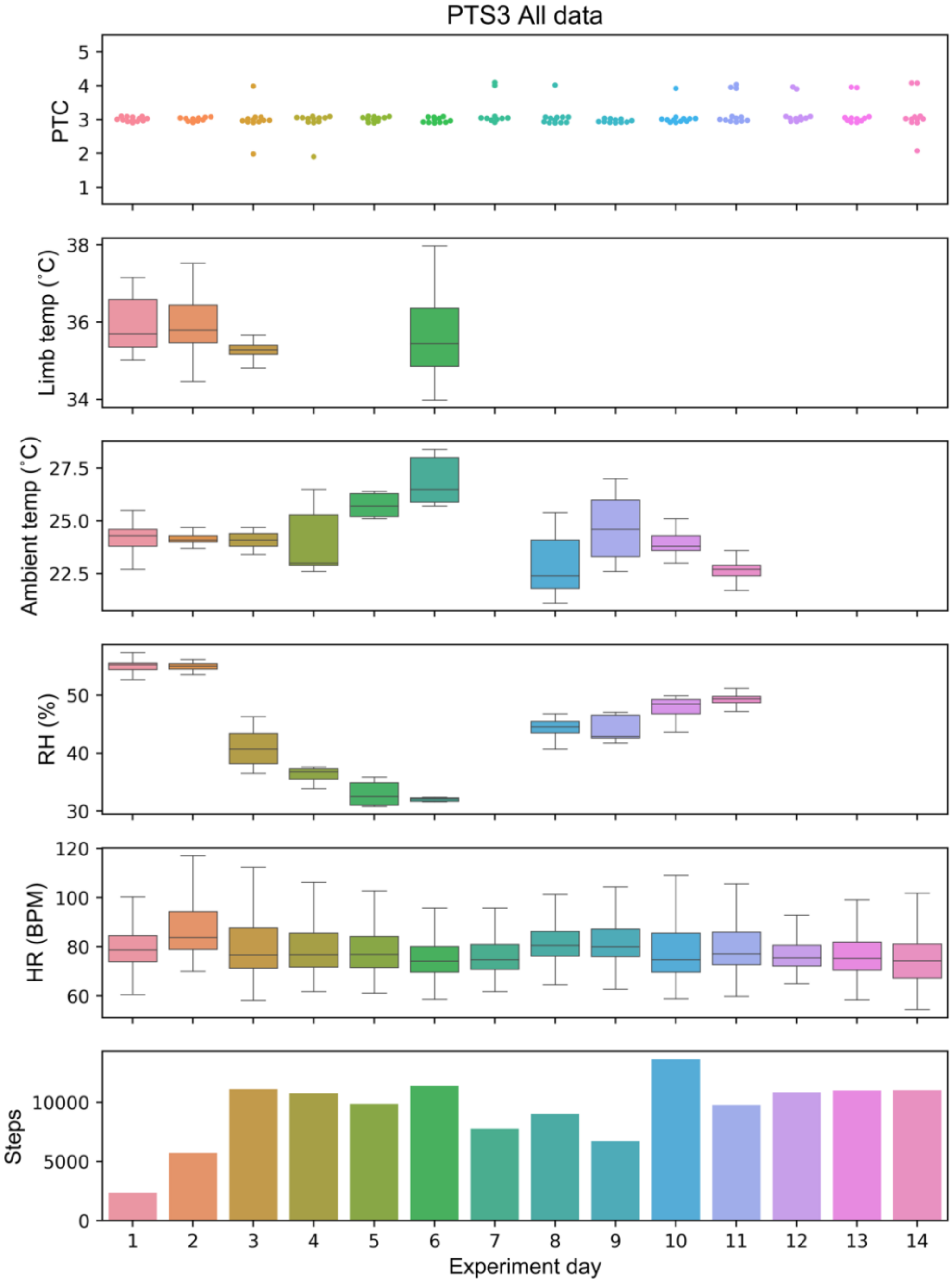


Figure 30: Intraday swarm plots of PTC, box plots of limb temperature, ambient temperature, ambient humidity and heart rate, and a bar chart of total step count are displayed for PTS3.

8.2.3.3 PTC Level Trends

When reviewing PTS3s data separated by PTC levels (Table 16), it is possible to see that PTS3 was on the whole comfortable for the vast majority of the experiment, with only a few instances of being slightly uncomfortably warm, and very few instances of being slightly uncomfortably cool. The 2 instances of a PTC of 2 were when sitting at a desk in an office.

Table 16: PTC data for PTS3 is presented alongside the average limb temperature, ambient temperature, ambient humidity, heart rate, and step rate.

	PTC1	PTC2	PTC3	PTC4	PTC5
Count	-	2	142	14	-
Limb Temp (˚C)	-	-	35.9	35.3	-
Ambient Temp (˚C)	-	23.5	24.4	24.5	-
Ambient Humidity (%)	-	55	43	42	-
HR (BPM)	-	101	80	79	-
Step rate	-	0	66	104	-

In the 142 instances of being thermally comfortable, PTS3s limb temperature ranged between 34.8 – 37.7 ˚C, whilst ambient temperature ranged from 21.9 – 27.0 ˚C. Ambient humidity ranged between 31 – 57 %, and finally, HR ranged between 60 – 110 BPM. The most frequent activity was working (58 instances), followed by relaxing (49 instances), walking (16 instances), driving (6 instances), commuting and socialising (5 instances respectively), housework (3 instances), shopping (2 instances) and exercising (1 instance). PTS3 was most frequently at work (58 instances), at home (41 instances), outside (14 instances), private transport (7 instances) and either on public transport or at restaurants/ bars/ cafés (4 instances). In PTS3s own words, he found that a PTC = 3 was his ‘standard’:

> *“3 would just be normal. So, it’s almost that I couldn’t tell the temperature either way. It wouldn’t be particularly warm, or particularly cold and that’s what my standard- as a- I’d regard myself as standard most of the time”*

In the 14 instances of PTC = 4, unfortunately, the skin sensors were not recording data at each of these instances. However, the ambient temperature sensors recorded temperatures ranging from 23.1 – 26.6 ˚C, the ambient humidity was between 35 – 49 % and PTS3s

HR was between 58 - 112 BPM. There were far fewer activities which were recorded as being slightly thermally uncomfortable. The most common activity for PTS3 to be uncomfortable in was walking (10 instances) and commuting (4 instances). Locations which were recorded as being PTC = 4 were being outside (10 instances) and public transport (4 instances).

When these recordings were discussed with PTS3, his recollection corroborated the collected ESM data:

> *"it was probably when I was going for a lunch time walk, sometimes I go out for a 45-minute walk. And especially in these temperatures that's it's been recently as well- that's when it's felt the most uncomfortable."*

Additionally, he mentioned that usually, discomfort on the trains was worst when there were delays:

> *"The minute- especially with the trains where you get a train that's been cancelled, it makes it worse that you're packed in more and it is literally like you're nose to nose to people."*

Finally, although there were no recorded cases of PTC = 5 when I discussed what would be happening this level of thermal discomfort occurred, he stated that:

> *"I guess, for me 5 would be that I'd have to take them [prostheses] off and my legs were sore, you know, and would be read- possibly blisters- those sort of things [...] I've totally learnt life lessons to stop me getting to a 5."*

8.2.4 Participant 4

The fourth participant (PTS4) was a male transtibial amputee in his late forties. He had worn a prosthesis for 18 years, following traumatic amputation of his left leg. PTS4 had a carbon fibre suction socket and used an Iceross Activa (Össur, Iceland) which was 6mm thick on the anterior and 2mm thick on the posterior. Suction was assisted by also using a 3mm Alpha Hybrid suction sleeve (WillowWood, USA). PTS4 wore his prosthesis continuously throughout the day.

PTS4 lived and worked in a county surrounding London. He, like the other participants, was an office worker. His day would commence at 6:30 am, and he would get ready for work before commuting via car for about 30 minutes. Generally, his work was seated. On some days, PTS4 finished work in the middle of the day to golf, otherwise, he would leave work by 5 pm. In the evenings, PTS4 would typically eat dinner, spend time in the garden, do house chores, followed by a period of relaxing watching the television. Weekends typically also involved golfing, housework and general chores. PTS4's daily routine can be considered as active.

8.2.4.1 Experience of thermal discomfort

PTS4s experience of thermal discomfort was similar to PTS3, in that he didn't tend to experience thermal discomfort in cooler weather, and it was exacerbated in hotter conditions:

> *"it only gets exaggerated in the heat. You don't sweat a lot when it's cooler."*

However, interestingly, when discussing thermal discomfort, it was exclusively in relation to discomfort caused by sweat. Excessive sweating generally led to deviations in function caused by sweat displacement and required removal of the prosthesis:

> *"There can be- not exactly slide off- but there's movement in it and it becomes slippery and then you don't feel so connected, and then you're not so connected so you have to take the leg off and dry it off and go again."*

The routine of removing the prosthesis to dry off the skin and liner though was relatively rare, and PTS4 would only need to intervene on warm summer days of if he was doing an activity which required slightly more exertion that generic everyday activities:

> *"I'd say it's rare for me to actually take the leg off and dry it off. It's not that bad. If it's a really hot summers day, and maybe I try to walk a bit quicker, like just go over that... everyday activity, then, I may have to take it off"*

8.2.4.2 Overall data summary and interday data

PTS4 had the sensors for a total period of 9 days. However, data were collected for only 6 days due to various commitments that would have been impractical to wear the sensors for. During this period, I was in regular contact with the participant to conduct safety checks. On the sixth day during a 'check-up' call, PTS4 mentioned that he had started to notice that it felt as though air was able to channel underneath the liner whilst he was walking where the sensor wires were located. Although he stated that he did not feel that it reduced his suspension, continued participation could have potentially begun to affect suspension. Therefore, PTS4's study was terminated early as a precaution. Unfortunately, even though the skin temperature sensor was working upon leaving the lab, the sensors recorded 6 days of saturated and therefore unusable data. The 6 days of collected data are presented here (Table 17, Figure 31, and Figure 32), though PTS4 did not complete an exit interview.

Table 17: Total and intraday modes for PTC and averages for limb temperature, ambient temperature, ambient humidity, and heart rate, as well as total steps per day for PTS4 are presented.

	PTC	Limb Temp ± SD (˚C)	Ambient Temp ± SD (˚C)	Ambient RH ± SD (%)	HR ± SD	Steps per day
All Data	3	-	26.9 ± 3.1	45 ± 8	80 ± 16	-
Day 1	3	-	28.5 ± 3.2	39 ± 8	89 ± 15	8513
Day2	3	-	30.5 ± 2.0	42 ± 5	71 ± 8	2778
Day3	3	-	29.3 ± 1.7	41 ± 3	73 ± 9	1966
Day 4	3	-	25.7 ± 2.9	50 ± 9	79 ± 19	13968
Day 5	3	-	24.8 ± 2.5	51 ± 6	90 ± 16	11525
Day 6	3	-	28.3 ± 1.7	37 ± 5	76 ± 7	2675

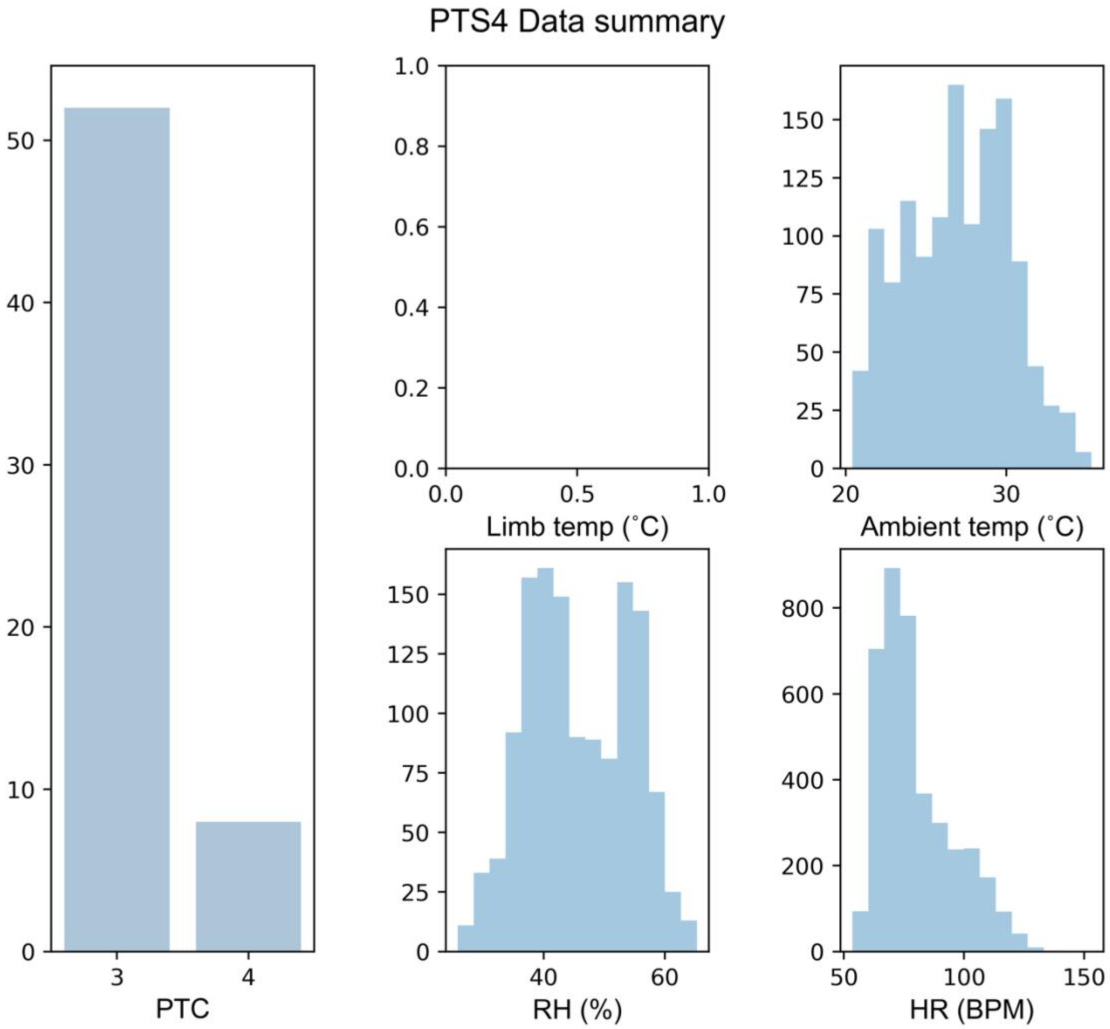


Figure 31: Histograms for PTC, limb temperature, ambient temperature, ambient humidity, and heart rate for PTS4 are displayed. The y-axis on all plots corresponds to numeric 'count'.

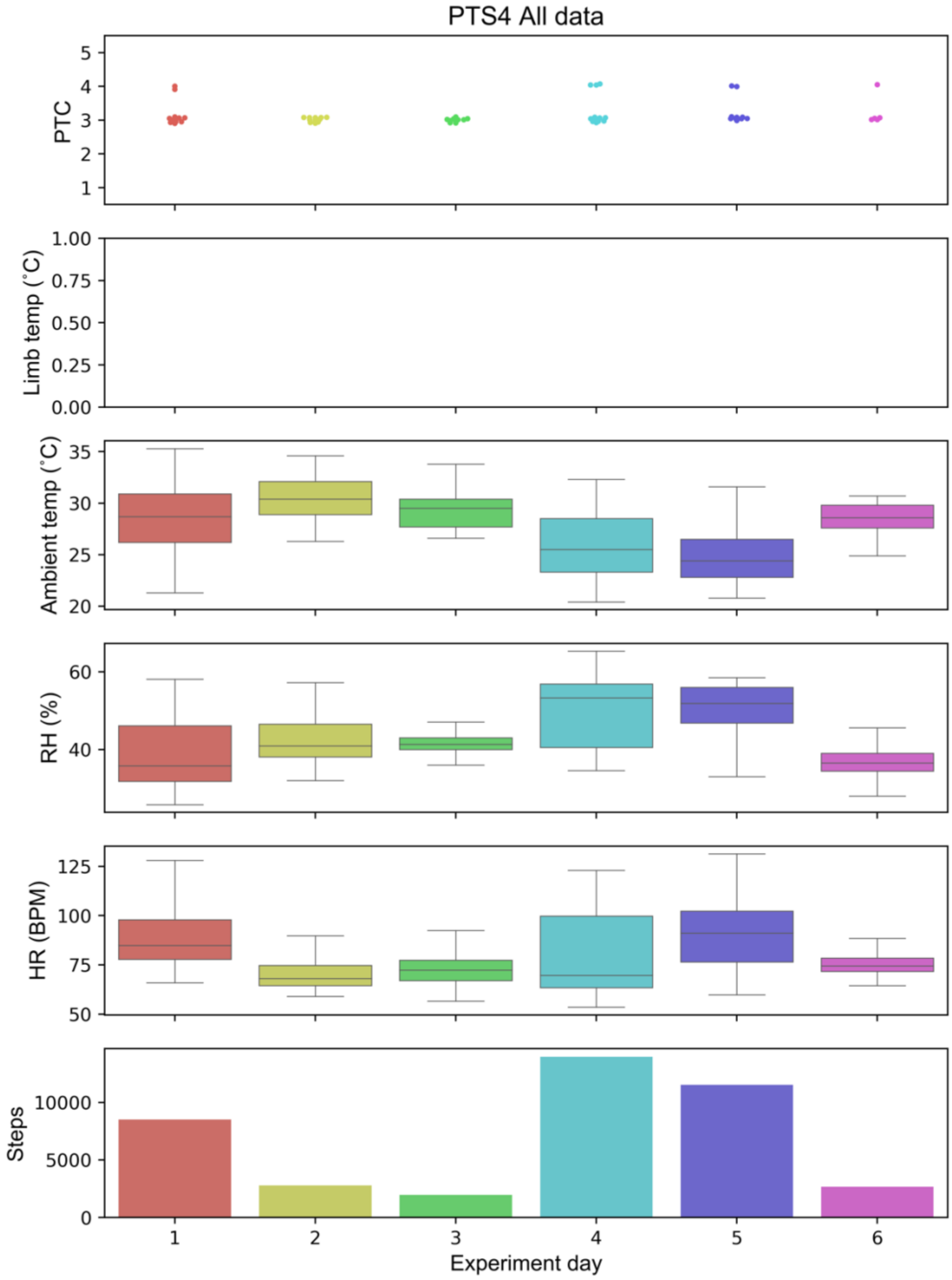


Figure 32: Intraday swarm plots of PTC, box plots of limb temperature, ambient temperature, ambient humidity and heart rate, and a bar chart of total step count are displayed for PTS4.

8.2.4.3 PTC Level Trends

In total, 60 PTC instances were recorded by PTS4. PTS4 was mostly comfortable throughout the experiment and only recorded 8 instances of being slightly uncomfortably warm (see Table 18).

Table 18: PTC data for PTS4 is presented alongside the average limb temperature, ambient temperature, ambient humidity, heart rate, and step rate.

	PTC1	PTC2	PTC3	PTC4	PTC5
Count	-	-	52	8	-
Limb Temp (˚C)	-	-	-	-	-
Ambient Temp (˚C)	-	-	28.8	26.8	-
Ambient Humidity (%)	-	-	42	45	-
HR (BPM)	-	-	79	92	-
Step rate	-	-	47	154	-

By far the most common activity and location for PTS4 to record a PTC = 3 was when he was working at the office. His ESM data revealed that in almost all of these instances, he was sat at a desk in an air-controlled environment. The next most common activity was relaxing (14 instances), followed by housework and exercise (3 instances), driving and food preparation (3 instances) and finally walking, eating and self-care (1 instance respectively). Aside from work, the most common locations were home (16 instances), outside (7 instances) private transport (2 instances) and a clinic (1 instance). Instances of PTC = 3 occurred in ambient conditions ranging from 21.3 – 33.6 ˚C, ambient humidity ranging from 30 – 53 % and finally an HR between 63 – 123 BPM.

The few instances where PTS4 was slightly uncomfortably warm were predominantly when he was exercising outside (5 instances). Although participants were advised to remove sensors before undertaking exercise, in these instances, PTS4 was golfing on a hilly golf course and therefore was not partaking in an impact sport. In two other cases, PTS4 was undertaking housework such as hoovering or carrying items in his garage. The final PTC = 4 recording was when PTS4 was eating dinner in his garden. When sensor data is reviewed, PTS4 experienced slight thermal discomfort when the ambient conditions were between 22.6 – 29.5 ˚C, with a humidity of 39 – 57 % and an HR between 77 – 109 BPM.

8.2.5 Participant 5

The final participant (PTS5) was a female through knee amputee in her late teens and had a congenital amputation of her right leg. Her prosthesis was made up of a carbon fibre socket and an Iceross Seal-In X5 liner (Össur, Iceland). She wore her prosthesis for at least 12 hours a day, only removing the prosthesis to sleep.

At the time of participation, PTS5 was a university student on summer break. Therefore, she was living between her hometown and university city. Over the summer, her routine would start by waking up by 9 am, followed by food preparation, eating and getting ready for the day. The day typically consisted of a combination of running errands, university work, socialising, getting lunch out and gym, physio and track sessions. As a competitive athlete, PTS5 would often train two to three times per day (gym and track), up to five times per week. When not on summer break from university, her day would also include commuting to university to attend lectures and more intense studying and work. Weekends typically would also involve either training in the morning, competing, or socialising if she were not competing that particular weekend. As a competitive athlete, PTS5s' lifestyle was extremely active.

8.2.5.1 Experience of thermal discomfort

PTS5s experiences with thermal discomfort also similarly increased in the warmer seasons, were minimised in cooler seasons and generally triggered by physical activity:

> *"there is notable difference that it does come more often obviously in the summer, when it's hot. Generally, if like the seasons cold, I don't get that many problems, so it is generally when the environment is hotter than normal, or I've been out for a long time like walking around for a long time"*

However, PTS5 also stated that it was not just the outside temperature, but also the weather conditions, with direct sunlight triggering thermal discomfort:

> *"It is, yeah, like the outside temperature, especially if there's like direct sunlight, because it can be like quite, like right now, it's quite warm and quite muggy, but there's not much direct sunlight, so I guess my leg doesn't absorb as much heat so it's not so bad"*

It was not clear though if the effects of direct sunlight were consistent even if the prosthesis was covered by clothing. PTS5 also disentangled heat and sweating as aspects of thermal discomfort and stated that sweating was the main source of irritation for her, rather than simply feeling overheated:

> *"it's not the heat as such, the heat is uncomfortable, but what actually causes the issues I think, is like, when it gets a bit sweaty and it starts rubbing"*

When discussing the consequences of this sweating, although PTS5 did not explicitly mention sweat pistoning, she did feel that her gait was affected by sweating. Although it is not possible to conclusively say if sweat pistoning is the cause for this, it would be highly likely:

> *"I think I'm more sensitive when I'm walking, I like, it might not be as efficient. So, I'm quite a good walker, but if I've got heat problems, I might have a bit more of a limp say"*

In terms of the emotional consequences of thermal discomfort, PTS5 stated that:

> *"it just, yeah generally makes me feel a bit crap, I guess. I don't know how else to put it."*

This shows that, once again, thermal discomfort is a phenomenon with far-reaching consequences. Additionally, PTS5 found herself regularly limiting her activities due to thermal discomfort:

> *"it just I guess it like, hinders me from doing any sort of leisurely, like more leisurely walking than I need to be doing."*

Finally, PTS5 also mentioned a similar self-care routine to the other four participants. However, although she found that she could avoid thermal discomfort by removing her limb, it caused excessive disruption to her daily life:

> *"so, if I, like make an effort to like go and dry my leg, I can sort of avoid it. But sometimes, it's honestly like, I just feel myself getting so sweaty so often, so, yeah [...] I'd probably need to if I could like once an hour, but I won't do it once an hour 'coz' it's really disruptive"*

8.2.5.2 Overall data summary and interday data

PTS5s length of participation in the study was originally intended to be 14 days- as with the other participants. However, after the first 7 days, the participant misplaced the ambient sensor and therefore, the first 7 days of data were incomplete. Upon discussing this with the participant, they agreed to start the experiment again. Unfortunately, even though the replacement sensor was working upon leaving the lab and was reported to be working throughout the study when the sensor was received, the collected data was irretrievable. Summaries of the collected data are presented in Table 19, Figure 33, and Figure 34.

Table 19: Total and intraday modes for PTC and averages for limb temperature, ambient temperature, ambient humidity, and heart rate, as well as total steps per day for PTS5 are presented.

	PTC	Limb Temp ± SD (˚C)	Ambient Temp ± SD (˚C)	Ambient RH ± SD (%)	HR ± SD	Steps per day
All	3	32.7 ± 2.2	-	-	84 ± 15	-
Day 1	3,4	-	-	-	84 ± 16	6139
Day 2	3	31.8 ± 1.8	-	-	86 ± 20	7876
Day 3	3	-	-	-	84 ± 17	3954
Day 4	3,4	-	-	-	87 ± 17	7788
Day 5	3	-	-	-	86 ± 11	6737
Day 6	-	-	-	-	-	-
Day 7	-	-	-	-	-	-
Day 8	3	-	-	-	93 ± 15	6054
Day 9	3	-	-	-	83 ± 11	8490
Day 10	3	-	-	-	79 ± 14	2404
Day 11	3	33.2 ± 2.5	-	-	81 ± 15	5542
Day 12	3	33.2 ± 2.1	-	-	80 ± 13	6093
Day 13	3	30.1 ± 1.9	-	-	65 ± 8	37
Day 14	3	33.8 ± 1.9	-	-	90 ± 15	4121
Day 15	5	-	-	-	84 ± 13	6692
Day 16	4	31.2 ± 2.1	-	-	86 ± 14	9054
Day 17	3,4	32.0 ± 2.0	-	-	86 ± 12	6657
Day 18	4	29.0 ± 1.4	-	-	95 ± 18	5044
Day 19	3	33.0 ± 2.1	-	-	82 ± 17	6103
Day 20	4	32.2 ± 1.0	-	-	82 ± 12	2220
Day 21	3	33.4 ± 1.2	-	-	79 ± 14	2062

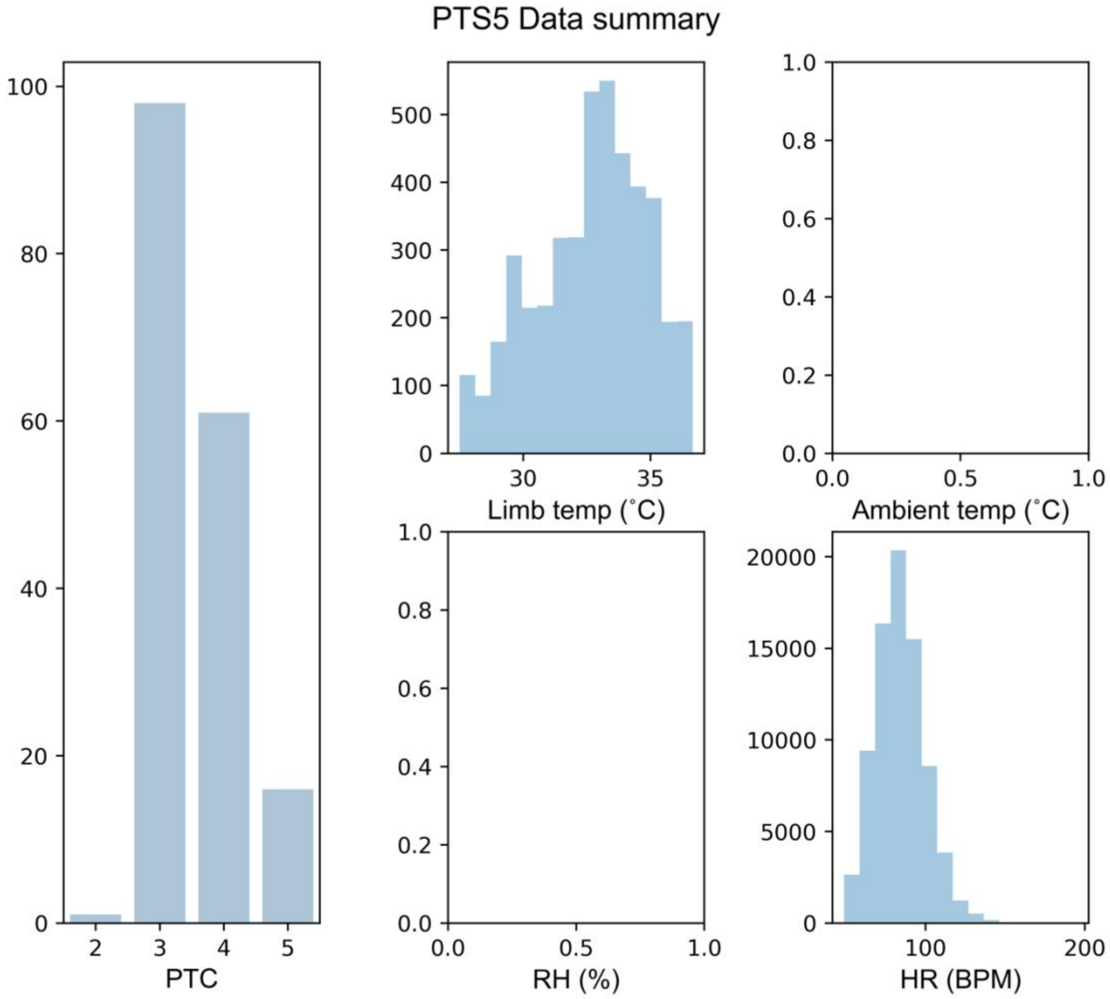


Figure 33: Histograms for PTC, limb temperature, ambient temperature, ambient humidity, and heart rate for PTS5 are displayed. The y-axis on all plots corresponds to numeric ‘count’.

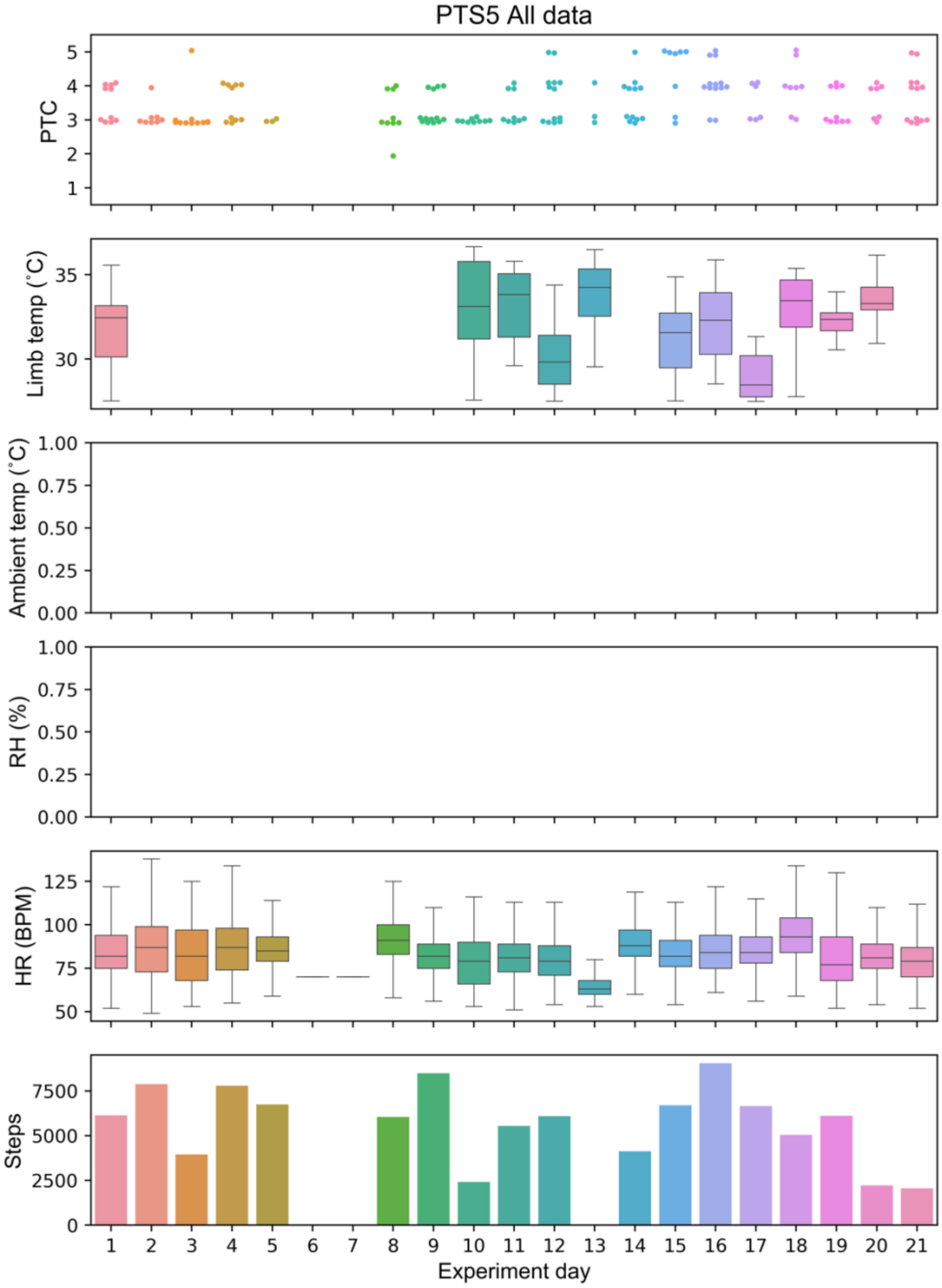


Figure 34: Intraday swarm plots of PTC, box plots of limb temperature, ambient temperature, ambient humidity and heart rate, and a bar chart of total step count are displayed for PTS5.

8.2.5.3 PTC Level Trends

PTC data is presented in Table 20. PTS5 most frequently felt thermally comfortable, with 98 of the PTC recordings being at this level. However, as with most of the other participants, a large number of PTC recordings were also at a level of being slightly uncomfortably warm (PTC = 4). PTS5 did not record any values of PTC = 1.

Table 20: PTC data for PTS5 is presented alongside the average limb temperature, ambient temperature, ambient humidity, heart rate, and step rate.

	PTC1	PTC2	PTC3	PTC4	PTC5
Count	-	1	98	61	16
Limb Temp (˚C)	-	-	33.1	32.0	33.3
Ambient Temp (˚C)	-	-	-	-	-
Ambient Humidity (˚C)	-	-	-	-	-
HR (BPM)	-	62	77	82	90
Step rate	-	0	39	36	124

When reviewing the most infrequent PTC recording, PTS5 only recorded one instance of being slightly uncomfortably cold (PTC = 2). The collated data revealed that the participant was making breakfast at home at this point in time. The participant was not wearing the skin temperature sensors and only heart rate was captured- at a value of 60 BPM. In the exit interview, I asked PTS5 to recollect this instance and she explained that:

> *"Yeah, my friend had like a fan on in the living room. It was just cold and I thought oh I suppose I'm a bit cold. I felt like goosebumps on my limb and I can feel that- you know when your hairs are on edge- against my liner"*

Instances where PTC = 3 occurred when limb temperature ranged between 29.7 – 35.3 ˚C and HR was between 54 – 117 BPM. PTS5 was thermally comfortable in when conducting a multitude of different activities but was most frequently comfortable when relaxing (29 instances). PTS5 was also comfortable whilst conducting self-care activities (15 instances), napping (11 instances), working (10 instances), eating (9 instances), preparing food (8 instances), driving and shopping (5 instances respectively), socialising (4 instances), doing housework (3 instances) and when walking (2 instances). The most frequent location by far for PTS5 to feel comfortable was at home (68 instances), followed by restaurants/ bars/ cafés (8 instances), public spaces and private transport (6 instances), the gym (5 instances), outside (4 instances) and finally clinics (1 instance). When asked to describe thermal comfort qualitatively, PTS5 explained that:

> *"Generally, if I was a 3, I'd just be chilling and not doing much. I'd be sat down, doing… work, or whatever- just nothing much at all, and I wasn't getting any sensations or feelings in my leg. Yeah, just comfortable. No problems there, no discomfort"*

Participant 5 recorded 61 instances of being slightly uncomfortably warm over the duration of the experiment. At the time of these recordings, limb temperature ranged between 27.7 -36.3 ˚C and HR was between 61 – 111 BPM. Many different activities were tagged as being slightly uncomfortably warm and included relaxing (13 instances), driving (10 instances), socialising (9 instances), working and self-care (7 instances respectively), exercise (5 instances), eating and walking (4 instances respectively), shopping (2 instances) and finally housework (1 instance). These activities most commonly took place whilst at home (16 instances), followed by being outside or in private transport (11 instances respectively), at restaurants/ bars/ cafés (10 instances), in public spaces (7 instances), at the gym (5 instances) and finally at a clinic (1 instance).

To understand the reasons behind many of the common activity and location themes, PTS5 was asked to provide further information. When PTS5 was relaxing but slightly uncomfortably warm, she stated that it was usually because *"the room is hot, or also when I've had training earlier in the day and my leg is still like calming down"*. PTS5 was also often uncomfortable when driving due to issues with her cars air conditioning:

> *"the air con' in my car- so I've got a new car recently- and the air con' just doesn't work. It just blows out room temperature air"*

In her experience, however, her general experience of a PTC = 4 rating could be described as:

> *"When I can feel that my leg is hot and uncomfortable and red and sweaty. But I can still sort of, like, tolerate it, and I'm alright. But it is like not comfortable. But it's still like walkable, bearable."*

In contrast, when PTS5 experienced a PTC = 5 recording, she felt that she had to intervene as discomfort began to merge into pain:

> *"I thought I'd save the 5s for the times when I need to stop what I'm doing and actually take my leg off and give myself a minute to get back to normal here [...] just so my leg can calm down, so it'd be almost to the edge of pain sort of thing. Yeah. That's what I'd save 5 for."*

When 5s were recorded, PTS5s limb temperature ranged between 29.7 – 36.1 ˚C and her heart rate was between 69 – 120 BPM. The most common activity for PTS5 to feel extremely uncomfortably warm was when driving (6 instances), followed by self-care (3 instances), socialising and relaxing (2 instances respectively) and housework and exercise (1 instance respectively). These activities took place in private transport (6 instances), at home (3 instances), in restaurants/ bars/ cafés and the gym (2 instances respectively) and outside or in clinics (1 instance respectively).

8.2.6 Participant overview

Although participants each had differing ages, genders, levels of amputations and prosthesis prescriptions, all of the data was reviewed and analysed from the perspective of coded ESM activity (Table 21).

Table 21: All data from participants was analysed from the perspective of activities conducted.

Activity	PTC	Count	%	Limb temperature	Ambient Temperature	Ambient Humidity	Heart Rate	Participant (# events)
Commuting	2	2	6.3	28.2	22.8	44	66	PTS1 (2)
	3	11	34.4	33.3	24.9	42	81	PTS1 (6), PTS3 (5)
	4	19	59.4	29.6	24	45	82	PTS1 (12), PTS2 (3), PTS3 (4)
	5	3	9.4	28.9	23.3	44	89	PTS1 (2), PTS2 (1)
Driving	3	16	41.0	34.3	27.3	43	85	PTS2 (3), PTS3 (6), PTS4 (2), PTS5 (5)
	4	17	43.6	32.8	-	-	87	PTS2 (6), PTS3 (1), PTS5 (10)
	5	6	15.4	34.5	-	-	85	PTS5 (6)
Eating	3	24	70.6	32.2	24.5	42	72	PTS1 (8), PTS2 (6), PTS4 (1), PTS5 (9)
	4	10	29.4	33.3	26.4	42	86	PTS1 (1), PTS2 (4), PTS4 (1), PTS5 (4)
Exercise	3	6	30.0	-	-	-	92	PTS2 (2), PTS3 (1), PTS4 (3)
	4	11	55.0	29.6	27.7	41.8	83.3	PTS1 (1), PTS4 (5), PTS5 (5)
	5	3	15.0	-	-	-	-	PTS1 (1), PTS2 (1), PTS5 (1)
Food preparation	2	1	4.5	-	-	-	-	PTS5 (1)
	3	17	77.3	32.6	-	-	76	PTS1 (3), PTS2 (4), PTS4 (2), PTS5 (8)
	4	4	18.2	-	-	-	90	PTS1 (1), PTS2 (3)
Housework	3	17	53.1	-	26.3	41	80	PTS1 (1), PTS2 (7), PTS3 (3), PTS4 (3), PTS5 (3)
	4	13	40.6	30.3	25.7	43	84	PTS1 (2), PTS2 (7), PTS4 (2), PTS5 (1)
	5	2	6.3	-	-	-	-	PTS1 (1), PTS5 (1)
Napping	3	16	100.0	33.3	-	-	75	
Relaxing	2	1	0.6	-	-	-	-	PTS2 (1)
	3	128	79.5	33.1	24.5	41	80	PTS1 (21), PTS2 (15), PTS3 (49),

								PTS4 (14), PTS5 (29)
	4	29	18.0	32.4	24.8	43	87	PTS1 (5), PTS2 (12), PTS5 (12)
	5	3	1.9					PTS1 (1), PTS5 (2)
Self-care	3	31	63.3	31.9 (8)	25.0 (3)	45 (3)	77 (18)	PTS1 (8), PTS2 (7), PTS4 (1), PTS5 (15)
	4	15	30.6	32.0 (4)	-	-	85 (11)	PTS1 (1), PTS2 (7), PTS5 (7)
	5	3	6.1					PTS5 (3)
Shopping	3	8	80.0				88 (8)	PTS2 (1), PTS3 (2), PTS5 (5)
	4	2	20.0					PTS5 (2)
Socialising	2	4	10.5	29	21.8	52	74	PTS1 (4)
	3	16	42.1	33.9	27.3	36	79	PTS1 (3), PTS2 (4), PTS3 (5), PTS5 (4)
	4	16	42.1	31.6	24.5	42	86	PTS1(2), PTS2(5), PTS5 (9)
	5	2	5.3					PTS5 (2)
Walking	3	36	52.2	33.9	25.1	41	82	PTS1 (4), PTS2 (12), PTS3 (17), PTS4 (1), PTS5 (2)
	4	30	43.5	32.8	24	43	83	PTS1 (3), PTS2 (14), PTS3 (9), PTS5 (4)
	5	3	4.3					PTS1 (2), PTS2 (1)
Work	2	5	3.2					
	3	124	79.0	32	25.5	44	80	PTS1 (11), PTS2 (26), PTS3 (55), PTS4 (25), PTS5 (7)
	4	26	16.6	33	24.1	46	82	PTS1 (6), PTS2 (14), PTS5 (6)
	5	2	1.3					PTS1 (2)

8.3 Discussion

As presented in Section 3.5, previous studies by other researchers into thermal discomfort amongst prosthesis wearers have mostly been devoted to short deployments of temperature sensors in laboratory environment. The only exception was an out-of-lab study by Segal et al., which still maintained a high degree of control via researcher intervention. In Chapter 7, a study which extended slightly beyond the status quo of prior research was presented, by conducting a multi-hour, out of lab experiment where participants had full freedom to conduct activities of their choosing. However, whilst this approach was novel, it was apparent that the time window for data collection had to be increased and more modes of sensing and data collection would likely be required to understand thermal discomfort amongst prosthesis wearers.

Therefore, in the previous two chapters, study 3 has been presented, which represents an innovative approach to conducting amputee thermal discomfort research. Study 3 is not only the first multi-day but the first multi-week investigation into the phenomenon of thermal discomfort. The study also can credibly be considered as a holistic investigation into thermal discomfort by adopting a multi-modal sensing strategy and also a mixed-methods approach to data collection. In doing so, it has been possible to collect 685 logged PTC events, which constitute the experience of five prosthesis wearers over 10 cumulative weeks of investigation. Moreover, these PTC events are not only contextualised with participant reported activities, but also with lived accounts of thermal discomfort.

When planning this thesis, the aim has been to address the question:

> *Under what circumstances does thermal discomfort arise in real-life for lower-limb prosthesis wearers, and what are the consequences of this phenomenon?*

In study 3, the focus has been to try and deeply understand the circumstances behind thermal discomfort using mixed-methods research and multi-dimensional datasets. Prior to conducting study 3, I had assumed that prosthesis thermal discomfort could be modelled in a similar way to thermal discomfort modelling within non-amputees. Such an assumption makes it possible to imagine the existence of ‘comfort thresholds’ of each parameter (e.g. skin temperature or ambient temperature), which would make prosthesis wearers increasingly likely to be thermally uncomfortable when exceeded. However, the collected data shows no clear evidence of positive correlations between level of thermal discomfort and any of the quantitative sensed parameters. When reviewing the collective sensor data, no clear trends or correlations present themselves in relation to PTC- either on an individual participant basis or as a collective study population. Therefore, it is reasonable to state that the collected quantitative data in this study has not been shown to be linked to PTC, making it difficult to come to a sensor-based insight as to the circumstances in which discomfort occurs. In itself, this finding may appear unassuming. However, prior proposed solutions to thermal discomfort (e.g. Section 3.7) have been designed using the assumption that maintaining skin temperature of the residual limb will maintain thermal comfort. Data from this study does not support the core assumption of these types of solutions. Given that the currently developed experimental solutions have yet to be converted into practical solutions, it is necessary to consider if solutions which aim to maintain parameters such as residual limb skin temperatures will actually work as a preventative measure to thermal discomfort amongst lower-limb amputees.

Given the multidimensionality of the collected data set, it is also reasonable to assume that there may exist an interplay between individual parameters that have a combined effect. This still remains an interesting proposition, however, after preliminary investigations using data fusion techniques, there is a lack of trend evidence between combined parameters and PTC levels. Nonetheless, it is critical to note that such preliminary investigations have been conducted on a subset (10%) of the collected data which have no missing parameters. Therefore, it may be that the lack of any clear evidence is simply due to the small sample set of multimodal data.

With minimal evidence supporting the theory that levels of thermal discomfort are associated with sensable parameters, other aspects of thermal discomfort were examined. Therefore, when reviewing a combination of the PTC logs and the interview transcripts, it became possible to approach the research question from a different perspective. When conducting an activity analysis (Table 21), activities such as commuting, and exercise were commonly slightly uncomfortably warm (4) or very uncomfortably warm (5). In total, 70% of (post)-exercise and 68.8% of commuting activities were rated as a 4 or a 5.

The first activity- exercise- is one which can be expected. Although participants were instructed to not wear sensors during exercise, many of them reported activities shortly after finishing a session of exercise. Therefore, the participants would likely be experiencing a PTC in response to increased cardiac output. Physiologically, cardiac output often remains elevated post-exercise [125,126]. On the other hand, commuting is an activity which is predominantly inactive (a few instances of individuals walking to work were coded as walking, rather than commuting). In these instances, when one considers that participants were mostly commuting through central London at rush hour, busses, suburban rail and underground trains would likely have been crowded. Although there is no evidence of elevated ambient temperature or humidity, it may have been intangible aspects of the commuting environment such as crowding, an enclosed and uncontrollable ambient environment or the length of commute which lead to thermal discomfort.

It is interesting to note that there were no activities that either exclusively elicited a comfortable or uncomfortable PTC rating. To try and determine differences between comfortable and uncomfortable instances, sensor time-series data were reviewed to examine what occurred before specific PTC ratings. However, there were no distinguishable trends that were evident that differentiated comfort and discomfort. Even when reviewing summary statistics of ‘typical’ values of mean limb temperature, mean ambient temperature and humidity and mean heart rate, when filtering by activity, there were still no clear indications of sensor-based differences in comfortable and uncomfortable activities.

However, reviewing the primarily qualitative data revealed multiple interesting concepts. The first concept is the feeling of control for prosthesis wearers. This is best exemplified by PTS2, who frequently experienced thermal discomfort when walking with other people. In this situation, she found herself not being able to set her own pace and having to try to keep up with other individuals. PTS2 particularly noted that she felt particularly lacking in control because she did not want to slow other people down to a more comfortable pace for her. Additionally, PTS3 frequently experienced thermal discomfort whilst commuting on the train, stating that:

> *"in the situation of say being stuck on a train. I can't go anywhere It's just waiting until it's time to get off"*

Therefore, it may be that when either a physical stimulus or an unideal environment is experienced, and prosthesis wearers have limited or no control over the situation, perceived thermal discomfort is experienced.

When debriefing with PTS2, she also made a pertinent comment that although she does experience thermal discomfort, through lived experience, she has learnt ways to adapt her environment to make her comfortable:

> *"I feel like I've done quite a lot to get to that position [...] So I know that I need to open the window, I know my environment and I'm mostly in my environment- my environment is set up so I feel comfortable and relaxed generally. I go out of my way to be comfortable at most times, so that set up is I feel fine"*

The reported experience highlights that prosthesis wearers may often actively adapt their behaviour and environments to pursue thermal comfort, demonstrating the importance of comfort to life with a prosthesis.

Whilst study 3 represents a novel contribution to the field of thermal discomfort amongst prosthesis wearers, there are limitations which must be considered. One limitation which was highlighted by PTS3, PTS4 and PTS5 was the lack of tracking PTC during exercise. For all individuals who took part in the study, it was clear that exercise made up an important part of their daily lives. Whilst this was done to both preserve equipment and to minimise participant risk, it is important to acknowledge that research presented in study 3 does exclude an activity which participants state causes high levels of thermal discomfort. Therefore, thermal discomfort may occur more frequently in participants daily lives when exercise is included.

When reflecting on the sensors which were either built or bought for this study, it is clear that improvements would be required for future studies. Of the two bought sensors, the Fitbits were dependable, collecting the most complete data sets over the course of each participants' study. In comparison, the ambient sensor (a product from BlueMaestro, UK) had multiple issues resulting in data loss. A common issue was that the coin-disc battery could be displaced even with the battery cover on, resulting in the device resetting. This was the main reason for the lack of ambient data for PTS2. However, even after improving the battery holder, issues still persisted. For example, the sensor reset midway through PTS3s experiment, resulting in missing data at the start of the study. For PTS5, aside from one sensor being lost, resulting in the loss of the first weeks' worth of data, during check-in phone calls, the participant reported that the sensor was working. Therefore, data were likely lost between the study ending and the sensors being returned. The custom-made skin temperature sensor system also demonstrated two modes of failure. Firstly, data were lost on occasion due to wire breakages. In these circumstances, data up to the point of breakage were preserved. As has been demonstrated in study 2, this is to be expected and the reason why sensors were adapted to be easily replaced by participants. The second mode of failure, however, was more curious, as the sensor system would randomly become stuck in a boot loop. The reason for this fault still remains unclear even after contacting the manufacturer of the sensor board and extensive code review. The multiple sensor failures highlight that real-world studies require sensors that have been extensively tested by multiple individuals, in multiple situations for extensive periods of time. Although this would have been preferable, a constrained project timeline prevented more extensive testing than could be conducted, which may have identified the boot issue ahead of usage with participants.

After considering all of the findings, it is possible to state that thermal discomfort amongst amputees is indeed highly complex and subjective. From the data collected in study 3, it was not possible to reduce thermal discomfort amongst amputees to a simple set of relationships between quantitatively recorded ambient, physiological parameters and personal experiences. However, to understand the circumstances of why thermal discomfort arises, it appears that psychological concepts such as perceived control of the situation and the duration of time spent in an environment or situation may be influential. It may, therefore, be the case that when prosthesis wearers are in a situation which they cannot control or a situation for an extended period of time, changes in physiological or ambient conditions will likely result in thermal discomfort. However, given the limited sample size, it would be prudent to investigate these considerations as a focus and with more prosthesis wearers.

9 GENERAL DISCUSSION

The work presented in this thesis represents a novel contribution to the research space of thermal discomfort amongst prosthesis wearers. The focus of the thesis was formulated after an extensive literature review, which indicated that most prosthesis wearers' experience overheating and hyperhidrosis. This phenomenon of 'thermal discomfort' can be attributed to a combination of less effective thermoregulatory responses due to reduced body surface area [128], and the insulating effects of sockets and liners which retain heat and sweat due to their low thermal conductivity [127,128,234] and impermeability [199]. The resultant hot and humid skin-prosthesis interface [105,110,143,145,165,183] has been shown to reduce prosthesis wear [166] and create the perfect conditions for skin infection in the likely event of skin damage [58,164,165]. The consequence of thermal discomfort and skin damage can be a long period of time (177.6 ± 113 days to heal [107]) where the person might not be able to wear the prosthesis [150]. Additionally, thermal discomfort can also have social consequences, as the presence of bacteria can generate unpleasant odours, which can lead to increased social anxiety and isolation [206].

When prior research into prosthesis related thermal discomfort was examined [110,130,154,182,183], it could best be summarised as almost all laboratory-based, focused exclusively on male, transtibial amputees, predominantly limited to sensor-based research and structured around a 'rest-exercise-rest' protocol. Observations typically centred around mean limb temperature change during an experimental protocol, which was found to range between 1.7-3.1˚C in controlled laboratory settings [110,130,183], or up to 3.9 ˚C outside of a lab [216]. Only one study (Ruiz et al. [199]) attempted to explore thermal discomfort by adopting a qualitative approach to research. The research found that participants reported prosthesis slippage when sweating was initiated, and the participants attributed this to increases in physical activity and climate. However, only four amputees participated in this study, and no formal qualitative analytic method was used, therefore, there was an opportunity to conduct more in-depth and rigorous qualitative research on this topic.

To summarise, thermal discomfort amongst prosthesis wearers can be thought of as a phenomenon which we knew existed, and of which we had identified some contributing demographic and lifestyle factors via statistical analysis of questionnaire data, as is typically done in medical research. Researchers have then subsequently aimed to quantify changes in limb temperature using temperature sensors. However, the prior art is limited, in how it has constructed knowledge. If research on this topic were to continue using the same approach, we would never reach an understanding of what are the deeper consequences of thermal discomfort- i.e. *how* does it affect peoples lived experience of prosthesis wear? Additionally, we would be limited in understanding that thermal discomfort occurs, with no understanding of the *contexts* that it arises, and to the extent of the phenomenon. These questions are essential to direct the development of solutions which minimise and resolve thermal discomfort, based on the context in which it is experienced. Therefore, this thesis aimed to answer the following research question:

> *Under what circumstances does thermal discomfort arise in real-life for lower-limb prosthesis wearers, and what are the consequences of this phenomenon?*

To help investigate the research question, research methods which have been used in experiments investigating thermal discomfort in the built environment were reviewed. This parallel research field demonstrated how thermal comfort can be investigated outside of the laboratory [63,91,115], and how technologies such as wearable activity sensors can be utilised [109]. Finally, further literature review relating to how to structure the research from a methodological perspective lead to the decision to frame this thesis as a mixed-methods investigation (Section **Error! Reference source not found.**), making use of a variety of quantitative (Section 4.2.1) and qualitative methods (Section 4.2.2).

9.1 Research Findings summary

In ***Study 1***, a qualitative study is presented which aimed to explore the realities of life with a prosthesis, with a focus on thermal discomfort. The qualitative analysis resulted in the formation of two ‘grand’ themes which could be thought of as positive influences and negative influences on the prosthesis wearing experience. In the analysis, the prosthetic limb appeared as a negative determinant, with negativity predominantly focussing on individual problems with the limb. Subthemes which related to fostering positivity resulted in the thought exercise of how technology aside from the prosthetic device could be used to augment the prosthesis wearing experience.

When the research question central to this thesis is considered, study 1 provided insights extracted from the lived experiences of thermal discomfort reported by prosthesis wearers. These insights helped to explore consequences of thermal discomfort. One of the first consequences to note was that prosthesis wearers generally felt warmer in daily life than they did prior to amputation. Comments such as *“I’m- I’m always hot, I don’t think I’m ever not hot”*, and general descriptions of prosthesis wearers changing their attire to include shorts and t-shirts- even in wintertime- demonstrate frustrations and lifestyle adaptions caused by thermal discomfort. As expected, when participants experienced hyperhidrosis, prosthesis pistoning tended to occur- for some requiring immediate termination of activities (e.g. cutting a run short to remove prosthesis). However, the often-reported consequence of thermal discomfort is to enact a self-care routine multiple times per day, wherein the prosthesis is removed, the residuum dried, cleaned and left to cool off, and then the limb reattached.

The necessity of frequent self-care routines of prosthesis removal - the frustration of knowing that wearing more than minimal clothing will amplify thermal discomfort, and the social anxiety caused by sounds, smells, and liquids are the real-world consequences of thermal discomfort. The medical consequences caused by thermal discomfort such as skin problems are a justifiably serious consequence of thermal discomfort, but the consequences which have been highlighted in study 1 demonstrate the importance of ‘day-to-day’ impact of thermal discomfort. In the past, literature has necessarily focussed on the consequences of thermal discomfort to reductions in prosthesis function, pain and skin damage. However, for the individuals living with a prosthesis, the social consequences of thermal discomfort such as social anxiety due to sweat patches on the groin, squelching noises when walking, or too much attention being drawn when a limb detaches due to sweat pistoning are of critical importance.

In ***Study 2***, the aim was to try and focus on how thermal discomfort arises using limb temperature and ambient temperature sensors. The study began by adopting a similar protocol to prior amputee thermal comfort studies by asking participants to walk on a treadmill in a lab environment whilst wearing temperature sensors. Once completed, the same participants were asked to conduct unsupervised activities of their choosing (on a different day) whilst wearing sensors out of the laboratory. In addition to the sensors, participants were also asked to record their perception of thermal discomfort as they completed their activities. When data from both sub-studies were reviewed and analysed, there were two primary contributions to knowledge. The first knowledge contribution came from comparing average limb temperatures (from temperature sensors placed at the same sensing sites) for each participant between each sub-study. This analysis revealed evidence that limb temperatures were significantly higher for participants in the out of lab study than the in-lab study. The implication of this knowledge contribution provides motivation to conduct thermal comfort research in naturalistic contexts and environments. The second knowledge contribution was a contribution to protocol, as the study highlighted clear deficits in sensing technologies. Firstly, when the PTC data was reviewed, it was evident that the lack of notification strategy to prompt PTC recording, coupled with a relatively short sub-study resulted in a sparse dataset. Given the intention of data collection was to find the circumstances which cause thermal discomfort to arise, collecting *enough* data to begin to form correlations between objective measures such as limb temperature and ambient temperature was important. Therefore, significant effort was put into designing research tools and an experimental paradigm which could work towards exploring the research question.

In ***Study 3***, significant time and effort were devoted to countering deficiencies identified in study 2, so that a real-world study could be conducted for long periods of time to collect ‘large’ amounts of data. The final study resulted in the creation of a multivariate data collection system, which enabled residual limb temperature, heart rate, activity, ambient temperature and humidity data to be captured, as well as ‘tagged’ perceived thermal comfort reports. The data collection system was created using three sensors, and an iPhone. However, to augment the data further, real-world data collection was augmented with pre and post-study interviews. Therefore, Study 3 represents a mixed-methods research experiment. In total, five prosthesis wearers participated, for between 1-3 weeks. In total, a multivariate dataset was created which is composed of 685 PTC events. Each PTC event had corresponding objective sensor data matched to each reading, as well as user-reported activity and location. After reviewing all of the collected data, on an individual participant basis and a collective basis the collected sensor data did not present any clear evidence of correlations which could be used to construct an understanding of how thermal discomfort arises. However, when reviewing all of the collected qualitative data and experience sampling data, it became apparent that ‘control’ had a role to play in thermal discomfort. For example, PTS2 felt most thermally uncomfortable when walking with other people- when she had no control on the pace. PTS3 felt most thermally uncomfortable when stuck on trains- when he was unable to make adaptions to his environment. PTS1 noted that thermal discomfort was worse in situations where he could not intervene and that the longer this was endured, the worse is became ‘psychologically’. When reviewing entrance and exit interview data, the theme of control is important to note, as participants often recalled similar experiences of carefully crafting self-care routines to manage thermal discomfort or adapting their environments to their precise and relatively unique requirements. Therefore, it is unsurprising that thermal discomfort can arise when prosthesis wearers are unable to control and adapt the contexts which they find themselves in.

9.2 Contribution to Knowledge

In prior research studies, surveys had indicated that thermal discomfort reduces quality of life, however, we didn't know how, or why it does. Study 1 and study 3 found that thermal discomfort acts to make prosthesis wearers feel irritated, tired, and annoyed, so much so that they often act to limit activities to essential tasks if they think they will encounter discomfort. Thermal discomfort also acts to reduce Quality of Life through the introduction of social anxieties such as heat and sweat related smells, displaced sweat stains, or squelching caused by pistoning. Each of these can act to make prosthesis wearers feel self-conscious and uncomfortable in public places.

However, many prosthesis wearers devote time to learning how to arrange their immediate environments to prevent thermal discomfort from ever arising. For some, this may mean always sitting near a fan in their office environment. For others, it may mean optimising the selection of items around themselves whilst working from home to minimise movement, which could trigger thermal discomfort. Finally, some individuals chose to modify their attire and find themselves almost wearing t-shirts and/or shorts- even in cooler seasons- to try to avoid experiencing thermal discomfort.

Despite the efforts to prevent thermal discomfort, for many prosthesis wearers it was still necessary to enact self-care routines multiple times per day which involves the removal of the prosthesis and liner, a full wipe down of the residuum and prosthesis, and, usually a period of rest without the prosthesis. Many prosthesis wearers who enacted this routine noted that it was ultimately a frustrating burdensome chore, but unfortunately one of the necessary consequences of thermal discomfort and the reality of life with a prosthesis.

Prior to commencing the research studies, the research question had been formulated with the hypothesis that it would be possible to understand the circumstances in which thermal discomfort arises. The idea was that it would be possible to find relationships between factors such as limb temperature or ambient conditions and reported thermal discomfort. However, these relationships have not been identified in the data collected in study 2 or study 3. However, it has still been possible to make a meaningful knowledge contribution on how thermal discomfort arises, mostly using ESM and interview data. Firstly, a seemingly obvious, but previously unidentified concept is that thermal discomfort amongst prosthesis wearers is not a binary concept. Instead, as individuals go through their day and experience different activities and surroundings, their thermal comfort levels change in reaction to these changes. However, comparable objective measures, activities and locations can still result in differing levels of thermal comfort. Further follow up investigation and analysis into these scenarios in particular lead to the formulation of the theme of control- or rather lack of control as potentially playing a role in thermal discomfort arising. When prosthesis wearers cannot intervene or modify their environment, thermal discomfort is worse, and it becomes worse the longer that it is endured- acting as a phenomenon which can be thought of as ‘cumulative’.

Though the goal should still be to completely prevent thermal discomfort, realities of the current design of prosthetics make this a non-trivial challenge for science, engineering and design. Without radical change in how wearable legs are *‘worn’*, or the materials which are used, we will either be shifting the problem (for example, the phase change alpha temp liner, which acts as a temporary heat store) or solving thermal comfort at the expense of factors such as weight if adopting active solutions. However, prior technical solutions to thermal discomfort have focused around maintaining limb temperature at a constant value and heat dissipation to maintain equilibrium. This makes sense from a thermodynamic perspective, however, thermal comfort must be appreciated as a psychological problem, as much as it is a thermodynamic one. The knowledge contributions distilled here could lead to possible avenues in which thermal comfort can be psychologically managed and minimised- if not prevented. For example, technologies could be created which offer temporary relief to afford prosthesis wearers a mechanism of reclaiming thermal comfort, without removing their limb. When prosthesis wearers are in situations such as commuting, a technology which can offer temporary ‘shot’ of cooling could provide essential relief. The ability for the wearer to be able to trigger the action- to take control of the situation- could potentially act to mitigate the feelings of lack of control and some of the consequences of thermal discomfort.

9.3 Future research

As it stands, three directions for thermal discomfort research to progress in are evident. The first direction would be to continue efforts to collect data outside of the lab, utilising a similar approach to that presented in study 3. Though not perfect, the research approach introduced represents the necessary direction for collecting meaningful and contextually valid data on the topic of thermal discomfort. However, notable adaptions should be made to studies which continue this type of research. The primary focus should be in ensuring total sensor resilience. To do so, it would be wise to architect a wearable sensing network which backs up data on a regular basis to a cloud location, which can be accessed by researchers at any point during a study. Additionally, the usage of real-time alerting for when data anomalies occur (e.g. a period of 5 minutes of saturated skin-temperature data could trigger an alarm) would enable researcher intervention. Backups, alerting, and interventions would have prevented much of the data loss events experienced in study 3.

When considering the sensors themselves, it goes without saying that much more work should be invested in temperature sensors which are compatible with prosthesis interface research. Thermistors are only *just* suitable given their small size; however, as demonstrated by their regular wire failure, they present their own challenges when being exposed to extended use. The ideal temperature sensor would be thin, flexible, accurate, precise and ideally, wireless. With current technologies, this may be too much to ask for in one sensor. However, avenues such as flexible printed circuit boards, and wireless technologies such as radio frequency sensors could be combined to create such a system. Failing that, progression in ‘predictive’ temperature sensor approaches as demonstrated by Mathur et al. [154] could provide a promising alternative solution to placing sensors in direct contact with the residuum. There also remains one dimension of thermal comfort which has yet to be sensed in a research study. Skin wetedness, the amount of sweat which is present on the surface of the skin, is a concept which has been indicated in study 1 and three as being important to comfort. However, to date, it has not been possible to sense this in-situ due to a lack of commercially available sensors which would be suitable for a prosthesis interface. However, given that skin conductance varies in the presence of different quantities of sweat, the creation of a skin wetedness sensor- likely using flexible circuit boards- is possible. With all of these sensor aspects resolved, a study which aims to extend the foundation set by study 3 could be designed. One additional improvement could be in the time periods during which data is collected- study 3 only collected data in summertime. It would be interesting to collect data at multiple times per year (ideally from the same participants) to observe seasonal effects. An obvious additional goal would be to collect data from more participants to amass a dataset which is both of reasonable scale and variability. In doing so, statistical research avenues, and even machine learning methods, could become a viable and appropriate direction for future research and analysis.

The second direction for future research stems directly out of the research findings extrapolated in Study 3- wherein lack of control was identified as a trigger and aggravator for thermal discomfort. More research should be conducted in way of qualitative exploration to investigate this concept in detail. Moreover, there is an opportunity to begin prototyping prosthetic device accessories which could provide an ‘as-needed’ cooling effect, rather than an ‘always-on’ device, as has been developed so far. This insight leads to the hypothesis that in situations where wearers are unable to control their thermal context, ‘wearer activated’ accessories could provide a way for them to regain control and minimise thermal discomfort. Though this approach could not be thought of as a full preventative approach, it could provide relief from all, but the most intense situations experienced in daily life.

One alternative direction for future research would be to take a machine learning approach, much in the same way that thermal comfort in the built environment uses ubiquitous sensors to train temperature control algorithms. To create a valid machine learning model for prosthesis wearers will require the collection of large amounts of data from many participants. As experienced throughout this thesis, recruitment was a non-trivial task, and in long-term out of lab studies, sensor loss and broken or intermittently working sensors are likely to occur and therefore reduce the size of the collected data corpus, making this style of research challenging. The utility of a machine learning algorithm in prosthesis thermal discomfort would be to automatically control limb temperature in an attempt to maintain thermal comfort. However, research presented in this thesis did not find evidence to support the development of active solutions which maintain a constant limb temperature as a surrogate for maintaining thermal comfort. Therefore, the practical value of mobilising significant resources to explore this research avenue remains unclear.

Research conducted in study 1 and study 3 had recruitment criteria which were open to all genders and level of amputations. In comparison to the preceding literature, this is a unique characteristic of the research presented in this thesis. Though outside of the focus of the central research question, steps were retrospectively taken to investigate if gender and amputation levels had any influence on the experience of thermal discomfort. All transcripts and themes captured in study 1 were reviewed to try to identify any noticeable between participants of different genders and levels of amputation. In study 3, summary statistics and graphs were also reviewed alongside one another and organised to cluster similar genders and levels of amputation. Additionally, both raw and processed ESM data were reviewed and clustered with the same differences in mind.

Though one could expect there to be many differences, there were almost no noticeable differences that could not equally be attributed to other factors. The only identifiable difference comes from PT4 (female, TFA, unilateral) and PT5 (female, TFA, bilateral) in study 1. Both of these relatively young and female participants described how the visual appeal of their prosthesis was important to them, choosing to wear a cosmesis. No male participants (study 1 or 3). reported usage of a cosmesis. Both participants had experienced thermal discomfort through different seasons and after completing light exercise. In comparison, PTS3 (male, TTA, bilateral) and PTS4 (male, TTA, unilateral) reported that they only really experienced thermal discomfort in warmer seasons and after experiencing moderate exercise. Neither wore a cosmesis. Here, it seems as though gender is not the primary cause of reduced thermal discomfort. However, it could be that young female prosthesis wearers are more self-conscious about trying to hide a prosthesis (primary effect) and therefore also wear a cosmesis (solution to primary effect). The solution to the primary effect adds another insulative layer, which reduces the amount of heat that can naturally dissipate (secondary effect). The tertiary effect may be that thermal discomfort is experienced more frequently. If reviewing thermal discomfort through the lens of gender and amputation level, a layered analysis approach (as demonstrated here) may be required to identify differences in experience appropriately.

There may be many other differences in how different genders and levels of amputees experience thermal discomfort. However, to formally investigate these aspects, it would be necessary to conduct a study with sufficient participant numbers to be able to group similar participants. In future work, if thermal discomfort is explored using only a mobile ESM approach, it will be possible to conduct fully remote research studies using participants own phones. By being entirely remote, recruitment will likely become much easier as individuals from across the country (or world even) could be targeted for participation. A sufficiently large data set would make it possible to investigate gender and level of amputation effects with rigour to ensure the validity of findings.

In the current paradigm of ‘wearable’ prostheses, the best solution to thermal discomfort will be one which is not noticeable and entirely preventative. To do so, it is likely that a solution which meets this exacting expectation would arise from the materials in which the prosthesis is made from. Such materials would necessarily need to transport and dissipate heat and sweat entirely away from the limb, as they are generated. However, in meeting these conditions, mechanical comfort and durability should not be compromised. In Appendix 6, the current materials landscape has been explored extensively, and at present, materials which meet these criteria are not in existence. Therefore, there is much work to be done at the base level of the materials which we construct our prostheses out of, if we are to continue within the paradigm of wearable limbs.

Looking beyond the context of thermal discomfort, the method used to collect data in study three could also be adapted to collect data situated in real life experiences for many other prosthesis wearer phenomena. Although it has not been discussed in depth in this thesis, data collected using methods similar to that in study 3 could have value in mediating the prosthetist-prosthesis wearer relationship. As indicated in findings from study one, if data could be framed in a way that helps prosthesis wearers have informed discussions with their prosthetist, prosthesis wearers could be rewarded with a more positive wearing experience through improved prescriptions.

10 CONCLUSION

Thermal discomfort amongst prosthesis wearers is a prevalent, impactful and pervasive phenomenon which can affect prosthesis wearers lives in multiple negative ways. Through three studies, thermal discomfort has been researched both in and out of the lab and using a blend of quantitative and qualitative research methods. Additionally, in contrast with previous research, not only have individuals with amputations other than transtibial amputations been included, but female participants have featured in both Study 1 and Study 3. Each of these individual facets would situate this thesis as being novel in the context of thermal discomfort research amongst prosthesis wearers. However, in combining all of these facets into one thesis and into a knowledge contribution, the work presented here acts to progress thermal discomfort research. Subsequent research in the field should consider how out of lab protocols can be used; however, greater sensor resiliency is an essential focal point for future studies. Though correlations were not evident between the sensed objective measures in study 3 and PTC, evidence of correlations could have been hiding in data lost due to sensor failures. Future work should also aim to explore the theme of lack of control, and the role it plays in thermal discomfort. This thesis acts as a call to arms for scientists, engineers, designers, and medical professionals, to better investigate and solve the issue of thermal discomfort for lower limb prosthesis wearers. Nonetheless, for anyone choosing to tackle the phenomenon of thermal discomfort, the research presented here should act as a cautionary note. With prostheses in their current design and form factor, thermal discomfort amongst prosthesis wearers is *not* a problem which will be solved by a solely thermodynamic approach, because thermal discomfort is *not* merely a thermodynamic phenomenon. To truly work towards effective mitigation or prevention of thermal discomfort, this phenomenon must be considered as it truly is- a messy, complex, multifaceted, and essentially human problem, which just so happens to arise because of the limitations of prosthetic limbs. It is not static, it is inconsistent, and its consequences are far-reaching. Even if it proves impossible to eradicate thermal discomfort with current technologies, technical interventions which embrace thermal comfort as complex, and articulated human phenomenon will stand a better chance of making a meaningful positive change to life with a prosthesis.

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12 APPENDICES

APPENDIX 1: STUDY 1 QUALITATIVE INTERVIEW GUIDE

Interview phase	**Description**
Pre-interview	Information sheet and consent forms printed [Y/N?] Ensure participant is comfortable
Introduction	Introduce self and background Introduce PhD process to provide context Explain purpose is to explore everyday UX of prosthetics Explain format of interview Opportunity to ask Q's Give information sheet + obtain consent Explain audio recorder and turn on
Initial questions	Age Are they currently working? If yes, what do they do? If no, have they worked previously? How active are you? What activities/ exercise do you do? How frequently? What prosthesis do they wear? How old is their prosthesis? How did they become a prosthesis wearer? [SENSITIVE]
Getting the prosthesis	What prosthetist clinic do you visit? How often do you visit? Do you have a regular prosthetist? Discuss relationship with staff (what's good, what's bad) Can you talk me through a typical appointment? (process, relationships, emotions) Can you talk me through a fitting appointment? (process, relationships, emotions, length of time/ frequency of visits) How do you raise issues with prosthetists? Have you changed your prosthesis before? How did that come about? Did you ask for something?
General issue enquiry	Are there any issues you have experienced within the last year? What, when, how, why? (Influence on daily life) Did it get resolved? (How?) Are there any recurring issues you've had? What, when, how, why? (Influence on daily life) Did it get resolved? (How?)
Thermal comfort inquiry	Have you ever experienced thermal discomfort when wearing leg? What were you doing? Where were you? Where there any consequences? How frequently does this happen? How much does it impact your life? Have you spoken to your prosthetist about this? How did you address it?
Pistoning issue inquiry	Have you ever experienced pistoning when wearing leg? What were you doing? Where were you? Where there any effects? How frequently does this happen? How much does it impact your life? Have you spoken to your prosthetist about this? How did you address it?
Skin issues inquiry	Have you ever experienced skin issues when wearing leg? What were you doing? Where were you? Where there any effects? How frequently does this happen? How much does it impact your life? Have you spoken to your prosthetist about this?

	How did you address it?
Day-in-the-life walkthrough	Can you talk me through a typical day with your prosthesis? (Focus on activities done, the leg, issues, when it goes on or off, any times the leg is explicitly noticeable) Do you ever run into difficulties in the day due to your prosthesis? How do you resolve them? Does your prosthesis ever prevent you from doing something? What, when, how, why?
Closing	If you could change or improve one thing about your prosthesis, what would it be and why? Do you have any additional questions? Close and inform of what will happen with interview data

APPENDIX 2: STEINHART-HART CALIBRATION

In study 2 and study 3, all thermistors were calibrated using Steinhart-Hart equation. To calibrate thermistors using the Steinhart-Hart equation, it is necessary to measure the resistance of a thermistor at three known reference temperatures, to solve three simultaneous to obtain constants A, B, and C. Upon obtaining the constants, Equation A1 can be used to produce accurate thermistor measurements.

Equation A1

$$\mathbf{T} = \frac{\mathbf{1}}{\boldsymbol{A} + \boldsymbol{Bln}(\boldsymbol{R}) + \boldsymbol{C}[\boldsymbol{ln}(\boldsymbol{R})]^3}$$

Equipment:

- To measure reference temperatures, a 222-051 precision thermometer (± 0.05˚C) (ETI, United Kingdom) was used, with a 160-222 probe.
- To provide a reference thermal mass to measure, a 10-litre water volume was used, temperature controlled using ice to cool, and a Fluval E 200W Electronic Water heater (Fluval, Germany) to heat.

Experimental procedure:

Resistance values were obtained over three reference temperatures; 10 ˚C, 25 ˚C, and 40 ˚C. Before starting an experiment, temperature adjustments were made to the water volume to achieve the desired reference temperature. To determine a stable temperature had been reached, readings were taken every 5 minutes using the ETI thermometer post adjustment. When two consecutive readings were the same, readings were taken every minute for 5 minutes. When there were no fluctuations, the water volume was ready for use. The ETI thermometer and thermistor being calibrated were submerged at opposite ends to the container to the heater (Figure A2.1), with data loggers initiated and left to stabilise for 1 minute. A note of the timestamp was taken, and 60 second timer was set. During these 60 seconds, the display of the ETI thermometer was video recorded. Once the 60 seconds were complete, a new reference temperature needed to be set, and the procedure repeated.

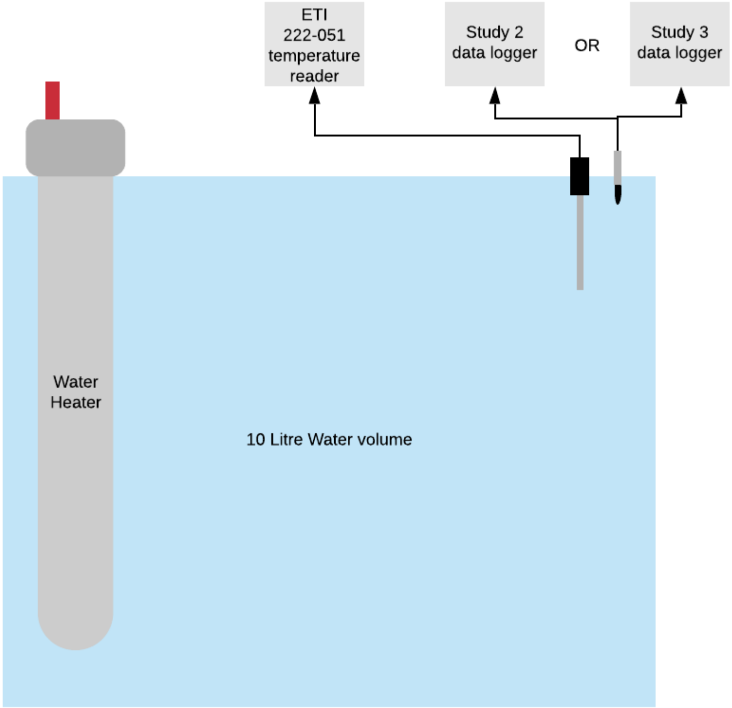

Figure A2.1: A plastic container filled with 10 litres of water was used as a reference water volume. The thermistor being calibrated, and the reference thermometer were placed at opposite ends of the container to the water heater.

Analysis and calibration:

Once reference resistance data at 10, 25, and 40 ˚C was obtained for a thermistor, the resistor data obtained during the 60-second timer window was extracted and averaged. The average temperature recorded during the 60-second timer window was also extracted and averaged. These corresponding pairs of reference resistances at observed reverence temperatures were used to solve simultaneous equations to obtain values for constants A, B, and C. The data logger code was then configured for each thermistor, so that each of the found constants could be used when the data logger calculated temperature using the Steinhart-Hart equation.

APPENDIX 3: STUDY 3 (PRE-INTERVIEW GUIDE)

Interview phase	**Description**
Safety check	Double check that participant doesn't have diabetes Double check that participant hasn’t had skin issue in last 30 days Double check that participant isn’t undergoing any type of medical intervention that could interfere/ be interfered with by study
Info sheet/ consent	Provide info sheet Ask if any question Provide consent sheet (ask if any questions) Ask if happy to participate
Demographics/ amputation details	Age Duration of amputation Circumstances of amputation Type of prosthesis (socket and liner)
Basic background	Average duration of daily use? Typical usage of prosthesis Talk through typical daily routine?
Skin irritation	Have you experienced skin irritation? What/ when/ how long?
Thermal discomfort	Have you experienced thermal discomfort? What/ when/ how long?

APPENDIX 4: STUDY 3 (POST-INTERVIEW GUIDE)

Interview phase	**Description**
Study retrospective	Open ended- how'd you find it? What was good? What was bad? What could have been better? Anything happen during study of note?
Interpretation of thermal discomfort	What does thermal discomfort mean to you? What would a level of 1 mean? What would a level of 2 mean? What would a level of 3 mean? What would a level of 4 mean? What would a level of 5 mean?
Review of PTC data	Free form based on collected data Focus on specific events of interest If participant cannot remember, provide time, data, even snippets of data to job memory Ask what they were doing, what had they been doing Focus on 'world building' around the data