# Friction Between Human Skin and Incontinence Pads in the Presence of Topical Barrier Protection Treatments

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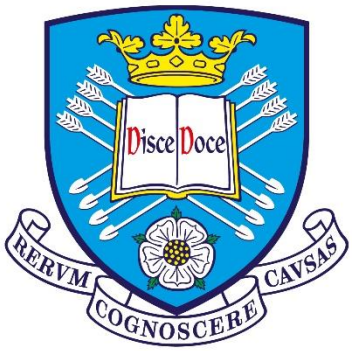


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# Abstract

This research project investigated skin friction in relation to skin damage in the skin-pad interface, which is relevant to those living with incontinence, as well as professionals in the medical community who seek to treat the condition. This is a common and debilitating skin condition, and the tribological behaviours of skin treatments for this condition are not well understood.

An initial experimental study focussed on developing protocols to understand the properties of skin in an untreated and treated state. The results gave insights into skin hydration, roughness, deformation, and friction. This study evidenced the suitability of the protocols for *in vivo* testing, and highlighted relationships between skin moisture and stratum corneum roughness, moisture and friction, and deformation and friction. With the addition of skin treatments, it was found that glycerol and *Vaseline* both considerably increased the friction coefficient, whereas *Cavilon* did not. *Cavilon* also produced a more consistent friction response across all participants. In addition, it identified that *Cavilon*, an advanced formulation developed specifically to protect skin of those with incontinence, performed differently to glycerol and *Vaseline*.

To put the experimental studies into context an online questionnaire was designed to reach a community of people living with incontinence to learn about their experiences of incontinence-associated dermatitis (IAD). Knowledge was gained into various management techniques, including choice of treatments and absorbent products. User-defined data about the skin-pad interface was collected, such as incontinence severity, symptoms of IAD, and bodily locations affected. The dataset helped to establish factors that impacted the severity levels of IAD, which aided in the development of a new question based diagnostic tool to categorise people according to the severity of IAD that they experienced. If made available for public use in the future, it could play a role in the early stages of diagnosis.

The protocol from the first experimental study was adapted to assess tribological interactions in the skin-pad interface, with IAD specific skin treatments and different wetness conditions. In a wet-pad state *Cavilon* reduced friction, and had much lower dynamic and static coefficients of friction than the other barrier treatments (*Sorbaderm Barrier Cream* and the barrier spray). *Cavilon* provided stable friction coefficients in reciprocating sliding, whereas the other treatments, and untreated skin, did not display this unique characteristic. The barrier spray gave rise to high static friction coefficients, and exhibited the most stick-slip. *Cavilon*, *Sorbaderm*, and the barrier spray were all found to reduce directional differences in the static coefficient of friction; indicative of reduced shear loading.

A number of strategies were identified by which skin protection can be realised. Recommendations applicable for use by clinicians and those living with incontinence to form part of a preventative management regime for IAD, with the hope of improving the lives of those living with incontinence.

# Acknowledgements

Thank you to my primary supervisor Professor Matt Carré for introducing me to the subject of skin tribology as part on my MEng dissertation, which from there inspired the beginning of this PhD journey. I am thankful for the support and endless discussions which helped to shape and develop my work. Thank you to my secondary supervisor Professor Roger Lewis who provided valuable feedback on areas of my work throughout the PhD.

I would like to thank Professor Alan Cottenden, the founder of the conference *IMechE: Incontinence the Engineering Challenge*. I attended this conference at the beginning of my PhD and it introduced me to the important and societally relevant area of research being conducted into incontinence and incontinence-associated dermatitis. I was also fortunate at this conference to meet Professor Nicola Waters who supported the development of my questionnaire; offering her expertise and critique during the design phase.

I extend great thanks to the technical support and advice I received from Jamie Booth, who knows how to design and build just about anything, and also brought a lot of laughter to the lab. I also cannot thank enough Professor Elena Rodriguez Falcon who provided me with generous support throughout my undergraduate studies, which led me to strive to fulfil my academic goals. I also am grateful to my mentor Hayley who has given me so much valuable guidance, support, as well as friendship throughout my PhD.

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# Contents

# List of Figures

# List of Tables

# Glossary

*Adhesion component*: Caused by attractive surface forces between the skin and material, which contributes to the skin friction model, where the friction experienced in an interface is due to a combination of adhesion and deformation.

*All-in-ones*: these are often the most absorbent product type for incontinence. They are full-size pants which wrap around the body secured with adhesive side tapes for easy removal. They are recommended to people with severe incontinence and faecal incontinence.

*Baseline properties*: The natural untreated properties of skin.

*Blanchable and non-blanchable skin*: Blanchable skin redness/rashes fade turn white when a person presses on them. Non-blanchable skin remains red and does not fade with application of pressure, which is indicative of bleeding beneath the surface, increasing the risk of developing a pressure ulcer.

*Candidiasis*: A fungal infection caused by a yeast called candida albicans. It tends to develop in moist, warm folds of the skin so it can be a particularly prevalent symptom of incontinence-associated dermatitis.

*Combo product user*: A person who uses more than one type of absorbent product, e.g. an incontinence pad and pull-ups.

*Cutaneous*: The skin, e.g. cutaneous conditions.

*Deformation component*: The deformation component of the friction model arises due to the nonlinear, viscoelastic properties of skin, where the soft tissue is able to deform giving rise to hysteresis and ploughing. The friction model assumes the friction experienced in an interface is due to a combination of adhesion and deformation.

*Deformation*: In this thesis the term *deformation* is used to refer to the measurement of the maximum stretch or extension of the skin under a set negative pressure.

*Denuded skin*: This is the loss of the epidermal tissue, which occurs due to prolonged contact with moisture and friction.

*Double incontinence:* Where an individual has both urinary and faecal incontinence. Sometimes referred to as 'Both' within the figures and text of the thesis, can also be referred to as dual incontinence.

*Emollient*: A product designed to smooth the skin by creating an occlusive film to prevent transepidermal water loss.

*Endogenous*: Originating from inside the body.

*Erosion*: Superficial skin breakdown.

*Erythema*: Reddening of the skin caused by dilation of the blood capillaries, which can result from irritation such as friction.

*Excoriated skin*: This type of tissue damage is a result of linear erosion by mechanical means.

*Fascia*: Fibrous connective tissue surrounding muscles

*Fitzpatrick Scale*: A categorisation tool used to classify people according to skin sensitivity to UV light. It is a widely used tool within dermatology specifically used to identify a person's risk of skin cancer. Within the scope of skin imaging studies like in this research, the Fitzpatrick skin type is important for participant recruitment as higher skin types have a higher content of melanin so cannot provide the level of imaging detail required to successfully analyse the layers of the skin.

*HIG Severity Index*: The HIG Severity index was developed in this thesis to categorise the severity of a persons' incontinence-associated dermatitis according to the frequency and duration of their symptoms, whilst taking into account the symptoms that they experience. Also referred to as a 'diagnostic tool'. (HIG = Human Interaction Group, University of Sheffield Research Group).

*Humectant*: A substance that increases the water content in the stratum corneum due to its water-binding capabilities. Examples of humectants are: Glycerol, aloe vera, urea, hyaluronic acid, and panthenol.

*Hydrophilic*: A material of treatment that attracts water.

*Hydrophobic*: A material or treatment that is water repelling.

*Hysteresis*: A term relevant to the deformation component of friction model, it is related to the viscoelastic recovery of skin after it has been deformed, i.e. the spring back of the skin.

*Incontinence-associated dermatitis*: Skin damage that is associated with exposure to urine and/or faeces.

*Langer's lines*: Skin tension lines which lie across the across the skin and are in a parallel orientation to the collagen fibres. Surgical incisions made parallel to Langer's lines may heal better, therefore they have great significance in the skins mechanical response.

*Macerated* skin: The breakdown of skin which results from prolonged exposure to moisture.

*Moisture-associated skin damage*: This condition arises when the skin has prolonged exposure to moisture, a specific form of which is incontinence-associated dermatitis.

*Moisturisers*: Designed to increase the moisture content of the skin.

*Natural Moisturising Factors*: a combination of substances important to maintaining skin hydration.

*Necrosis*: Necrosis is the death of body tissue. It occurs when too little blood flows to the tissue and appears as darkened tissue.

*Non-woven fabric*: Specially engineered fibrous materials composed of several layers of bonded fibres. Non-woven fabrics are widely used, for example in the following products: diapers, absorbent incontinence products, surgical gowns, and household wipes.

*Occlusive*: An occlusive treatment is one that prevents water loss from the skin and increases hydration by forming a barrier on the skin.

*Pads:* Absorbent pads with adhesive backings to secure to regular underwear. Generally, they are recommended for those with mild to moderate urinary incontinence, though there are pads specifically designed for those with faecal incontinence. There are different shapes and designs of pads available for consumers to purchase.

*Pull-ups*: Disposable absorbent incontinence product which are like pants. They provide a better freedom of movement than all-in-ones due to the elasticated waistband, so are more suited to active people. They are recommended to people with severe incontinence and faecal incontinence.

*Replica*: A material made to replicate one or more of the physical properties, function or behaviour, e.g. the topography of the skin. Other words that are commonly used are skin model, skin phantom, skin equivalent, synthetic skin, skin substitute, and artificial skin.

*Transepidermal water loss*: The water that diffuses up through the skin layers and evaporates from the skin to the external environment. The measure can be an indicator of skin health, and high values can be indicative of a damaged skin barrier. Transepidermal water loss is a natural process that occurs in the skin to regulate its water content.

*Treated skin:* Skin sites that have had topical products applied to them.

*Untreated skin*: Skin which has not had any application of treatments as part of the study.

*Xerosis*: A medical term for dryness of the epidermis; it can appear scaly or flaky, and sometimes accompanied by feelings of tightness, itching, or pain. The risk factors of can be friction, low humidity, and use of soaps, and it is also a symptom of skin conditions such as dermatitis and psoriasis.

# Abbreviations

| | |
|---|---|
| c.u. | Corneometer Units |
| CoF | Coefficient of Friction |
| CoV | Coefficient of Variation |
| D1, D2 | Direction 1, Direction 2 |
| DCoF | Dynamic Coefficient of Friction |
| DEJ | Dermal-epidermal Junction |
| FI | Faecal Incontinence |
| IAD | Incontinence-Associated Dermatitis |
| MASD | Moisture-Associated Skin Damage |
| NMF | Natural Moisturising Factors |
| OCT | Optical Coherence Tomography |
| P1, P2, P3, etc. | Participant Number |
| PU | Pressure Ulcer |
| SC | Stratum Corneum |
| SCoF | Static Coefficient of Friction |
| SD | Standard Deviation |
| TS1, TS2 | Test Session 1, Test Session 2 |
| UI | Urinary Incontinence |

## *Skin site abbreviations*

| | |
|---|---|
| CAV | Cavilon skin site |
| CTR | Control site |
| GLY | Glycerol skin site |
| L1, L2, L3, L4 | Skin site labels |
| VAS | Vaseline skin site |

# Nomenclature

| | |
|---|---|
| $F_{adhesion}$ | Friction that arises due to adhesive junctions forming between the skin and contact material. |
| $F_{deformation}$ | Friction that arises due to deformation of the skin |
| $F_N$ | Normal load, the force applied on the *z*-axis between the skin and the contact material, measured in N. |
| $F_R$ | Friction force, the resistive force that arises in the *x* and *y*-axis due to the motion of skin in contact against a material. |
| $n$ | Number of people. |
| $p$ | Probability of a statistical test. |
| $r$ | Pearson's correlation coefficient or regression coefficient. |
| $R_a$ | The arithmetic mean surface roughness, measured in µm. |
| $R_{rms}$ | Root mean square roughness. |
| $R_z$ | Average maximum height of the profile taken using the highest peaks and lowest valleys within the sampling length. |
| $U_e$ | Elastic deformation of the skin which happens immediately after negative pressure (suction) is applied to the skin. |
| $U_f$ | Maximum extension of the skin under a negative pressure. |
| $U_r$ | Elastic recovery of the skin when the negative pressure is released. |
| $U_v$ | Delayed deformation of the skin under negative pressure that occurs due to its viscoelastic properties. |
| µ | Coefficient of friction, calculated by dividing the friction force by the normal load. |
| $\mu_s$ | Static coefficient of friction, a peak in friction coefficient where movement between the surfaces has been initiated but resistive forces are building and sliding has not yet begun. |
| $\mu_d$ | Dynamic coefficient of friction. The average friction coefficient taken when surfaces are sliding relative to one another, calculated when the friction coefficient is relatively stable. |

# Declaration

I, the author, confirm that the Thesis is my own work. I am aware of the University's Guidance on the Use of Unfair Means (www.sheffield.ac.uk/ssid/unfair-means). This work has not been previously presented for an award at this, or any other, university.

# 1 Introduction

Wherever there is surface contact with skin there is potential for frictional loading to occur. Sometimes friction is helpful, for example, grip on surfaces such as rugby balls, climbing walls, and yoga mats. However, when skin receives unwanted friction then redness, inflammation, blistering, open wounds, and pressure sores can occur. Skin damage can be managed by altering aspects of the tribosystem. In the case of a blister on the heel, this is a multi-layer tribosystem. The elements concerned are the heel, sock, and shoe, along with the presence of sweat. Other tribosystem influencers include the tightness of the shoe, contact pressures across the heel, bone structure, skin thickness, number of cycles of movement, and sliding speed. A similar description can be said of an incontinence pad and skin relationship, however there is the added complication of excess wetness, urine, faeces, altered pH, and the presence of different protective skin treatments. Different body shapes and sizes also complicate the research, as there is not just one surface contact relevant to the formation of incontinence-associated dermatitis (IAD); affected body areas can include the buttocks, groin, and upper thighs.

IAD is a form of moisture-associated dermatitis that develops when the skin has chronic exposure to urine and/or stool. The variability of the surface that comes into contact with the skin also complicates things as there are variety of absorbent products available for consumers to purchase, each with different absorbent capacitates, moisture wicking abilities, and material composition. Based on all of these factors it is very likely that the tribosystem is unique for every individual who experiences IAD, which as a result means that people present with a variety of different symptoms to one another, as well as different severities.

The complexity of the skin and incontinence pad interface creates an incredibly challenging area of tribology investigate. This can be off-putting for researchers to study due to the number of decisions that need to be made in both the protocol design, and development of equipment to create an experimental tribosystem to extract data that represents a complicated real world scenario. This *in vivo* research better captures the complexity of the skin's friction in response to loading, in wet and dry pad conditions, and in the presence of barrier products, than an experimental environment that uses synthetic skin, or tissue samples. *In vivo* measures of this hostile environment are rare, therefore the research

within this thesis could act as roadmap or inspiration for other researchers wanting to explore the area of protecting the skin from incurring IAD.

Skin treatments play an important role in helping to manage and prevent IAD. There are a wide variety of products used to manage the condition, but very little research has been done to compare the frictional performance of treatments, which makes it difficult to understand the potential protective tribological mechanisms and frictional benefits of various treatments. Knowledge of the desirable frictional properties would drive innovation in product development, and benefit companies, clinicians, and users. Some of the treatments are used to provide a protective barrier from moisture and friction, and others function as cleansers, moisturisers, or contain topical medicines like antibiotics, or antifungals. Knowledge is currently lacking surrounding the efficacy of treatments in their ability to reduce friction, and determining the best ways to modify and optimise the skin-pad tribosystem will lead to improved management of skin health, and could assist in the development of new treatments.

There are several influencing factors on the friction behaviour of human skin, resulting in the coefficient of friction (CoF) being dependent on the material properties of the contact surface and the skin, as well as the presence of fluid films in the interface (e.g. sweat or topical treatments), or the natural oils present on skin. There is a general consensus amongst researchers that experimental parameters such as normal force, and sliding velocity have an effect on the CoF. The main mechanism of skin friction is assumed to be adhesion; however, it has become more widely recognised in recent years that deformation also contributes. The area of the body tested also has an effect on the observed friction coefficient, due to the depth and deformability of the skin layers, surface topography, and the presence of subsurface anatomical features, such as bony prominences. Being able to modify the skin-pad interface to the extent of lowering the dynamic and static CoF between the surfaces is assumed to present a scenario where the risk of incurring skin damage is lower. The skin-pad interface presents a hostile environment where skin is in a high moisture environment, making it a prime circumstance for skin to experience high friction forces, and incur tissue breakdown.

## 1.1 Aims and Objectives

This project aims to better understand the friction between the skin and incontinence pads to identify ways in which skin damage can be both managed and prevented. This research was undertaken to gather new insights into tribological relationships that occur in the skin-pad interface under different conditions, and secondly to highlight ways in which friction can be reduced, or friction mechanisms modified through the use of skin treatments. The research is intended to develop suitable experimental protocols to measure skin friction fundamentals, and the tribological differences between skin treatments. In addition, the aim is to build a picture of the topical treatments that perform optimally

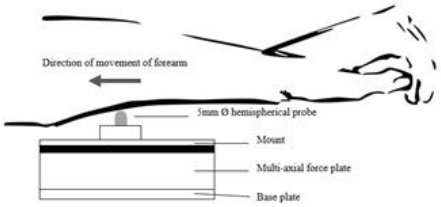
within the skin-pad interface. A further purpose of the research is to put together a series of recommendations which could be used in the future to better inform health practitioners, and those living with IAD, of how to optimise the conditions in the skin-pad interface for the prevention of skin damage.

Objectives:

1. Conduct a comprehensive literature review into the most important topics spanning the research interest, in areas such as skin friction, IAD, and skin treatments used to alleviate IAD.
2. Develop experiments with thorough and reliable methodology and protocols to establish the best techniques to measure skin properties (moisture, roughness, and deformation), and skin friction response over time, with and without skin treatments applied to the skin.
3. Apply the developed protocol to *in-vivo* testing of human participants. Analyse the results of the skin fundamentals study to build an understanding of how skin treatments change the properties and friction between the skin and probe.
4. Integrate a patient-led approach by delivering a quantitative and qualitative IAD questionnaire to bridge the gap between academic research and lived patient/community experience.
5. Adapt previous experimental methodologies to understand friction in the skin-pad interface and investigate the friction responses with different treatments and wetness conditions.
6. Form recommendations which could be applicable for use by continence clinics, hospital care, patients, and the general consumer living with IAD.

## 1.2 Key Project Stages

The three main studies that formed the core of this thesis are outlined below in Figure 1.1.





Study 1: Experiments to study skin friction fundamentals

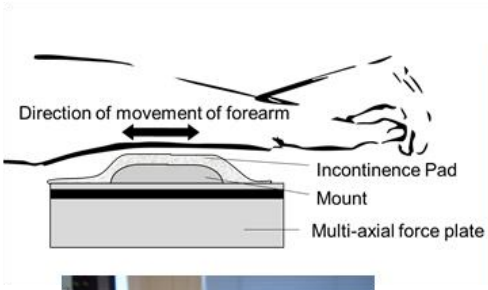
- Experimental design.
- Pilot test were carried out.
- Skin tests were conducted to measure roughness, moisture, deformation, and friction, of untreated skin sites, and those with skin treatments applied.

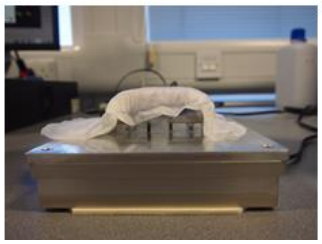
Results were used to explain the relationships between the studied parameters and the robustness of the protocols. Comparisons were made between untreated and treated skin sites to determine whether treatments caused measureable changes to the skin properties and friction.


Study 2: Questionnaire

- Questionnaire design.
- A draft questionnaire was developed.
- The finalised version was made available for participants to complete online.
- Collection of online responses.

Results were used to understand how the severity of IAD was related to other factors such as the sort of absorbent product used, and type of incontinence experienced. They were also used to highlight the numbers of people affected in the community, the symptoms suffered, and the types of absorbent products and skin treatments that people use.



Study 3: Experiments to study skin friction in the skin-pad interface

- The skin fundamentals experimental protocol was modified.
- Skin-pad experiments were carried out.
- The friction was measured in the skin-pad interface when treatments were added, as well as the effects of dry versus wet conditions.

Results were used to highlight the differences that treatments have on the friction in the skin-pad interface in wet and dry conditions.

*Figure 1.1 – A summary of the key project studies that formed the research presented in this thesis.*

## 1.3 Structure of Thesis

Chapter 2 provides a review of the key areas of literature relevant to the research: incontinence, incontinence-associated dermatitis, skin friction, and skin treatments.

Chapter 3 shows the design and development process of an experimental methodology to measure skin properties and friction of untreated skin, and skin containing treatments.

Chapter 4 presents the findings from the skin fundamentals study where five participants were tested, and the results laid out in two sections; the first showing results for untreated skin, and the second results looking at skin sites where treatments had been applied. The change in friction coefficient between untreated and treated states was assessed, along with determining whether relationships existed between roughness-moisture, friction-moisture, deformation-moisture, friction-roughness, friction-deformation, and deformation-friction.

Chapter 5 introduces the questionnaire that was developed to gather information for people living with incontinence and IAD in the community. This chapter highlights some of the key questions that were designed in order to gather information from this group of people.

Chapter 6 presents the results from a community based incontinence questionnaire which was completed online by 117 respondents.

Chapter 7 shows the skin-pad protocol that was revised from the existing protocol from Chapter 3, and presents the results of the study using the protocol. The changes in friction between untreated skin and skin treated with barrier products was investigated, using an incontinence pad as the skin contact surface.

Chapter 8 brings the thesis to a close with the summary of the main outcomes, key findings, future recommendations, and how the research adds to literature.

## 1.4 Dissemination of Research

The dissemination of the different research studies in this thesis are detailed below.

Chapter 4

> 44th Leeds-Lyon Symposium on Tribology, 4-6th September 2017, in Lyon, France. *Tribomotion: Where Performance and Motion Meet Friction.* Abstract entitled 'Topical Treatments and their Effects on Volar Forearm Moisture and Friction.'

IMechE: Incontinence: The Engineering Challenge XI, 28-29th November 2017. Abstract titled: 'Monitoring Skin Health and the Effects of Topical Treatments on Moisture, Structural and Frictional Characteristics'.

Proposed paper: This paper would include the experimental results for the skin fundamentals study, including key correlations observed between skin properties and the friction measures.

Chapter 6

The findings of the questionnaire were presented to the Sheffield City Council Scrutiny Committee who were running a focused session debating the question 'Are the continence services meeting the needs of the people?'. This meeting was held on the 27th January 2020, in the Sheffield Town Hall. A report was developed by the council based on the findings from the meeting. The report was entitled 'Continence Services Scrutiny Working Group Final Report, March 2020.' The full report can be found at the following link, https://sheffieldcc.moderngov.co.uk/documents/s41026/Continence

Incontinence: The Engineering Challenge XIII, 16-17th November 2021, Online. Abstract entitled 'Results of a Questionnaire to Investigate Incontinence and Incontinence-Associated Dermatitis in a Community-Based Population.'

Proposed paper: This paper would include the key findings from the community-based questionnaire, and also introduce the question-based diagnostic tool (The HIG Severity Index) used to categorise incontinence-associated dermatitis severity.

Chapter 7

Incontinence: The Engineering Challenge XII, 13-14th November 2019, in London, UK. Abstract entitled 'Friction Between Human Skin and Incontinence Pads in the Presence of Barrier Protection Products'.

The 2nd World Conference on Advanced Treatments & Technologies in Wound Care, 24-25th October 2019, in Düsseldorf, Germany. Abstract entitled 'Friction Between Human Skin and Incontinence Pads in the Presence of Barrier Protection Products'.

Incontinence: The Engineering Challenge XIII, 16-17th November 2021, Online. Abstract entitled 'Friction Between Human Skin and Incontinence Pads in the Presence of Barrier Protection Products'.

Proposed paper: This paper would include the experimental study results in relation to the tribological differences between barrier protection products in the skin-pad interface, and would detail key recommendations for stakeholders.

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[2] M. J. Adams, B. J. Briscoe, and S. A. Johnson, "Friction and lubrication of human skin," *Tribology Letters*, vol. 26, no. 3, pp. 239-253, Jun, 2007.

# 2 Literature Review

## 2.1 Introduction

The skin is a complex mechanical interface offering advanced protection to the internal systems and organs of the human body from biochemical and physical interference. Mechanical skin trauma is a regular occurrence across the population and it results, for instance, in: heel blistering, incontinence-associated dermatitis (IAD), skin lesions, callus formation, tearing, and pressure ulcers (PU). The clinical application of tribological studies can lead to improved management of injuries associated with hazardous interfaces, as well as leading to the development of better skin treatments to prevent injury and improve healing times. The study of skin tribology is of great importance to the general population because the knowledge gained can help to prevent skin damage, and reduce the severity of injuries and skin irritations such as, moisture-associated skin damage (MASD), PU, blister formation, and skin tears. The formation of denuded skin (skin damage caused by moisture and friction leading to loss of the epidermal tissue) impacts quality of life by restricting social and physical activities, it causes pain and increases the risk of developing PU. However, in certain environments, for instance, when an individual has incontinence, the skin has prolonged contact with urine and is susceptible to damage. Understanding the friction that skin experiences in such situations comes down to building knowledge of the mechanical complexity of the interface, as well as inter-human differences such as body shape, size, activity levels, pad choice, presence of skin treatments, and the severity of incontinence experienced. Ultimately incontinence and IAD should be a societal healthcare priority because the conditions are both costly and time consuming to health services, and with an ageing population the need for improved diagnosis and technological advancement is great.

The study of skin friction has garnered huge amount of interest from researchers over the past decades, starting with a widely cited early piece of research by Highley *et al.* [1], who studied the effects of a water film on the coefficient of friction (CoF) between the skin and a nylon ball. Despite great research effort over the years, the contributing factors to friction of skin are still not well understood, partly due to the complexity of the biomechanics of the skin, and the vast number of surfaces that skin comes into contact with.

Technological innovation in the management of incontinence is needed, but the stigma associated with the condition not only prevents sufferers from seeking help, but also inhibits researchers and industry

from making advances that have been made in other similarly prevalent health conditions [2]. Global ageing is accelerating and the issue of incontinence will become more of a problem in the coming decades; it was reported that Europe in 2017 was the most aged region in the world with 25% of the population over the age of sixty [3]. By 2050 this number is set to increase to 34% of the population. The evidence points towards it being in the interest of society, industry, clinicians, and governments to invest in this area of healthcare.

This literature review covers several areas of importance to provide context for the thesis: a summary of incontinence in the community, mechanisms of IAD, existing skin friction literature specific to the volar forearm, and other experimental techniques used for *in vivo* testing. The scope of the experimental work in Chapter 7 was narrowed to focus on urinary incontinence (UI), partly due to this being the most commonly experienced form of incontinence. This constraint also enabled a greater focus on the tribology involving artificial urine and treatments in the interface rather than adding further interfacial variables and complexities such as artificial faecal matter.

## 2.2 Incontinence in the Community

Incontinence is highly prevalent in the UK, but estimates of the percentage of people affected vary substantially, partly because the condition goes widely under-reported due to the social stigmas associated. It is thought that 14 million adults are affected by incontinence [4], but estimations vary greatly depending on the selection criteria of populations, which makes it very difficult to make comparisons across studies. Results of studies also differ depending on the definitions used, the severity criteria for participation, and the study methods. The following bullet points report statistics from various research studies conducted since 2005. The list highlights that across research there are a wide range of estimates given to indicate the numbers of people living with incontinence.

- There are estimates that 4-7% of under 60 year olds and 4-17% of those over the age of 60 experience daily episodes of incontinence [5].
- One in three women experience UI during their lifetimes [6]
- Rortveit *et al.* [7] reported that 10-20% of nulliparous women under the age of 45 report UI.
- Cooper *et al.* [8] conducted a study of all women over the age of 21 at one medical practice in the UK, out of the 1415 respondents 40% had UI, and 8.5% found it to caused significant problems, but only 17% of those with significant problems had sought medical help.
- A literature review of prevalence of UI across a number of different countries found that most studies reported prevalence within the range of 25-45% [9].
- The most inclusive definitions of UI have resulted in general population prevalence rates of between 5% and 69%, in women of 15 years of age or higher [5].

- The prevalence of UI in nursing homes is far higher than in the community; a systematic review of 16 studies found that residents in nursing home have UI prevalence of between 43% and 77% [10].

The statistics offered above give an indication how embedded incontinence is in all walks of life. Although the numbers vary between studies, they all highlight that there are a large number of people living with this condition and there is no doubt that these figures are far higher than the general population are aware. The lack of people presenting in the community is partly due to embarrassment to seek medical help, not realising help is available, or not believing symptoms are severe enough to warrant seeking medical advice. Nationwide consumer research by the National Association for Continence in the United States found that women on average wait 6.5 years before being diagnosed with symptoms of UI [11].

One of the recent developments in continence care in 2021 is that the NHS is gearing up to roll out new pelvic health clinics to support and prevent incontinence [6]. The service will initially help up to 175,000 women. As well as the one third of women that experience UI after birth, one in ten experience faecal incontinence (FI), and one in twelve suffer pelvic organ prolapse. The initiation of new clinics is much needed, and it is a good sign that awareness is rising. As a result, it is hoped that many women will be helped and lives improved.

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*Definitions*

The International Continence Society (ICS) defines UI as 'the complaint of any involuntary urinary leakage', whilst IAD is defined as skin damage that occurs as a result of exposure to urine and/or faeces.

Other terms for IAD include: nappy dermatitis, nappy rash, irritant dermatitis, moisture lesions, perineal dermatitis, and perineal rash.

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*Topics not covered*

Although important health challenges that require research and innovation within care and management, the topics of faecal incontinence (FI), catheters, and stomas are not covered in this thesis. It is very important to state that these eliminated factors can and do cause IAD. However, these are not in the remit of the thesis, and it is directed to one topic only so that the skin-pad interactions can be investigated to a greater extent. There is a big overlap with treatments used to treat the IAD associated with FI and double incontinence, so the research presented is still relevant to the FI and dual diagnosed population. Catheters and stomas pose a significant risk for developing skin irritations and infections, so tribology study in this area is a very important branch to investigate in further research.

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## 2.3 Incontinence-Associated Dermatitis

In a systematic review by Beeckman *et al.* [12], it was identified that IAD can affect between 5-50% of incontinence sufferers at any one time. Due to studies conducted in various care and community settings there are wide variations in the incidence and prevalence numbers reported. Additionally, amongst the medical profession there sometimes can be confusion in differentiating IAD from PU which can lead to misclassification and under-reporting of IAD. Inevitably incorrect care pathways and skin care regimes are then recommended to patients. Improving diagnostic tools would provide patients with the correct skin management regime, and also the prevention of skin breakdown is proven to be cost effective [13, 14].

### 2.3.1 IAD Symptoms

The observable symptoms of IAD, taken from Beeckman *et al.* [15] include: erythema (redness on light skin tones or purplish on darker skin tones), discolouration which is diffuse or with irregular edges, there may be erosion (superficial skin breakdown), and also candidiasis may be present. Additionally, there may be presence of lesions (vesicles, papules, pustules), and the erythema will be either blanchable or non-blanchable, whereas with PU they tend to be non-blanchable. The physical sensations associated with IAD are pain, burning, itching, and tingling, and examples of the bodily locations affected are the perineum, buttocks, upper thighs, and lower back. Beeckman *et al.* [15] stated the perineal region is particularly susceptible to co-existence of PU and IAD due to over-hydrated skin and seated pressure.

A combination of factors can coexist to cause IAD, which is why incontinence can directly pose a risk to the skin barrier function. Skin becomes more vulnerable as a result of the skin swelling, bacteria, active enzymes, inflammation, erosion of superficial layers, changes to the skin pH, and impaired barrier function. The type of incontinence whether UI, FI or double incontinence puts the skin at different risk of developing IAD, with liquid stool giving the greatest risk and severity. The length of time spent in a wet pad and frequency of voiding both factor in on the skin's susceptibility to breakdown.

Superficial PUs can often be confused with IAD [15, 16], which makes diagnosis and treatment more difficult. Having IAD can also make a person more susceptible to developing PUs; according to Beeckman *et al.* [12] up to five times more likely. Activity levels also impact the likelihood of developing PUs due to changes that occur in the skin barrier function.

Many scales have been developed by researchers and clinicians over the years to categorise and diagnose IAD [17-19]. The Ghent Global IAD Categorisation Tool (GLOBIAD) developed by Van den Bussche *et al.* [20] was released in 2017, and was developed as a worldwide collaboration between international experts and clinicians with the aim of creating 'an internationally agreed description of

IAD severity', and to provide a standard tool for clinicians to work from in practice and research. The tool primarily functions based on visual inspection of the skin areas affected. The inability for clinicians to consistently distinguish between IAD and PUs correctly, led to the development of two tools by Defloor *et al.* [21]. All tools tend to be targeted at more extreme cases of IAD, such as those exhibited in elderly care. Many of the IAD classification tools that exist are difficult to process, are time-consuming and not necessarily something a clinician would end up using in practice for these reasons, a point that aligns with statements made by Clarke-ONeill *et al.* [22]. Generally, the tools all require clinical assessment by a specialist continence nurse and contain graphic imagery, therefore the tools could be considered to be not very patient-friendly.

### 2.3.2 Mechanism of IAD

As previously discussed, the skin-pad environment is hostile, and if there is prolonged contact between the skin, pad, and the wet environment then the defence mechanisms of the skin can weaken and leave the skin susceptible to MASD, of which IAD is the most common variety. According to a recent review by Bader *et al*. [23] 'evidence into the underlying mechanisms causing IAD remains sparse', resulting in a wide range of knowledge gaps for future research. Though in a similar scenario to the skin-pad interface, Schario *et al.* [24] found that sitting on a hard surface with a cotton covering for 45 minutes increased skin temperature, stratum corneum (SC) hydration, erythema, and TEWL. It is likely that these changes also occur within the skin-pad environment due to the presence of moisture and humidity, alongside the skin being in contact with a nonwoven fabric (the pad).

The important anatomical structures that are at risk during an episode of IAD are discussed here. The corneocytes layers are within a lipid matrix, interjoined by protein links which add stability to the SC. The SC regulates water movement in and out of the skin which provides optimum hydration. The proteins, sugars and other components of corneocytes are known as natural moisturising factors (NMF) which play a fundamental role in maintaining hydration in the matrix. Incontinence results in a weakening of this structure leading to impaired barrier function [25], especially due to the irritants, e.g. enzymes present in urine and faeces. This increased enzyme activity especially occurs in those with double incontinence, which puts them at greater risk of developing IAD [15]. Plus, the increased pH causes swelling of SC, and over-hydrated skin is more susceptible to friction and more prone to breakdown. In the more extreme cases IAD loss of blood flow to tissue can lead to necrosis [26]. When the superficial skin layers become damaged, this automatically creates more risk for further abrasion since the protective surface layers are no longer intact. A large study in Germany conducted by Lahmann and Kottner *et al.* [27] analysed secondary hospital data from over 28,000 people and found that friction forces and shear were 'the strongest predictor for category II pressure ulcers', and complete

immobility of patients had strong association with deeper category III/IV PU. With the link between IAD and PU, it may be true that friction is the strongest predictor in this condition too.

## 2.4 Structure and Function of the Skin

The human skin is made up of two primary layers, the epidermis and the dermis, see Figure 2.1. The hypodermis, also referred to as the subcutaneous tissue layer, is not strictly speaking a part of the skin, however the border between the hypodermis and dermis is difficult to distinguish, and it is often included in illustrated diagrams. The hypodermis is a well vascularised layer which contains adipose tissue providing insulation and other protective functions, so it is integral to the biomechanics and physiological function of the integumentary system [28]. The correct functioning of the skin protects the body from potentially harmful microorganisms, and also has an important homeostatic role in regulating the temperature of the body.

A healthy skin surface has an acidic pH of 4–6. The pH of skin plays a fundamental role and assists in regulating the skin microbiome, as well as maintaining the optimal structure and barrier function of the SC [29]. Shifts in the pH levels can alter the bacterial growth on the skin and therefore disturb the integrity. Increased pH increases the swelling of the SC causes the skin to become more permeable and vulnerable to infections [30]. Some studies have shown that inflammation of the skin can increase skin surface pH, the same effects are observable with lab induced trauma (tape stripping) [31]. Topical dermatological treatments often have a slightly acidic pH which alters the biochemistry of the damaging environment, forming part of their protective function.

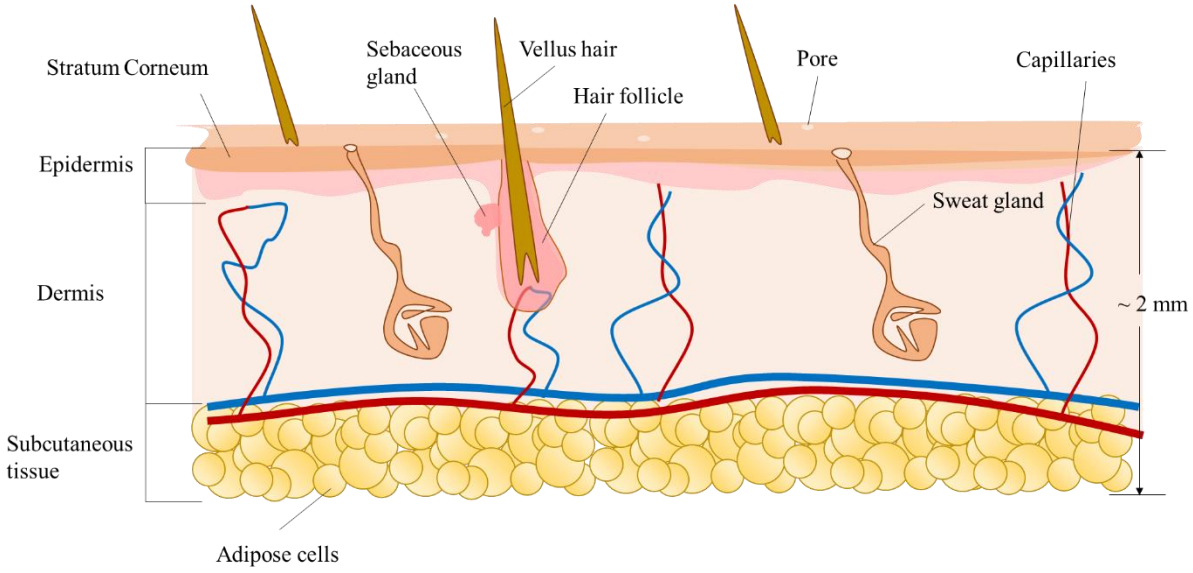



*Figure 2.1 - Layers of the skin*

The epidermis is comprised of five different cell layers on the thicker areas of the skin on the body. The areas of thin skin, for example the volar forearm, have four layers as they do not have an inner SC, most of the areas of skin on the human body can be classified as “thin skin”, exceptions include the palms and the soles of the feet. The SC, shown above in Figure 2.1, is the uppermost layer of the skin, composed of dead flattened skin cells which help to protect the underlying cells from microorganisms and dehydration. The top cells are sloughed off regularly and there is a fast cell turnover of approximately four weeks. The inner SC, see Figure 2.2, is only found in thicker areas of the skin such as the palms and soles of the feet. In the stratum granulosum organelles begin to die which generates the keratin to then form the inner SC and outer SC. The stratum spinosum contains macrophages (white blood cells) which are part of the immune response, this particular type of cell engulfs damaged cells, bacteria and other foreign bodies. The stratum basale is the base layer of the epidermis and this layer is bonded to the dermis by a basement membrane. This layer produces all of the keratinocytes of the epidermis and contains the nerve endings and melanin which gives skin and hair its colour and also protects the cells from UV light.

The cross-sectional structure of the SC and viable epidermis is shown in Figure 2.2. This figure also shows the mechanism of skin hydration which is facilitated by cell membrane water channels called aquaporins, of which aquaporin 3 (AQP3) is present in the skin. This particular aquaporin transports endogenous glycerol upwards to the SC, which pulls water with it, thus playing an important role sustaining in skin hydration [32]. It has been shown that skin xerosis is associated with low levels of endogenous glycerol [33].

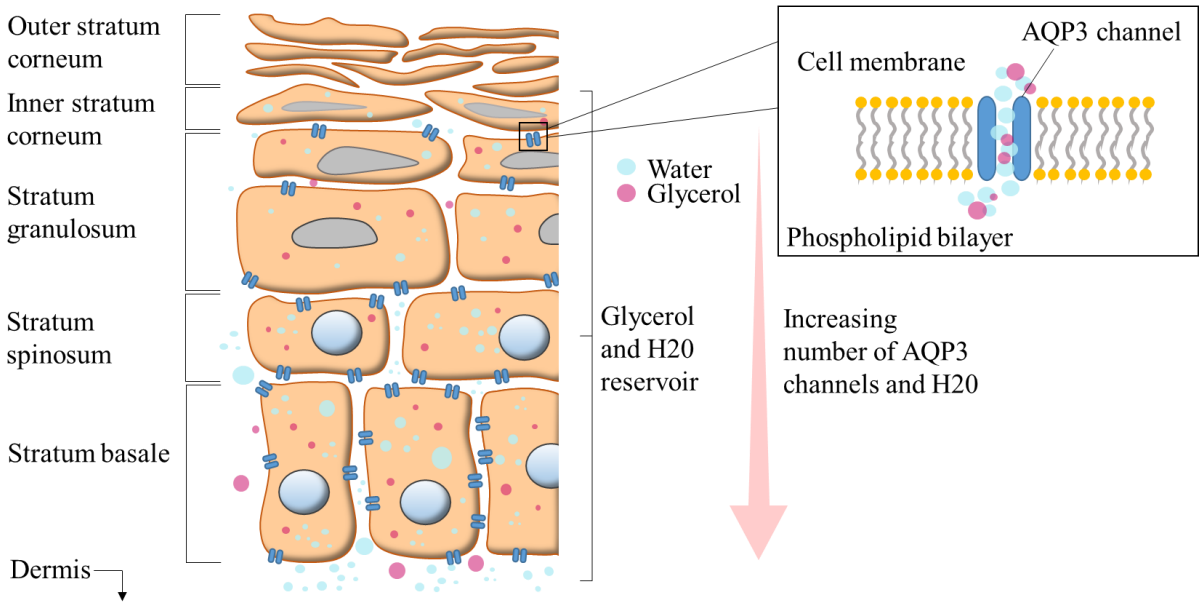



*Figure 2.2 – Cross-sectional structure of the stratum corneum and viable epidermis. Image reproduced from [32]. The glycerol referred to in this figure is endogenous, meaning that its originates from within the body.*

### 2.4.1 Mechanical Properties of Skin

The specific biomechanics of the epidermis and dermis give the skin protection against injury, and an ability to withstand movement, stretching and the external application of force, without losing skin integrity. The elasticity of skin enables the skin to recover when stretched and deformed. Bundles of collagen and elastic fibres are in a matrix when relaxed, but when a force is applied the fibres stretch; an elastic response happens first but this is seconded by a slow viscous response which gives the skin greater capacity for extension [34]. The dermis contains a network of elastic and collagen fibres, giving elasticity and strength. Collagen fibres give the skin tensile strength maintaining structure, and also keeps the skin hydrated by attaching to water. Skin is a viscoelastic material due to the water content, which provides greater deforming capabilities than if it just had elastic properties [35]. The skin contains approximately 20% of the total content of water in the body [36]. Collagen fibres have a tensile strength greater than that of an equal size cross section of steel wire, giving a capability to support over 10,000 times their weight [37]. One of the proven ways to help restore skin and collagen levels is the use of retinoid creams [38-41], which dermatologists and consumers use to their advantage for anti-aging purposes.

In order to obtain realistic results for the mechanical properties of the skin, it is necessary to test *in vivo*, due to the pre-tension that skin is under. A common device used to provide data on the biomechanics of skin is the Cutometer CM570 (Courage & Khazaka), it is preferred over other devices due to its ease of portability and being cost effective [42]. The Cutometer uses suction in order to measure parameters of skin biomechanics, but other researchers have also used methods such as indentation or torsion. Finding a consistent approximate elastic modulus for skin has proven to be a challenge for researchers. The different experimental methods and theoretical assumptions over the years have produced elastic moduli values that are orders of magnitude apart; ranging from 4.4 kPa to 57 MPa [43-46]. The Young's modulus of the SC varies greatly depending on the water content, as greater hydration increases the plasticisation [47], which then increases CoF due to increased real contact area.

Skin displays nonlinear stress strain behaviour, where under high strains a stiffening behaviour inhibits large deformations which would otherwise reduce tissue integrity [48]. The nonhomogeneous and strongly anisotropic behaviour of skin is complex, and these factors can make the use of *ex vivo* and skin simulant testing of limited applicability to capture this interesting aspect of *in vivo* biomechanical testing and tribology. During *in vivo* testing the skin is subject to a naturally arising preloaded stress, which is a very difficult scenario to recreate outside of the living human body. This stress has unequal distribution upon the surface layers of the skin, which in turn causes the skin to behave anisotropically. These areas of increased tension are known as Langer's lines, which lie perpendicular to the long axis of muscles and parallel to collagen fibres [49]. The lines form a pattern all over the body and can vary from person to person but generally have the same orientation.

Skin aging leads to reduced skin elasticity (i.e. how readily the skin springs back into its original shape), with levels for older aged people falling between 10-35% lower than a younger population [50]. This change in mechanical skin properties can result in more lines, folds, wrinkles, as well as skin distortions and higher shear forces. This combination of factors increases the risk of developing IAD, skin irritation, and PU as people grow older. Skin integrity and biomechanics are also affected by chronic conditions, such as dermatitis and psoriasis, which change the thickness and hydration of skin layers [51]. Skin requires different care throughout life due to various changes that occur from natural aging, medical conditions, and anatomical changes. Therefore, the study of barrier treatments is relevant and beneficial to large portions of society.

### 2.4.2 Topology of Skin

Roughness measurements are useful for several purposes within research; for characterising xerotic (excessively dry) skin [52, 53] , investigating skin ageing [54] [55], comparing irritation [56], determining SC roughness across different body locations [57], and also examining the effectiveness of response to treatments in dermatology [58]. There are several methods researchers have used to report measures of skin roughness. Some research techniques have involved skin replicas being made followed by roughness measures being taken using stylus or non-contact optical profilometry, such as optical coherence tomography (OCT) or atomic force microscopy. Others involve *in vivo* optical measurements or testing tissue samples. The parameter $R_a$ is reported in some studies, which is the arithmetic mean roughness; determining deviations from the centre line across the length of study, whereas $R_z$ is the average of the height of the highest 5 peaks plus the depth of the five deepest troughs.

Eberlein-Konig *et al.* [59] took skin replicas using a silicone dental impression material applied to the volar forearm, followed by roughness measures on the silicone samples using a standard stylus profilometer (Hommelwerke GmbH, Villingen-Schwenningen, Germany). The vertical motion of the stylus across the surface was converted into electrical signals. This technique, including the same equipment, was also adopted by Kampf and Ennen *et al.* [60], though they reported different roughness values with Eberlein-Konig *et al.* [59] quoting solely $R_a$, and Kampf and Ennen *et al.* [60] reporting the $R_z$ value. Kampf and Ennen *et al.* [60] admitted that 'the skin imprint technology has some limitations in figuring the finest structures of skin surface'. This methodology cannot completely capture the skin roughness, including the finer details, due to the replica's limited ability to flow into all of the skin surface texture [61], as well as the problem of shrinkage during curing [62]. However, the authors Dhadwal *et al.* [63] concluded that silicone replicas do have a use, as they show a statistically significant correlation to *in vivo* measures that use profilometry. Whether or not replicas will ever develop to have a practical ability to compare the efficacy of different skin treatments is questionable due to the multiple other factors that interlink to produce a humanlike skin response, including increased SC water content,

changed biomechanical properties, and in some cases the ability to adhere to the surface. However, with greater advancement of materials and forming methods then a surface responding more completely to the effects of a treatment could arise, and this would be a useful material to integrate into laboratory investigations. The benefits of advancing research in this area are it would provide a reproducible and more reliable test surface on which to gather data and to allow easier comparisons to be made.

Literature exploring the effects on skin roughness on age, skin hydration, tissue stretching, humidity, and the addition of skin treatments are outlined in Table 2.1. The different study methods are reported, including equipment used, number of subjects, whether acclimatisation was part of the protocol, and the variables that were investigated. All of the studies listed in Table 2.1 investigated the roughness of the volar forearm body region, no other skin from other bodily locations have been included so as to make the table most relevant for the focus of this thesis. As can be seen in the table, the roughness varies greatly depending on the experimental protocol and equipment used, so it is difficult to make comparisons. Part of the difficulty in comparing different studies is the reported measure of roughness, where usually either $R_a$ or $R_z$ is reported.

The impact of skin roughness on *in vivo* friction studies is a relatively unexplored area of study, as many of the studies focus instead on the roughness of the contact surface materials [64-68]. The reason why *in vivo* roughness measures are not quoted or studied is primarily due to the complex nature of the skin which can vary substantially due to age, climate, and other varying participant characteristics such as skin hydration.

*Table 2.1 - Overview of the studies in literature investigating volar forearm roughness*

| Author | Equipment | Subjects | Acclimatisation | Variables | Roughness, µm (mean ± SD) |
|---|---|---|---|---|---|
| [31] | Profilometry of volar forearm replicas | 377 | Not stated | Participants chosen according to skin dryness | $R_a$<br>15.52 (2.22) |
| [69] | Conformal scanning microscope HD100D | 12 | Yes<br>10 minutes | Humidity<br>Four directions analysed separately | No numerical values reported, only graphs |
| [60] | Silicone replica | 25 | Not stated | Adding cream (Roughness and hydration) | $R_z$<br>100.2 (19.7) |
| [70] | Interference fringe projection silicone replica, then scanned profilometry | 50 (aged 20 – 74) | Yes<br>20 minutes | Age | 21.8 (7.1)<br>Range<br>$R_a$ (16.92 – 28.50) |
| [57] | VivoSight, OCT system | 12 | Yes<br>15 minutes | Natural tissue stretching by changing elbow angle | $R_a$<br>Relaxed condition 3.22 (0.49)<br>Extended condition 2.93 (0.78) |
| [71] | OCT | 8 younger age (mean 33.5 years)<br><br>8 older age (mean 76.6 years) | Not stated | Age and body location | $R_z$<br>Young = 38.2 (4.3)<br><br>Old = 46.5 (7.1) |
| [72] | Visioscan VC 98 | 38 | Yes<br>10 minutes | Age | $R_a$<br>Children = 6.1 (1.1)<br>Young adults = 6.7 (0.8)<br>Old adults =10.3 (1.8) |

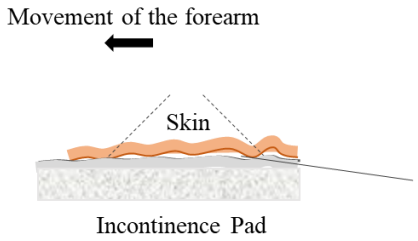
The time required for participants to acclimatise to the conditions of the room before testing is commonly between 10 and 20 minutes. Though in some instances in literature it is unclear whether this step was included within the protocol, see Table 2.1. A standard acclimatisation time for all researchers to adopt would be useful for more reliable tests. Also, most of the studies on the forearm do not consider the angular variations of the elbow and how this might impact skin roughness, but Maiti *et al.* [73] investigated this natural tissue stretching using extended and relaxed positions of the forearm. OCT is a popular method of imaging skin in the study of skin morphology and has been used to study epidermal thickness of the volar forearm, assessing severity of atopic dermatitis [51], and diagnosis of skin cancers [74] .

Not all works provided the numerical values for roughness within their reports which limits comparisons being made. For example, [69] did not report the roughness values in their work however they observed that roughness increased over time with exposure to low humidity (relative humidity 10%). The variations have brought about a need for a more reliable, and controllable protocols with which to test on and make comparisons.

## 2.5 Background of Tribological Behaviour of Human Skin

Skin friction is not a property of human skin itself but is instead a summation of the interaction of properties within tribosystem which takes into account properties of the skin, the contact material and the parameters involved in the contact, as well as mediums used within the interface. The range of experimentally measured friction coefficients, shown previously in Table 2.1, show that skin biomechanics, skin hydration, presence of water films, topical films, and residues all can affect skin friction.

On an atomic level of skin interactions, there is a lot going on that is invisible to the human eye. Within every interface, surfaces of objects fuse to the hands, fingers, and other areas of skin where there is contact. When the connection is discontinued then microscopic from the skin remains on the object, and often this is not perceivable, but can sometimes be experienced as a sticky feeling [75]. Fusing of skin to surfaces (i.e. the adhesive mechanism) occurs because several types of chemical bonding can happen. There is covalent bonding, where the atoms share electrons forming a strong bond, such as is the case with glues. Ionic bonding gives rise to sticky sensations, and hydrogen bonding is weaker, but still can be very strong, and finally, van der Waals forces happen in all bonding scenarios, they arise due to fluctuations in polarisations of particles in close proximity to one another. Van der Waals forces are the weakest of all chemical bonds, but when none of the other bonding types are occurring then they become very important.




Interface:
- Real contact area is smaller than the apparent contact area
- Two soft, viscoelastic, and anisotropic materials
- Two primary friction mechanisms: Adhesion and ploughing
- Wet conditions cause swelling of the pad and the stratum corneum meaning the real contact area increases and adhesion increases

Adhesion and ploughing are caused by microscopic tribological interactions:
- Covalent bonding – atomic sharing of electrons
- Ionic bonding - associated with sticky sensations on skin
- Hydrogen bonding – due to fluctuating polarisation of particles
- Van der Waals forces

*Figure 2.3 - Friction mechanisms in the skin-pad interface*

A historic and widely reported equation describes the friction model being composed of adhesion and deformation terms, as shown in Equation 1.

$$F_R = F_{adhesion} + F_{deformation} \quad [76] \qquad \text{Equation 1}$$

The adhesion component contributes towards the friction due to the breakage of interfacial junctions, whereas the deformation component arises due to interlocking and hysteresis (dissipated energy), that results from the material deformations within the contact [76-78]. A general observation throughout literature is that deformation plays less of a role in skin friction, and adhesion accounts for the main portion. Adams *et al.* [76] proposed that the deformation component is negligible compared with the adhesion component. However, without truly knowing the specific application or the loading variability during different activities then one could postulate that it is difficult to be sure of the true mechanisms at play. As Derler and Gerhardt *et al.* [42] pointed out, 'there are specific cases in which deformation mechanisms become important'.

The two components are exhibited in this equation as non-interacting, however the true applicability of this is yet to be explored. Masen [79] studied friction of the finger pad skin in dry and wet conditions and found that deformation had a significant contribution, and therefore should not be ignored. Hysteresis plays a greater contribution to skin friction than in smooth hard surfaces, and the hysteresis friction contribution depends on the geometry of the asperities and also the height of the ridges, as was found by Tomlinson *et al.* [78] in investigations of the human finger pad. Interlocking occurs when the asperities of the contact materials connect and therefore resist sliding, contributing to an increase in friction. The adhesion component is directly linked to the real contact area, which is the summation of

all the micro-asperity contact areas within the interface. The deformation component arises with the geometry of the contacts as well as the deformations of asperities resisting the relative motion.

Kwiatkowska *et al.* [80] recognised that a surface sliding over the skin gives rise to friction forces which are governed by both adhesion and deformation. During sliding the skin surrounding the contact is deformed and relaxed cyclically. There is a compression in front of the probe forming a "bow-wave", and the tissue becomes stretched behind, see Figure 2.4. Wrapping of the skin around the probe in this manner leads to extra resistance.

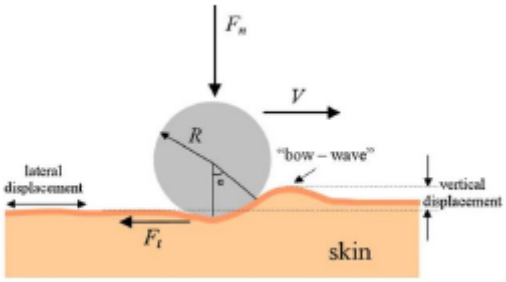



*Figure 2.4 - Sliding of a spherical indenter along human skin, reused from [80]*

The CoF can have two differing values depending on the relative movement of the surfaces; the static CoF (SCoF) is reported on the initiation of sliding of the two surfaces, and the dynamic CoF (DCoF) is reported when the two surfaces are moving relative to one another. Largely the research in this area has been focused on the DCoF in conditions of a constant velocity, leaving room for research to be done in reporting the SCoF. The ratio between the SCoF and the DCoF can be used to report the stick-slip between the surfaces as a measure of 'stickiness', as done by [81]. In fabrics that lie close to skin it is important to ensure that stick-slip is minimised as often this sensation is perceived uncomfortable. Derler and Rotaru [82] found that stick-slip 'decreased as a function of normal load and sliding velocity', and the amplitude of CoF typically varied by ± 25% about the mean during a stick-slip scenario. In situations where stick-slip is absent then variations in CoF are generally less than ± 10%.

Trying to model the skin and its behaviour is a huge challenge due to the complex and ever changing nature of skin. The human skin does not obey linear elastic rules of friction shown in Equation 2, however it is a useful equation to build a basis for understanding the parameters in this investigation. The parameter generally used to describe the friction relationship between two surfaces in dry sliding contact is the coefficient of friction μ which is the ratio of friction force ($F_R$) to the normal force ($F_N$) applied, see Equation 2.

$$F_R = \mu F_N \qquad \text{Equation 2}$$

This equation assumes the CoF remains constant regardless of the applied normal load and is also independent of the apparent contact area of the interface. In early years Amontons' first law of friction stating that 'friction force is proportional to the normal load' was concluded as applicable to human skin by Naylor [83], however since then, the friction laws have been both proven and disproven with regard to skin friction over a variety of contexts and loading conditions. The applicability has been found to depended on the size of the normal load applied, as well as the experimental protocol adopted, bodily location, and presence of topical agents. Despite the viscoelastic and nonlinear properties of the skin meaning the laws of friction do not apply in most cases, the equation remains an important part of biotribological calculations of skin in order to make comparisons between different surfaces, and numerous researchers use Equation 2 in the calculation of CoF. Falloon *et al.* [84] found that Amontons' law was applicable in their experiment which was conducted on 19 women investigating friction between dry volar forearms against nonwoven fabrics (absorbent incontinence products).

Where researchers have found that the friction coefficient does not adhere to Amontons' law then the relationship between the friction and normal force has also been described by Equation 3 [85], where the constant *k* has been found to be approximately 0.3; findings by Koudine *et al.* [86] showed *k* to be -0.28, and Sivamani *et al.* [87] found *k* to be -0.32.

$$F_R = \mu {F_N}^k \qquad \text{Equation 3}$$

## 2.6 Summary of Factors that Impact the Skin Tribosystem

The conditions within each tribological interface of the human skin varies greatly depending on the parameters displayed in Figure 2.5. Both the choice of the experimental protocol, alongside individual participant variations, give an indication as to why the reported CoF values in literature can vary greatly.

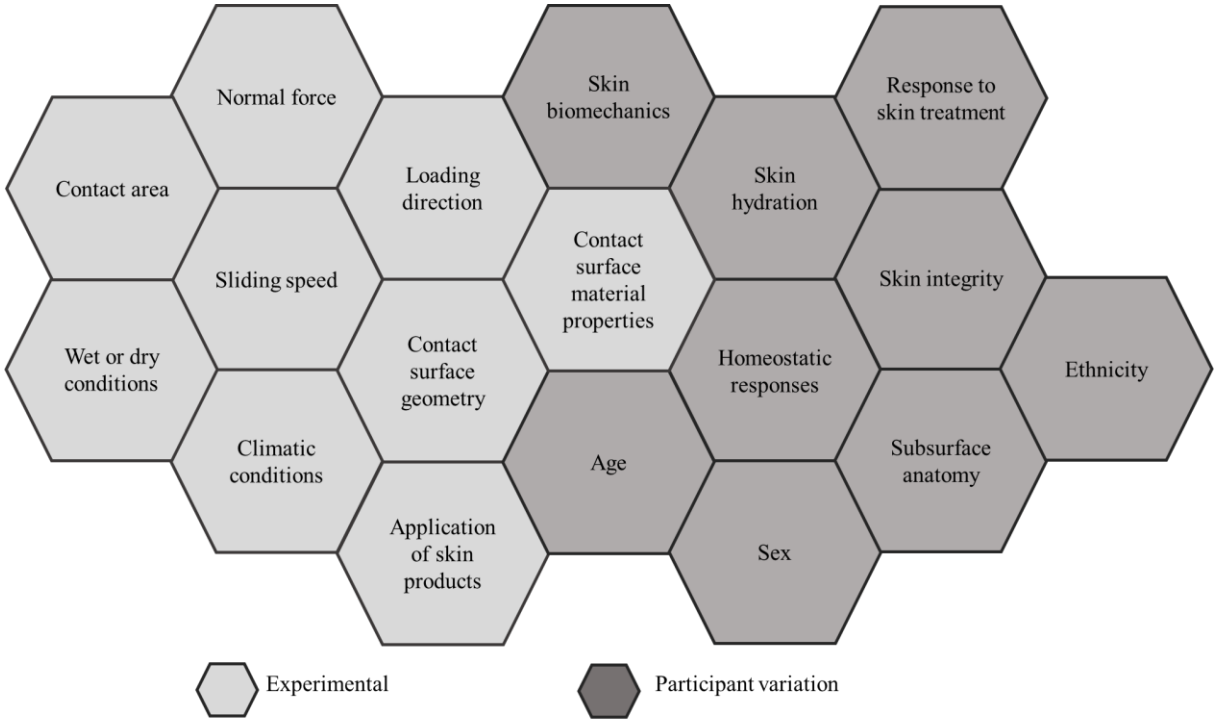



*Figure 2.5 - Different factors and parameters that affect the CoF in the tribological testing of human skin.*

Some of the key factors identified in Figure 2.5 are discussed in greater detail in Sections 2.6.1 to 2.6.5.

### 2.6.1 Age and Skin Health

As we age, healing of wounds becomes impaired and the skin structure changes; the dermal-epidermal junction becomes flatter which increases the susceptibility of the epidermis to injury. When skin damage does occur, the regeneration of cells is slower as it takes longer for formation and migration upwards through the skin layers. As discussed earlier, collagen plays a vital role in the biomechanics of the skin; as ageing happens the collagen formed is denser, which also reduces the skin's integrity [88]. In an experiment by Gerhardt *et al.* [89] the volar forearm skin was compared between young and elderly participants, and skin deformation mechanisms were found to be responsible for difference in CoF of skin against textiles. Elderly skin had reduced elasticity which resulted in greater tissue displacement and greater shear force.

Gitis and Sivamani [81] performed *in vivo* tests on sixty participants, and found the frictional and electrical properties of the untreated volar forearm did not vary much across sexes, age, or ethnicity. They justified the similarity of young and old skin due to the anatomical site being relatively protected from the sun, which therefore reduces skin ageing. With this finding they concluded that the volar

forearm remains an optimal anatomical location for skin product testing. Conversely, [90] reported that younger participants experienced a much higher friction force than those older. Veijgen *et al.* [91] and Falloon *et al.* [84] found age had no distinct effect on friction.

### 2.6.2 Hydration of Skin and Addition of Fluid to the Tribological Interface

Investigating the presence of moisture within a skin tribology study is different depending on the source of the moisture, therefore studies of natural skin hydration and interfacial additives give scope for a wide range of possible tribological systems, which makes the research area complex and engaging. For example, some studies may explore the frictional effects of varying environmental humidity, the presence of water or treatment films, or thick treatment layers.

The friction regimes found within skin tribosystems can be summarised as shown in Figure 2.6; not all elements of the curve may be seen within a system, however the illustration is a useful tool to visualise how hydration and hyper hydration can influence the CoF. Other authors have observed a linear correlation between moisture and skin friction [85, 92].

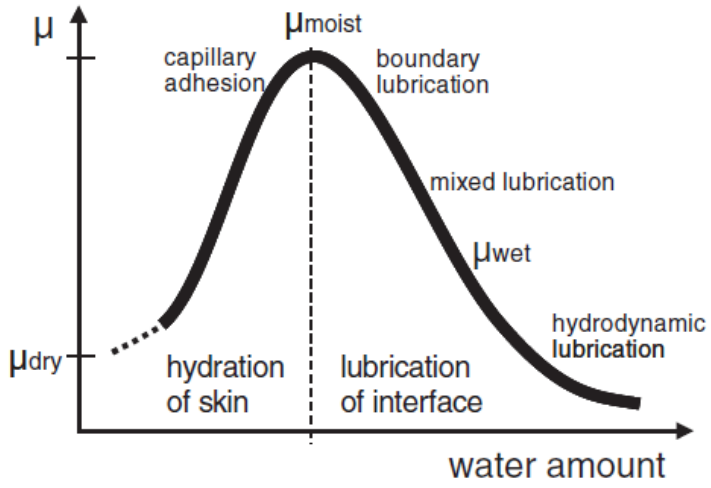



*Figure 2.6 Schematic representation of the bell-curve behaviour of CoF. Skin is never truly dry so the corresponding friction is not known around the dashed area of the curve. Reused from [93].*

With increased natural hydration of the skin, or increased humidity in the local microclimate surrounding the skin, it has become widely accepted that frictional force increases. One study by Gerdhardt *et al.* [94] found that CoF rose by 26-43% when textiles were wet, compared to their dry state. Many researchers have also investigated the effect of skin friction with a film of water applied to the skin. The consensus is that skin friction increases up to a certain point with increased hydration of

the skin [42, 76, 80, 95, 96], then when excess water is added the CoF begins to fall as a thin lubricating layer is formed. Water absorption into the skin is believed to be the major contributor to increased friction due to the softening and swelling of the SC, resulting in an increased real contact area [76, 82, 94]. Masen [79] proposed that with increasing skin hydration the skin softens, and by doing this the increased conformability means that skin can fold around the surface asperities of the contact material, resulting in increased adhesion. So the implication is that the adhesion and deformation components of friction interact with and reinforce one another.

Water films or skin treatment films within the interface could impact the friction mechanism and increase friction due to the formation of liquid bridges; whereby bridges of liquid form between asperities, and then the viscous shear forces cause friction to increase. Additionally, on a similar theme to liquid bridges, a substance accumulating in the interface could pool within grooves and folds of the skin and offer resistance to sliding due to the viscosity of the liquid, also known as viscous shear resistance. Some treatments may act to increase the friction in the skin-pad interface, and others could decrease the friction depending on the quantities applied, their formulations, wear-off rates, along with effects of the addition of urine, and differences in body shapes and subsurface features. Capillary adhesion is thought to be another impacting factor as it brings the two surfaces closer together thereby increasing the contact area [97]. Studies within literature mostly look at the friction interactions between the skin and hard contact surfaces such as steel, however in the context of this thesis the contacting material is an absorbent pad, so the tribosystem inherently behaves differently, but some overlapping features are likely present.

At the highest regions of friction, the moist skin is likely sensitive to pressure variations, and increased pressure is assumed to force water out of the interface, whereas a decrease in pressure can reduce contact between the surfaces and initiate the formation of capillary bridges. Increased skin hydration can result in a higher CoF which in turn can be a critical risk factor in the development of skin injuries such as blisters, MASD and PU. Pasumarty *et al. [98]*, Persson *et al. [97]*, and Tomlinson *et al. [95]* hypothesised that the friction between dry and wet finger contacts increases due to viscous shearing of liquid bridges and capillary adhesion. Whether or not these interactions play a major role in the skin-pad interface is yet to be understood, so future research needs to address the lack of understanding of these complex friction interactions.

### 2.6.3 Environment

Environmental conditions have been found to have an effect on the mechanical properties of human, for example humidity level can affect the stiffness of the SC [80, 99]. In a review paper Derler and Gerhardt [42] recommended in future work that ambient conditions be measured, along with the

roughness of the skin and contacting material. Klassen *et al.* [100] investigated the effects of changing climatic conditions and the results suggested that CoF increased with increasing temperature and relative humidity. This was recognised to be due to increased compliance of the skin at higher temperatures. The effects of the climatic conditions on friction are relevant considerations for conditions within the skin-pad environment, where there is presence of sweat, higher humidity, and the skin may be in contact with wet or damp absorbent products.

### 2.6.4 Hair

The way hair influences the CoF is largely not understood and more research is needed. Bueno *et al.* [101] looked at friction comparisons of different hairy textured fabrics; they found that entangled fibres on polar fleece had similar friction in both sliding directions. Deformation of the fibres occurred before sliding, known as hairiness shear. In unidirectional oriented fibre fabrics like velvet the friction forces were lower in the fibre direction with homogenous friction results, whereas against the grain friction results were higher and anisotropic with a very high friction response initially as fibres were bent backwards. The hairiness of fabrics may have some relevance when applied to the case of human hair as hair shafts are mostly unidirectional, however in some areas of the body hair, e.g. male facial hair, then entanglement of fibres happens. Cottenden *et al.* [102] determined that the reason why one of the test subjects had a lower CoF was due to more presence of hair than the other subjects and 'this hair acted as a lubricant by helping hold the nonwoven [fabric] away from the skin'.

### 2.6.5 Contact Material

The contact area in the tribosystem depends on the geometry and the material properties of both of the contacting materials. If the number of asperities in contact within an interface increases, then the real contact area increases which can increase both friction and CoF. For incontinence pads, the construction, surface finish and material properties can influence the frictional characteristics and comfort. The way skin interacts with fabrics such as pads and hospital textiles critically influences skin health. Numerous authors have channelled their research into better understanding fabrics next to the skin [84, 103-106]. Improvements to friction conditions in the skin-pad interface could be advanced further by using novel manufacturing techniques and by conducting greater research into nonwoven fabrics; a currently somewhat understudied area, but there have been a small number of studies carried out [84, 102, 107, 108]. The fibrous and porous structures of textiles make it a challenging surface to work with, and there is still a great need for further work into the tribological behaviour of skin-fabric interactions. This thesis aims to provide further knowledge of the skin-pad environment using *in vivo* experiments together with a whole incontinence pad (rather than a product that has been cut into samples

pieces), therefore maintaining the structural integrity of the contact surface and giving a more realistic interface.

The surface roughness of the contacting materials is another important element affecting the skin friction experienced. Hendriks and Franklin [64] found that the CoF between the forearm and surface reduced with increasing roughness. In the case of surfaces of greater roughness authors have found CoF to increase with increasing roughness [68]. Geometry of the ridges of asperities has also be observed to contribute to the amount of interlocking that occurs between the surfaces [68]. For low surface roughness, the CoF starts off higher relative to a medium roughness. Then as the probe roughness increases further the CoF climbs to greater levels. For low roughness the friction mechanism is dominated by adhesion and for higher roughness ploughing dominates.

## 2.7 Overview of Volar Forearm Skin Friction Protocols from Literature

This section highlights previous experimental methods in literature that have been used to examine and measure volar forearm friction. The volar forearm is a common site used for dermatological and tribological *in vivo* testing due to the site being easily accessible and relatively sweat-free, easy to hold in any orientation, and has minimal presence of hair. For cosmetic product assessment it has also been found to be an appropriate skin site because 'the volar forearm is representative of the face for measuring skin hydration and biomechanical properties' [109]. Table 2.2 summaries the protocols and findings from several friction studies that have been conducted on the volar forearm. The literature published primarily has differences in the loading contact area, contact material, motion of the probe, the use of different tribometers, interface additives (water or skin treatments), as well as in some instances investigating the effects of age, gender, or body location. Within the table some key elements of experimental protocols have been listed in order to make comparisons between research, giving an indication as to why the CoF varies between different experiments. In places where the protocol element was not mentioned then 'Not stated' is written in the column.

The experimental designs of skin friction studies vary; some involve linear movements across the skin and others a rotating probe, which is deemed to produce less reliable friction coefficients [42]. For protocols involving a linear or rotational method, the horizontal force initiating or sustaining the motion is divided by the normal force to give the DCoF or SCoF (Amontons' law). Relative movements of the contacts can be conducted in two ways; first the probe (or other contacting surface) can move and slide over the skin [110, 111], or second the skin moves and slides over the relevant stationary surface, which is mounted on a load cell to capture the normal load and the lateral force [66, 68]. The experimental method in this thesis looks at the latter type of surface movement; it is more representative of real life observations, and the shape and size of the contact surface determined the appropriate test type.

Table 2.2, highlights some key friction experiments conducted on the volar forearm over the last few decades, and includes the protocols that were adopted to achieve the reported CoF. Studies on the volar forearm are popular, however other body sites have been studied in detail too. Different anatomical locations display different friction coefficients [112], [113], and researchers have attributed this to differing levels of hydration, sebum and roughness. Maiti *et al.* [57] looked at the surface roughness and skin layer thickness at 21 different anatomical sites; they found variations in parameters across the body, which could partly explain the frictional differences observed throughout the table. Table 2.2 reports solely on the volar forearm location, as this is the test site studied in the experiments within this thesis.

*Table 2.2 - Friction coefficients of the volar forearm reported in literature*

| Author | Motion | Subjects | Varied factors | Contact surface | Normal force (N) or normal pressure (kPa) | Sliding velocity (mm $s^{-1}$) or rotation (rev/min) | μ |
|---|---|---|---|---|---|---|---|
| [76] | Reciprocating | 1 | Materials<br>Dry and wet conditions | Hydrophilic glass lens<br>Hydrophobic polypropylene probe (PP) | 2N | 8 mm $s^{-1}$ | Dry glass = 0.226<br>Wet glass = 1.600<br>Dry PP = 0.360<br>Wet PP 2.840 |
| [90] | Linear | 1 | None | Spherical ruby (3 mm) | 0.2N | 0.27 mm $s^{-1}$ | 0.7 |
| [102] | Linear | 5 | Three different nonwoven fabrics<br>Dry and wet skin | Nonwoven fabrics (flat) | Not stated<br>Normal pressure 0.1-8.2 kPa | 2.5 $mms^{-1}$ | Static CoF Skin for all three nonwoven materials fell between:<br>Dry μs = 0.3-0.5<br>Wet μs = 0.9 – 1.3 |
| [114] | Rotational | 29 | None | PFTE 15 mm | 2 | 150 rev/min | 0.26 |
| [84] | Linear | 19 | Disposable absorbent incontinence pads | Nonwoven fabrics:<br>Polyethylene<br>Cotton and Polypropylene<br>Polypropylene | Five normal forces investigated<br>With dead weights of 10, 20, 30, 50, 70g. | 2.7 $mms^{-1}$ for a 50mm sliding distance | Mean across all nonwoven fabrics:<br>μd = 0.402<br>μs = 0.428 |
| [96] | Rotational | 1 | Contact pressure<br>Dry and moist conditions | Stainless steel ring | Load on ring 0.94N – skin surface pressure 15 kPa<br>Load on ring 1.56N – skin surface pressure 24.8 kPa | 2.56 rev/s (equivalent to 96 mm/s) | 0.94 N<br>Dry skin = 0.16<br>Moist skin =1.42<br>1.56 N<br>Dry skin = 0.13<br>Moist skin =1.76 |
| [81] | Linear | 60 | Age groups<br>Young (18-40)<br>Middle (41-59)<br>Old (60+)<br>Treatments | 12 mm copper cylindrical probe | 0.2 | 1 $mms^{-1}$ for a 10mm sliding distance | Occluded skin increased CoF<br>Glycerine and petrolatum increased CoF to a greater extent than occlusion |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| [1] | Rotational | 12 | Dry and wet conditions<br><br>Addition of oil, and surfactant. | Nylon wheel | 0.28 | Not stated | 0.19-0.28 (untreated)<br>No other numerical values stated for other treated states |
| [115] | Reciprocating | 1 | Normal force | Polyethylene plate | 0.1<br>0.7<br>2.0 | Not stated | 0.8<br>0.57<br>0.37 |
| [105] | Linear – hand driven<br><br>Portable | 1 | Hospital fabrics | Four different hospital fabrics | 0 – 3.3 | Not stated | Hospital fabric 0.27<br>Foam dressing 0.36<br>Adult diaper 0.28<br>Bed protector 0.38 |
| [110] | Reciprocating | 1 | Dry and wet conditions | Steel ball 4 mm | 0.03 | 0.5 mm $s^{-1}$ | Dry 0.73<br>Moist 1.26 |
| [116] | Linear – hand driven<br><br>Portable | 19 | Fabrics<br><br>Sex | Different fabrics | Uncontrolled because it was a portable probe, and normal force varied between 0 – 0.7 | 35 $mms^{-1}$ for a 40mm sliding distance | Females<br>Wool 0.75<br>Polyamide 0.55<br>Polyester 0.65<br>Silk 0.48<br>Cotton 0.52 |
| [117] | Reciprocating | Not stated | Velocity<br><br>Dry and wet conditions | Polypropylene 10 mm hemisphere | Not fixed but monitored (1.05 – 9.48 N) | 0.03-0.1 mm $s^{-1}$ | 0.22 (sweat)<br><br>0.45 (no sweat) |
| [111] | Linear | 59 | Skin treatments<br><br>Sex<br><br>Ethnicity<br><br>Age | Copper 13mm cylindrical probe | 20g | 0.4 $mms^{-1}$ 10mm for a sliding distance | Untreated skin 0.45<br><br>For treatments only the percentage increase from untreated skin was reported, not the values. |
| [92] | Rotational Portable device | 1 | Normal force | Stainless steel cylinder (Ra = 0.57) | 0.5<br>1<br>2 | 10 $mms^{-1}$ | 1.78<br>0.80<br>0.53 |

The differences in CoF for different tribological skin-surface pairings are shown in Table 2.2, and these output values can be seen to vary, but most of the CoF values were found to be < 1. The reported DCoFs in the table range from 0.13 to 2.84, and some studies report SCoF values rather than DCoF. Most studies looked at alternating one or several factors, such as moisture, probe material, normal force, and speed. Experiments also differed in the chosen motion (linear, reciprocating, or rotational), the number of cycles, and the duration of testing.

The friction between skin and nonwoven fabrics (e.g. incontinence pads) has been investigated by Cottenden *et al.*, Falloon *et al.*, and Luís *et al.* [84, 102, 105], however the number of studies in this area of biotribology are few. Interestingly, Cottenden *et al.* [102] only reported results of the SCoF, with the justification that the SCoF is higher in order to initiate movement, so it is the priority to measure as it generates the maximum shear forces between the skin and incontinence pads. However, it could be argued that the DCoF is the most important as it has a longer duration, such as in the case of cyclical loading in walking or running. Both values are of interest in the skin-pad interface therefore the research in this thesis looks towards investigating both the DCoF and SCoF in wet/dry, and treated/untreated states.

Some research has found that sliding speed has an effect on the CoF; Tang *et al.* [118] found that as sliding speed increased from 0.5 $mms^{-1}$ to 4 $mms^{-1}$ between the volar forearm and a polypropylene ball the friction coefficient increased due to a greater occurrence of stick-slip behaviour. Ramírez *et al.* [117] found the velocity of the probe not to have a significant effect on the CoF in a skin-polypropylene interface, across the lower sliding speeds of 30 $\mu m^{-1}$ to 100 $\mu m^{-1}$. Since the viscoelastic properties of the skin vary depending on the individual being tested, then the dependency of the friction coefficient on sliding speed or force would be different for any given individual. Therefore, the complex nature of the interactions of the skin with soft contact surfaces makes it a challenge to link these skin properties and system properties.

Asserin *et al.* [90] found that friction force was proportional to normal load giving a constant CoF value of 0.7 and also found that Amontons' law applied within the range of 0-0.3 N (very low loads), but they stated that studies with more participants are needed; their study consisted of three participants. They also observed that SCoF increased with normal load, which they explained being due to the 'increase of the contact area between the spherical indenter and the skin surface, which increased the adhesive force'. Despite a lot of research being carried out into the effect of normal force on the CoF and whether Amontons' friction laws hold true, there is no conclusive evidence to give an absolute answer due to the vast contexts that are being studied. The range of experimental protocols indicated in Table 2.2 show there is a need for a robust protocol to be adopted by which multiple researchers can make direct comparisons to further enrich the field.

Many studies over the years have involved using differing materials in the form of solid balls or hemispheres. In experiments where the tribological investigations involved use of an incontinence pad as the contact surface, none maintain the full structural integrity of the pad. In preparation for testing they were cut into sample size pieces, for example in the works of Fallon *et al.* [84] undisclosed sized strips were used, and Salehi *et al.* [119] used samples of 50 mm diameter. In order maintain the absorbent core, structural integrity, and absorbent capacity, there is a need for tests involving a full size pad against the volar forearm. The experimental work conducted in this thesis aims to address this gap by using entirely intact incontinence pads in wet and dry states.

In order to get around the unpredictable nature of skin in conducting research, skin simulants have been an area of development for several decades. A multitude of researchers have attempted to develop synthetic materials for tribological tests, which simulate the mechanical behaviour of human skin [96, 110, 120]. Egawa *et al.* [121] observed their volar forearm silicone surrogates that skin friction and surface roughness were not correlated. The extent to which the materials are successful depends upon the parameter in question. Some skin models are able to successfully mimic certain elastic and indentation behaviours, like the one developed by Nachman and Franklin [110], where the artificial skin had an elastic modulus within the range expected of the human dermis. Production of realistic synthetic simulants is a powerful means of future tribological testing as it can enable a wide number of contact surfaces or skin treatment friction modifiers to be investigated under repeatable conditions. The ability to absolutely replicate human skin currently a long way off being solved and more research needs to be done.

## 2.8 Topical Skin Treatments

Determining the response of the skin to topical treatments is a well-studied area of both academic and industrial research within the skincare and cosmetics markets. The skincare market in Great Britain in 2019 was worth 2.16 billion Pound Sterling (£) [122], and is projected to grow rapidly over the coming decade. Wound care specialists need to understand which creams work best, and the NHS requires value and performance from treatments that are prescribed as part of wound care and condition management. The research covered in this thesis looks in depth at some commonly used skin treatments and offers insights into the frictional performance of products as well as establishing recommendations for protecting the skin from developing IAD. A key factor in treating this condition is understanding that IAD is preventable, and therefore by implementing the relatively inexpensive use of barrier treatments, and the right choice of absorbent products, then skin breakdown could be avoided.

Some examples of categories of products used in the prevention and treatment of IAD are shown in Table 2.3, along with some of their protective features.

*Table 2.3 – Examples of skin products used in the managements of IAD*

| Skin products | Features and protective mechanisms | Product examples |
|---|---|---|
| Barrier Cream | - Moisturiser<br>- Protects against bodily fluids<br>- Does not need to be applied often as they tend to resist wash-off | *Cavilon Barrier Cream*<br><br>*Sorbarderm Barrier Cream* |
| Barrier Spray | - Barrier against bodily fluids<br>- Treat broken, tender or irritated skin as they can be applied easily in a non-contact way to damaged skin.<br>- Fast drying<br>- Protect against friction | *Cavilon Barrier Spray*<br><br>*Sorbaderm Barrier Spray* |
| Medicating Cream | - Antifungal | *Clotrimazole* |
| Cleansing Lotion | - A gentle way to cleanse skin<br>- Reduced friction<br>- Leaves a protective layer on the skin | *Abena Washing Lotion* |
| Cleansing Wipes | - A gentle way to cleanse skin<br>- Removes the need to wash skin with water<br>- Reduced friction | *Contiplan wipes* |
| Protective or active ingredients which can be present within IAD products | - Dimethicone – a silicone water repellent barrier with moisturising capabilities. Additionally, dimethicone based treatments tend to be breathable<br><br>- Zinc Oxide – a natural antiseptic with antibacterial properties | *Cavilon Barrier Cream*<br><br>*LBF Barrier Cream* |

In Table 2.3 cleansing lotions and cleansing wipes are listed as part of the range of products used to help prevent and treat IAD, though they are not included in the experimental research within this thesis. It is widely accepted that no-rinse foaming cleansers and also wipes are a better cleansing regime than soap and water. The reason why products that promote gentle cleansing are important is because the traditional methods of washing with soap, water, and wash cloths can result in weakened skin. This happens because they disrupt the skin pH (becoming more alkaline), and disturb the microbiome leading to reduced skin integrity [123].

Advances in the development of barrier products have arisen from integrating polymer science research into treatment formulations. Some dry to leave a polymer layer, which is transparent and water repellent for 2-3 days; this has proven to be successful in managing skin damage as well as being cost-effective [124, 125]. Products such as *Cavilon* make use of this thin semi-permeable silicone-based polymer coating, which when applied to the skin offers advanced protection from extended periods of moisture exposure, compared to other conventional products [126]. With the development of these synthetic barrier products, greater skin management has been achieved.

Some treatments prevent water loss from the skin, others penetrate into the skin and release hydrating factors, and some are developed to improve interaction performance with the external environment, such as enhanced grip, or ability to assist in wound management. Barrier creams can be described as products that place a physical barrier between the skin and a harmful environment, and/or as a product to restore damaged skin. The use of protective barrier products is an important factor in managing IAD, however there can be some drawbacks; some products may affect the absorbency of pads by blocking pores and preventing fluids being locked away, resulting in leakage which increases the likelihood of MASD and IAD [127]. Knowledge of barrier products for treating IAD and MASD have significantly improved over the last few decades; traditionally creams were to be applied in thick layers, which then resulted in increased humidity and reduced the absorbency of incontinence pads. Advice has now changed and people are recommended to only apply thin layers.

A study by [128] found that changing an ointment to a barrier film, used once daily or three times per week, could save nursing homes approximately 47% to 78% in product costs and a further 56% to 81% in labour costs. An NHS supply chain report [129] went about a process to restructure the supply chain of provision of pads in Portsmouth Hospitals NHS Trust with the aim of giving people increased comfort, quality, and reducing MASD and IAD, with a standardisation of resources provided to patients. At the same time the goal was to achieve a cost saving of £100,000. The result of the changes was that a reduction in the product range from 27 lines to 4 lines achieving a cost saving of £125,000. The optimism within the report of the benefits of implementing the change seem overzealous, with touted positive outcomes that standardising the practice will ensure 'all patients received the right products for their needs', 'staff go straight for the right product every time', and there will be a 'reduction in stocked products, freeing up storage space and time'. The reported cost and time savings are believable; however, the long term implications of limiting resources could be considered a risk for reducing condition management due to the service being unable to distribute the most appropriate products to people in their care. The services within the UK vary widely, some trusts have dedicated continence services whilst others only provide the care as a side to other conditions. Reporting of IAD is not mandatory in the UK and therefore it leads to a lack of understanding the figures, likely resulting in a lack of prioritisation.

## 2.9 Protective Mechanism of Skin Treatments

The key purpose of skin treatments are generally one or a combination of the following points, they: act in conjunction with the keratin layer to restore moisture content, restore the packing of the lipid lamellae, improve cell turnover, repair barrier function, protect skin against the infiltration of bodily fluids, alter friction mechanisms, and improve tactile perception of skin [130]. For IAD, desirable functions of a treatment are to protect the skin from moisture overload and to act as a friction modifier

to lower the CoF and also reduce shear. The chemical structure of a substance is not always indicative of how hydrating it will be to the skin, for example glycerol, a common constituent ingredient of skin treatments and barrier products, was found to be more hydrating than diglycerol and triglycerol despite it having the lowest humectant ability [131]. With the link between moisture and CoF being strong, it could lead to conclusions that a barrier product with minimal moisturising capability would best protect skin.

The type of treatment selected influences the type of lubrication regime that takes place. When skin is wet and interfacial water film thickness increases, the adhesion element becomes less dominant and even can be replaced by a hydrodynamic regime, resulting in a lower CoF. The asperities are immersed and this minimises the contact between the two surfaces (boundary lubrication) [76, 132].

In an experiment looking at reducing Covid-19 PPE-related skin injuries Masen *et al.* [133] reported on the effects of numerous types of topical skin treatments including creams, waxes, powders, and thin films. They found that creams resulted in low friction due to reduced interfacial shear strength. Many of the creams tended to cause the SCoF to increase when left on the skin. The wax treatments offered long-term low friction, such as coconut oil and beeswax. Optimal oils/waxes were found to be those with a melting temperature less than that of human skin (30°C). Powders overall did not display any standard behaviour, however talcum powder was shown to be an enabler of low friction, which hypothesised by Deacon and Goodman [134] was due to the layered structure giving lubricant-like properties. Spray films were found to not protect skin from shear forces, with most giving a tacky feel, resulting in a high friction system. Limitations of the work were that experiments were only carried out on one individual, however due to the wide variety of treatments tested and under the circumstances of the pandemic this was a logical protocol.

When glycerol, a common constituent ingredient of barrier products, is applied topically it diffuses into the SC [135], and it creates a reservoir throughout the entire depth of the SC, [136, 137]. The glycerol also causes intercellular expansion whereby the corneocytes expand and so does the intercellular space. This process is often referred to as ‘bulking’ which increases ability for the SC to store water. When glycerol undiluted is applied to the skin it has the opposite effect, resulting in dehydration of the SC due to osmotic extraction from the SC, as glycerol can uptake three times its weight in water [138]. Glycerol is able to travel through the AQP3 channels and forms a reservoir within the upper epidermal layers which maintains the hydration, increases lipid metabolism and aids barrier repair. [138].

Tang and Bhushan [139] studied the effects of petrolatum film thickness, velocity, humidity and normal load on the CoF using atomic force microscopy. For the experiment they used 10 mm samples of rat tissue. They found that as the probe slides there was an increase in the friction due to hydrodynamic drag. As velocity increased up to 1000 μm/s, CoF and adhesion decreased for untreated skin and treated skin. At higher velocities, greater than 1000 μm/s, CoF and adhesive forces decreased with cream but

increased when untreated. The untreated skin at higher velocity had a different friction mechanism whereby deformation of the asperities occurred. Instead with *Vaseline* treated skin the mechanism is thought to be dominated by viscous shear.

Figure 2.7 gives an indication of the ways in which a lubricant in the interface protects the epidermis and subsurface layers of the skin from damage. In an untreated condition (A) it can be seen that pressure and shear concentrations develop ahead of the probe.

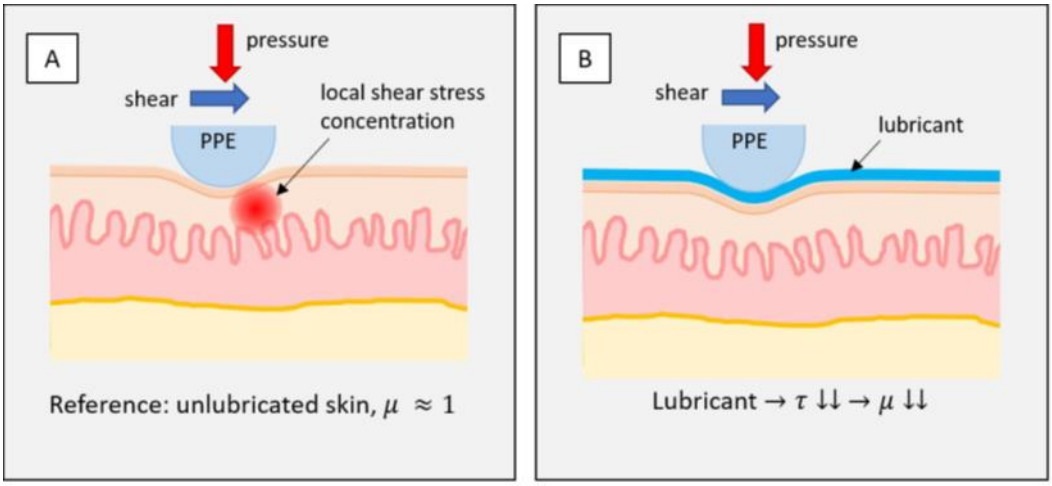



*Figure 2.7 – Image reused from [133] showing the mechanisms of friction in the A) unlubricated and B) lubricated skin.*

Overall, the use of CoF as an indicator of skin damage risk has been identified, and if the CoF is minimised then this reduces skin adherence to external surfaces, and ultimately reduces skin damage [140]. Study of friction and shear forces is important because the associated tissue deformations can strain the skin, and can inhibit blood circulation by cutting off supplies to blood vessels [141]. Eventually this can starve the skin of vital oxygen, and in extreme cases this can result in tissue necrosis, therefore it is of great priority to minimise the presence and the duration of these types of forces on the skin.

## 2.10 Incontinence Pad Structure and Function

The surface material is composed of a blend of fibres: polypropylene, polyethylene, polyester and viscose, which is designed to keep skin dry by quickly absorbing the liquid. Beneath this is an acquisition layer of polyester fibre which transport liquid from the surface to the core of the product for storage. The absorbent core of the product is composed of a combination of paper pulp and superabsorbent materials which can absorb many times their weight in water [142].

## 2.11 Summary

This chapter presents a review of the current of topics relevant to this thesis including: incontinence, incontinence-associated dermatitis, the structure and function of skin, skin friction, and skin treatments. Much work has been done within the area of skin friction to investigate the mechanisms which contribute to friction, but the application to skin damage, especially in the skin-pad interface, is limited. Skin health is of importance to the community of people living with incontinence and medical professionals, and this is reflected by the wide number of people living with incontinence, as well as the high estimations of the numbers of people who have IAD.

In tribology there are limited studies into the complex interface of skin-pad interactions, partly due to the unpredictable nature of these surfaces, and a lack engineers applied to working within this field. One way to solve this would be to bridge the gap between engineers and patients, therefore providing a patient-led approach to garner interest, application, and meaning to research. Studies in the area of incontinence-associated dermatitis typically involve clinical studies, or surveys to develop estimates of the percentage of people affected, particularly of those living in care-settings. There is a lack of focus into the wider-community of active individuals who have not reached out for help, who self-manage incontinence and their skin health.

The lack of benchmark protocols makes it difficult to make comparisons across studies due to varying factors such as contact material, body test site, interfacial additives, experimental parameters, and the inherent inter-participant differences in skin properties. It was highlighted that studies were not easy to compare partly due to the incomplete reporting of findings; some authors neglected to include the friction coefficient values, but instead showed solely graphs of their data. Therefore, improvements are needed on the reporting of skin friction data. Skin friction research usually just presents the DCoF and neglects to investigate the SCoF; a surprising finding considering that it is during the static state where the greatest shear occurs.

In this ever increasingly virtual world there is a need for an assessment tool that individuals can use at home, which is simple to conduct and easy to understand. This would enable clinical cost savings, enable patients to seek help in the comfort of their own home, and point them towards relevant services, resources, or treatments based on their assessed IAD severity and/or risk. This thesis presents a tool which could fill this gap, though it requires clinical evaluation to determine its effectiveness and relevance to healthcare.

Overall the gaps in the literature that the author aims to address are to:

- build an understanding of treatments used for IAD, and discover how they behave in a tribological context under set conditions.

- use the relevant contact surface of an absorbent pad in a complete state, rather than it being cut into strips which affects its structural integrity.
- develop a skin testing protocol of consistency which could be rolled out for future use within the department, or a wider research community.
- explore other aspects of skin properties and their relationships with skin friction.
- go beyond the lab to bridge the gap between research and the wider community, and therefore adopt a patient-led approach to the study.
- Investigate further the development of a patient-friendly IAD severity tool.
- Solve a problem which a user of pads may have, and be able to provide some user-friendly advice.

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# Design of *In Vivo* Experiments to Measure Relationships between Skin Moisture, Roughness, Deformation and the Coefficient of Friction.

# 3

## 3.1 Introduction

This chapter describes the protocol design and development process for the experiments that were conducted to measure relationships between skin properties and friction, and the effects of topical treatments. The experimental results are later presented in Chapter 4. Establishing reliable *in vivo* protocols early on in the research project was a key foundation for future experimental work involving the skin and incontinence pads. The design of an experiment protocol presents multiple possible directions which could be taken, and there will always be advantages and disadvantages to each constructed methodology. The finalised protocol was a series of several smaller protocols, including the chosen skin-treatment application process, individual device protocols, the order of equipment testing, and determining the analytical approach to each category of data.

Measuring skin *in vivo* is the best way to understand real-world skin interactions and properties. Skin substitutes, whether synthetic or animal tissue, do not exhibit the exact characteristics of human skin, though individual properties can be simulated. Many researchers have devised and/or have used advanced materials and methods to simulate certain properties of the skin, such as Young's modulus, tear strength and tensile strength [1] [2], friction [3] [4], [5], layer thickness, roughness [6], and impact response [7]. However, the existence of a material to cover the full complex behaviour of skin would be a huge leap in scientific understanding and manufacturing capability. Human skin behaves differently person-to-person and this presents a number of protocol related challenges due to a range of factors, including the natural variability of the skin e.g. differences in sweat levels, hydration, and transepidermal water loss (TEWL).

## 3.2 Aims and Objectives

The experimental aims were to build a greater understanding of the behaviour of the skin in response to the application of topical skin treatments, and to establish rigorous *in vivo* protocols.

Objectives:

Design the experiment framework, such as deciding the friction parameters (normal force, sliding speed, contact surface shape, size, and material), device settings, types of topical treatments to investigate, and the participant logistics.

1. Develop protocols for treatment application, skin testing, and the analytical approach for datasets.
2. Measure the effects of topical skin treatments on hydration, deformation, friction, and stratum corneum (SC) roughness.
3. Conduct skin tests without treatment to determine the baseline characteristics of each participants' skin, with which to contrast later treatment effects.
4. Investigate how the treatments *Cavilon*, *Vaseline*, and a 10% glycerol solution affect the skin after a short time window of 4-hours post-application.
5. Assess the effectiveness of the protocols to determine the capability to distinguish the differences between different treatments.
6. Use the experimental findings to determine whether the protocols show potential for use in the rest of the PhD based on their ability to establish differences between the treatments and their effects on the skin properties and tribosystem.

## 3.3 Experiment Summary

This pilot study was used to establish protocols and involved a set of non-invasive tests with five participants, completed over a period of three weeks. A sample size of four or more is sufficient to carry out a statistical analysis using t-tests, therefore recruiting five participants were deemed suitable for the study. Initially six subjects were recruited but one had to drop out due to errors in the treatment application procedure. Three different skin treatments, *Vaseline*, *Cavilon* and 10% glycerol solution, were applied to test sites on the left (non-dominant) volar forearm of each individual and compared against a control site. The volar forearm was used as the test site; it is one of the most common body sites to conduct dermatological testing in clinical research and is an area relatively unaffected by extrinsic ageing because volar regions of forearms are typically not exposed to UV light [8]. The volar forearm is easily accessible and has just a thin layer of vellus hairs which makes it a desirable location for friction tests as the presence of hair of varying thickness and density amongst participants could add

an additional layer of complexity when investigating the effects of treatments on the skin. Many other areas of the body have a combination of vellus hair and much thicker terminal hairs.

## 3.4 Equipment

The equipment presented in Figure 3.1 was utilised to to characterise skin properties: roughness, moisture, and skin deformation. Each device is discussed in further detail throughout this section. Use of a standard kit in this research, such as the MPA 580 (Courage-Khazaka, Cologne, Germany), will enable contextualisation and comparison with other skin data studies available in literature. The friction rig setup is shown in Figure 3.2.

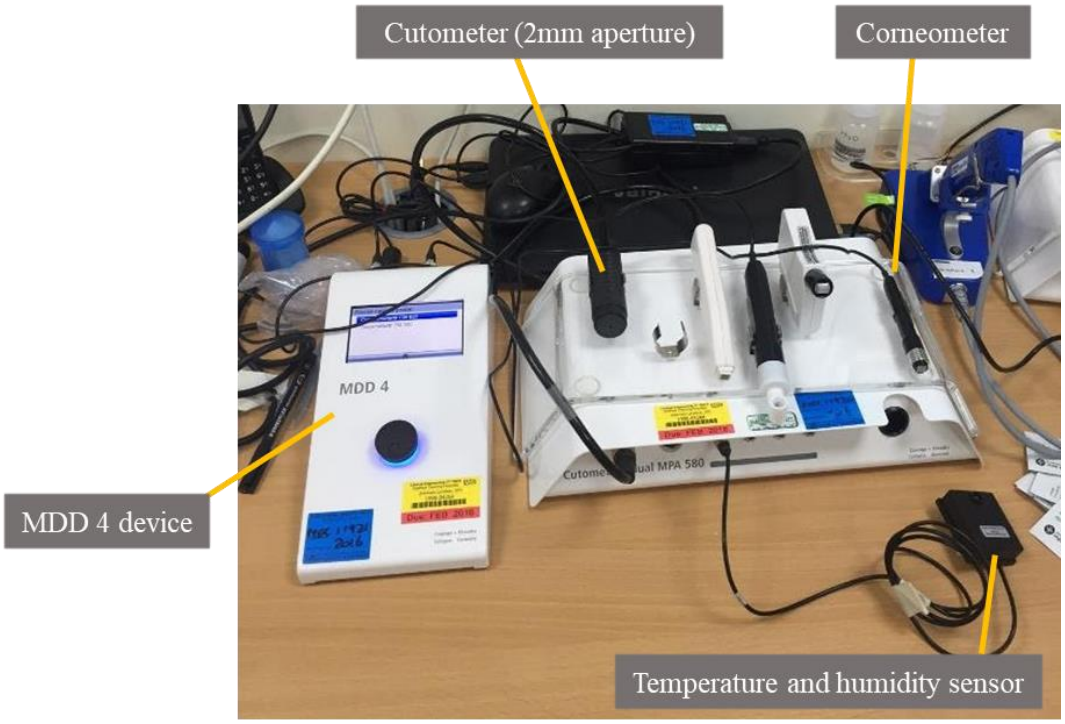


*Figure 3.1 - Equipment and setup of the MPA 580 kit used to provide skin characterisation measurements.*

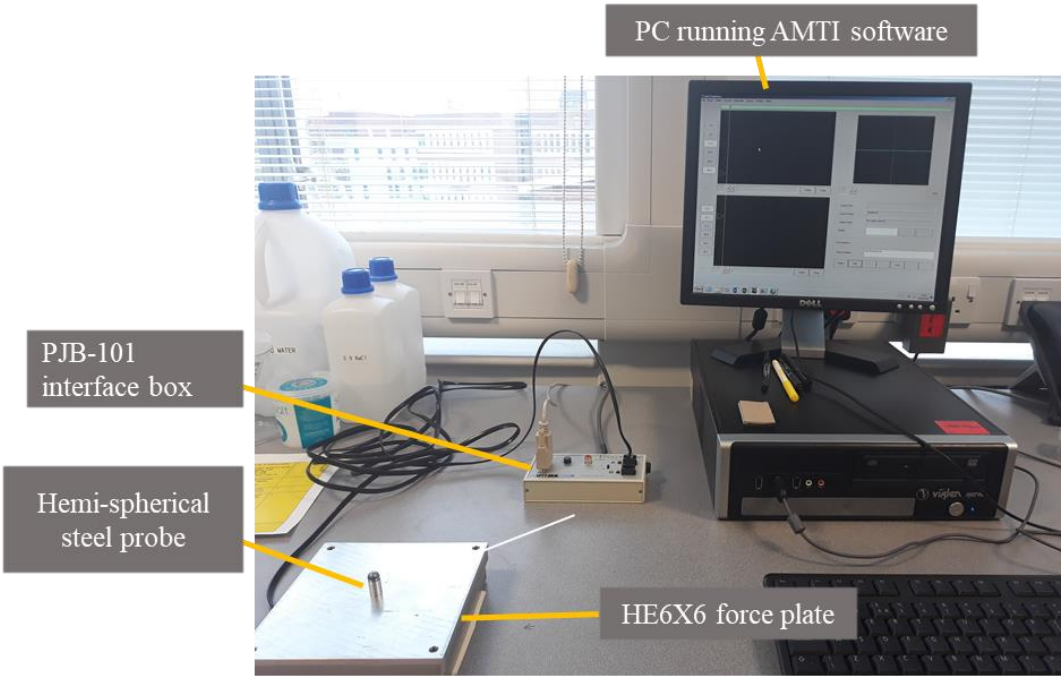


*Figure 3.2 - Equipment and system setup of friction measurement device.*

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### 3.4.1 Corneometer Measuring Skin Hydration

The *Corneometer*® CM825 probe (Courage-Khazaka, Cologne, Germany) was used to measure the hydration levels in the volar forearm up to a depth of 10 to 20µm, capturing data solely from the superficial skin layers rather than tissue at greater depth. When the probe contacts the SC surface then an electric field passes through the SC, between two electrodes in contact with the skin, and provides a value for the dielectric constant. The measurements are provided in Corneometer Units (c.u.), ranging from high resistance of 0 (no water at all) to low resistance of 120 (complete water saturation). The *Corneometer* is one of the most widely used instruments for measuring SC hydration due to its accuracy, international reputation, and affordability. There are other methods in which to measure SC water content such as Confocal Raman Spectroscopy or Infra-Red Spectroscopy, but these are more complex and costly than electrical methods, so usage in research is low. The *Corneometer* has many advantages including the readings being unaffected by substances on the skin, such as salts or residues of topically applied products [9]. Six readings were recorded per skin site; the first reading in each site was discarded during the analysis, as advised in the device protocol from the manufacturers. The measurement capture is triggered automatically at a pressure of 0.7 to 0.8N on the surface of the skin.

### 3.4.2 Cutometer Measuring Skin Deformation

The *Cutometer® MPA 580* (Courage-Khazaka, Cologne, Germany) is a very versatile piece of equipment for skin testing, it can measure many biomechanical values such as viscoelasticity, skin extension, and skin relaxation. The device has been proven to be a reliable and safe device for skin testing [10]. The data output provides several different values which give information on the skin stiffness, maximum extension, rate of extension, and viscoelasticity. The device offers four different modes of operation; Mode 1 uses a constant negative pressure, Mode 2 has a linear rising and linear release of negative pressure, Mode 3 measures with a constant pressure, followed by a linear release, and finally Mode 4 measures with a linear increase in negative pressure followed by an abrupt release. The Cutometer was used in this study to measure the mechanical deformation behaviour of the superficial skin layers by extension under loading provided by suction. Where 'deformation' is referred to within text and figure axes, throughout this chapter and Chapter 4, it relates to the maximum extension of the skin under loading rather than any other deformation behaviour such as viscoelasticity or tissue retraction. The firmness of the skin determines the resistance that the skin has to being drawn into the aperture. The chosen device protocol was to apply a negative vacuum pressure of 300 mbar, in Mode 3, with measurements being recorded over a time period of 20-seconds of suction, and then a further 5-seconds where the skin release rate was captured. By using Mode 3 with 20-seconds of negative pressure then it gives suitable time for skin extension; enough to make reasonable comparisons across participants. The Cutometer setup had a 2mm diameter eyelet in which skin was drawn into. A 20-second duration of negative pressure was chosen because it allowed the maximum extension of the skin to be reached and plateau. One reading was taken per site because in the pilot testing it was found that when three readings were taken per site they were consistent with each other.

The Cutometer measures the tissue elevation from a baseline level using a non-contact optical measuring system consisting of a light source and sensor used to correlate the light intensity changes from initial deformation to the apex height [11], with 0.01 mm accuracy. See the schematic in Figure 3.3.

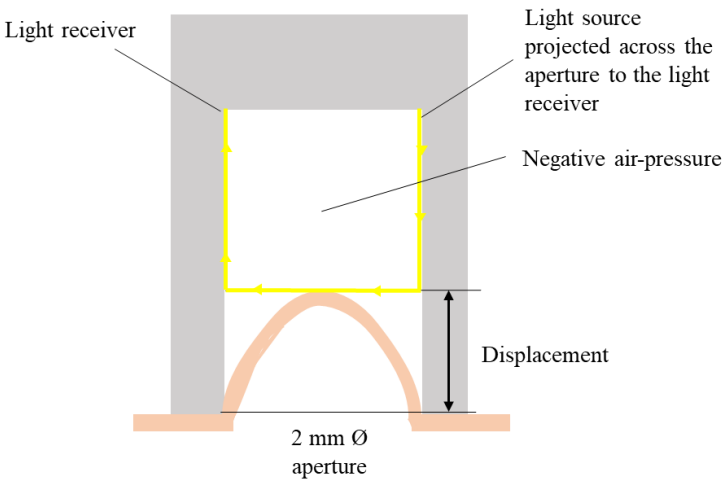


*Figure 3.3 - Schematic of the measurement principles of the Cutometer, adapted image from [12]*

An example a skin deformation curve obtained using the Cutometer is displayed in Figure 3.4. $U_e$, $U_v$, $U_r$ and $U_f$ are defined in Table 3.1.

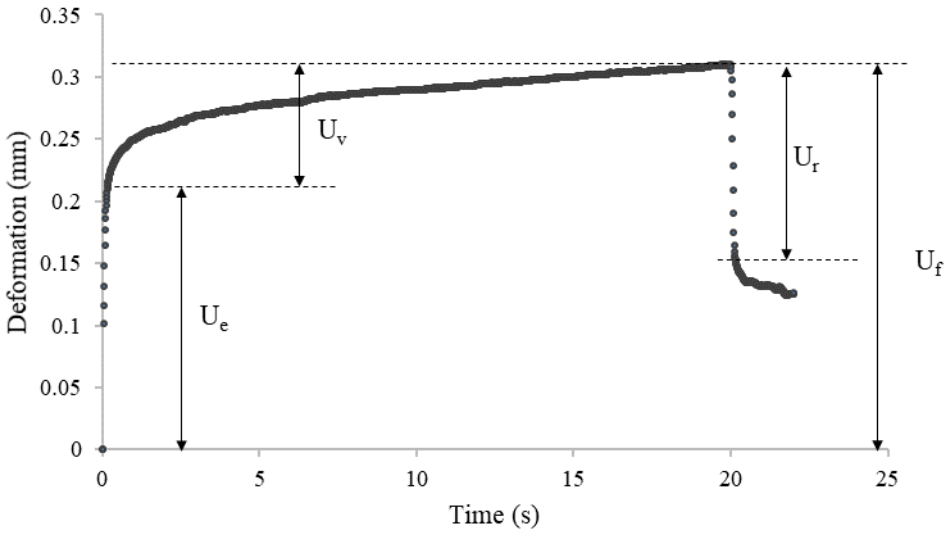


*Figure 3.4 - A time/deformation curve obtained using the Cutometer®, illustrating the viscoelastic properties of human skin. Data presented is from the experimental results, showing data from Test Session 1, P3, test site L3.*

*Table 3.1 - Nomenclature descriptors [12]*

| Absolute parameter U value | Relative parameter R value | Description |
|---|---|---|
| $U_f$ | $R_0$ | Maximum deformation/extension of the skin |
| $U_r/ U_e$ | $R_5$ | Immediate retraction to immediate deformation ratio |
| $U_v/ U_e$ | $R_6$ | Viscoelasticity to elasticity ratio |
| $U_r/ U_f$ | $R_7$ | Immediate retraction to maximum deformation ratio |

$U_e$ is the portion of the curve where there is elastic deformation of the skin as a result of the suction applied. The delayed deformation $U_v$ occurs due to the viscoelasticity of the skin. $U_f$ corresponds to the final distension of the skin and $U_r$ is the elastic recovery from the immediate release of the suction and where the retraction of the skin takes place [13]. When skin undergoes extension, there is an initial period of rapid elastic extension, followed by a slower viscoelastic extension, and in the latter part a period of creep when the load is maintained.

### 3.4.3 Multi-Axial Force Plate Measuring Skin Friction

The measurement device used for the friction tests was a multi-component platform system produced by Advanced Mechanical Technology Ltd. The equipment setup shown previously in Figure 3.1 features a HE6X6 force plate, a PJB-101 interface box and a PC, along with an RJ cable and a RS-232 cable. The principle by which the force plate works is based on the strain gauge flexibility technique, where three force components are measured in the x, y, and z axes. The maximum normal force which can be tolerated in the z axis is 44 N, but the device is also ideal for working with low loads, such as those used in the experimental work covered in this thesis. On the force plate a 5mm diameter hemi-spherical steel probe was mounted to provide the sliding surface for the forearm. The surface roughness of the probe was 0.361 ± 0.061 µm, measured using the *Alicona InfiniteFocusSL* optical 3D measurement system using the surface roughness profile tool.

During the movement of the volar forearm relative to the plate, the resultant horizontal force in the x-y plane is considered to be the frictional force. The participants were given full control over the execution of the load and speed of the tests, and they underwent training on how to achieve the required load of 1.5-2 N at a steady speed, giving a velocity of approximately 10 mm/s. This low loading regime was

chosen because it was an appropriate load and sliding speed for the participants to repeatedly achieve, with minimal discomfort, and was within the threshold of loads previously used on the departmental device in *in vivo* experiments [14]. A schematic of the friction test can be seen in Figure 3.5 where it shows the direction of movement of the forearm, where it is pulling towards the torso on the stroke. The forearm was lowered onto the probe and moved backwards for one slide before being lifted from the probe; this unidirectional sequence was repeated two more times.

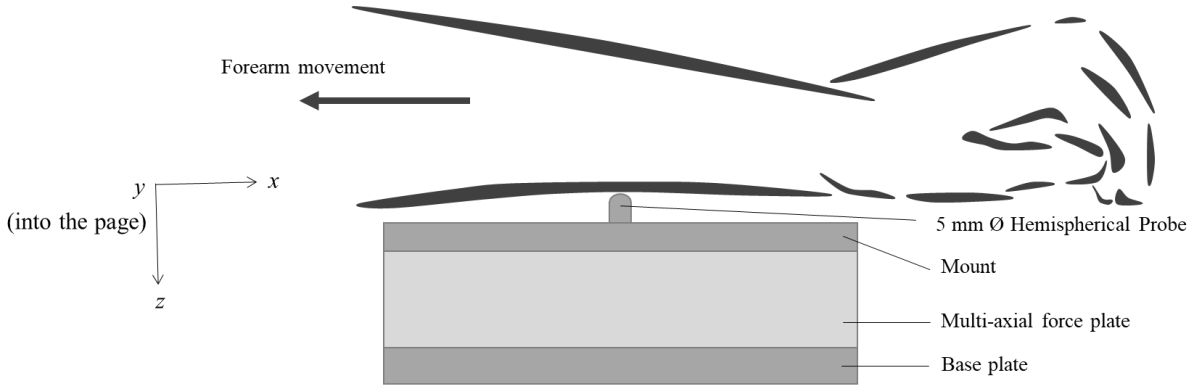


*Figure 3.5 - Schematic of the friction test experiment, showing the direction the forearm moves relative to the probe.*

The coefficient of friction (CoF) was considered to be the ratio between the friction force and the normal force, see the previous definition (Equation 2, Chapter 2); it only applies when the contacting skin and probe are sliding relative to one another. The CoF was averaged across the three slides according to the data analysis method outlined later in Section 3.5.1.

### 3.4.4 Optical Coherence Tomography

An imaging technology called Optical Coherence Tomography (OCT) enabled cross-sectional images of the skin sites to be captured to a high resolution. The device used was the clinically approved *VivoSight*® OCT laser system (Michelson Diagnostics Ltd., Kent, UK), which is a swept-source Fourier domain OCT. It enables a fast and non-invasive way of viewing the subsurface skin structure. The OCT technique is based on low-coherence interferometry; where light is split into two paths, with the first going into the tissue and the second to a reference mirror. The light scatter of the laser beam across the surfaces generates a 2D image [15]. This process allows layers such as SC, epidermis, dermal-epidermal junction (DEJ), and blood vessels to be identified [16], see Figure 3.8 for an annotated example of the identifiable landmarks. The *VivoSight* is commonly used in diagnostics and monitoring of non-melanoma skin cancers, and the images captured have an optical resolution of 1342 × 460 pixels. The

types of images obtained depend on the variety of scanning method applied; either an A-scan, B-scan, or C-scan can be chosen. In this work cross-sectional images were taken of 6mm width and to 2mm (the maximum imaging depth with this system). Although the resolution is high, the system does not have the capability to image to a low depth due to the required light transparency; so it is useful for imaging the skin and eyes, but not for example, the skeletal structure.

The hand-held probe of the OCT has a removable probe standoff, see Figure 3.6, which when in place can be used to steady the probe against the skin, prevent hand movement of the researcher or clinician, and set the correct scanning distance. The standoff was removed during this experiment to prevent any contact of the probe with the skin, since any applied force during imaging would affect the roughness values of the SC due to tissue deformation or stretching.

*Figure 3.6 - Removable probe standoff, image from [17].*

In the cross-sectional images below, see Figure 3.7 a), the SC can be seen as a thin, bright white layer on the top surface of the skin. Figure 3.7 b) shows a yellow line indicating the detected line across the surface profile of the SC that was generated using the Matlab algorithm; the analysis process is later discussed in detail in Section 3.5.1.

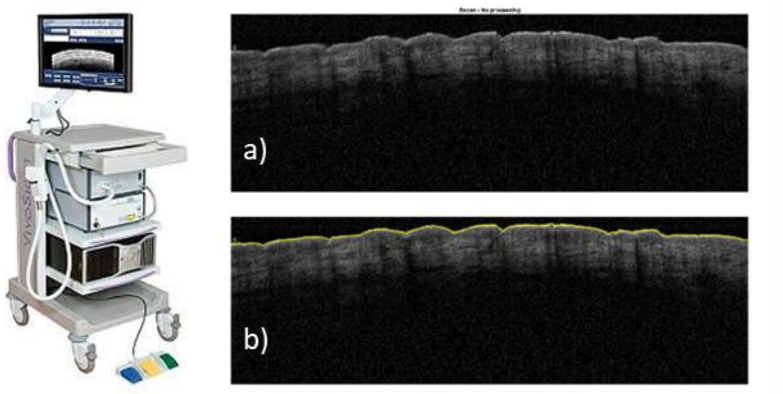


*Figure 3.7 - Optical Coherence Tomography, VivoSight Michelson Diagnostics*

An annotated image of the features that can be seen in a scan are shown in Figure 3.8. Below the SC is the epidermis which is separated from the dermis by the DEJ. Vellus hair penetrates into the top layer of the dermis. There is a slight colour change observable between the dermis and the subcutaneous fat layer (hypodermis), and blood vessels are indicated by the thin dark lines in the dermis. Any structures with liquids inside them appear black on the scan. The epidermis and upper dermis can be seen as having a more even consistency of colour indicative of packed collagen bundles with minimal fluids and vessels present, whereas the lower dermis has a mottled appearance due to less densely packed collagen bundles and a high numbers of vessels supplying blood and lymphatic fluid to the tissue [18].

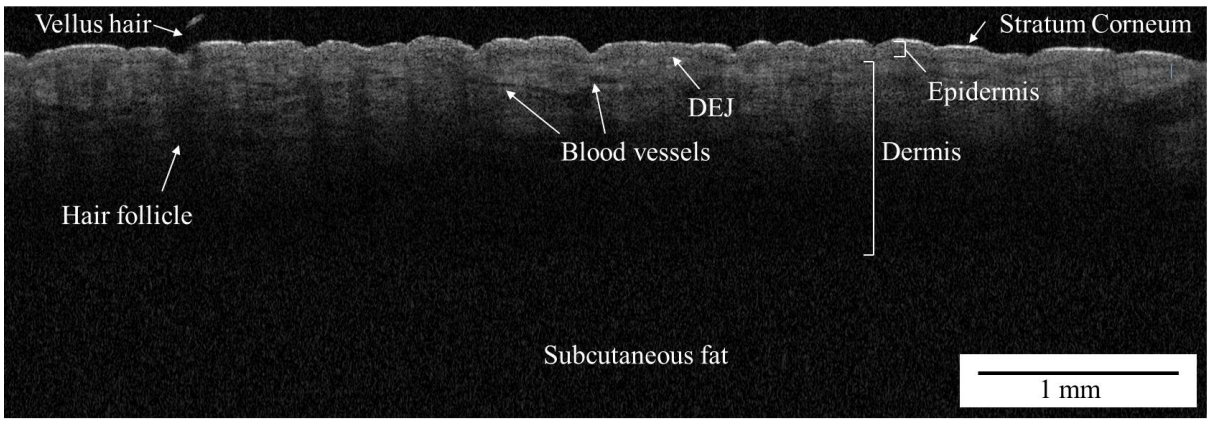


*Figure 3.8 - Cross-section of the dermis and epidermis taken using VivoSight® OCT laser system. Modified from [16].*

## 3.5 Experimental Design and Methodology

### 3.5.1 Data Analysis Protocols

Pilot tests were conducted to assess the data analysis techniques that, if appropriate, would be used in the full experimental analysis to calculate the DCoF from the raw friction data, and to also extract skin surface roughness values from the OCT images.

### 3.5.2 Data Analysis Protocol Used to Determine the Dynamic Coefficient of Friction

A pilot test was conducted on the in-house built friction rig, and a preliminary analysis of the data showed that it was possible for a participant to apply a fairly consistent normal load to the skin, whilst moving the arm across the contact surface within the target range of 1.5 to 2N, see Figure 3.9. The plotted CoF data points for each slide are shown in Figure 3.10, these data points were calculated by dividing the friction force $F_R$ by the normal force $F_N$. In order to extract just the DCoF from each slide the average CoF was taken across the mid 2-seconds of the sliding portions of the tests. Each 2-second window consisted of 100 data points, as the multi-axial force plate was set to record 50 data points per second. The DCoF was then averaged across the three repeat slides to give an overall CoF for each participant test site.

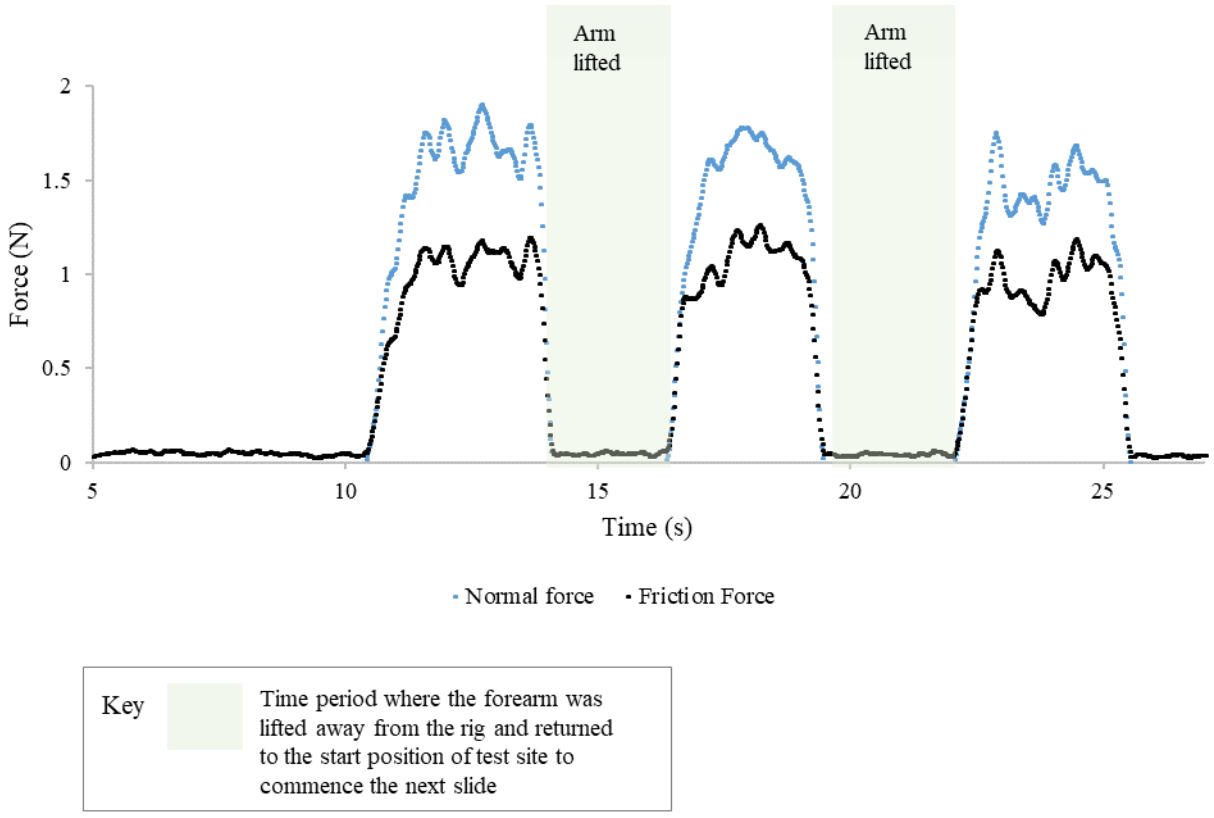


*Figure 3.9 - An example of a normal force and friction force profile.*

Using the ratio of the normal force to the friction force, the CoF has been plotted in Figure 3.10. The CoF remained fairly level throughout the mid to latter portions of each slide. This finding shows that within the context of this work, and over this small range of normal forces (1.5 to 2 N), then Amontons' law of friction, stating that 'friction force is proportional to the normal load', holds true. In the profiles shown in Figure 3.9 it can be seen that the normal force and friction force fluctuate slightly during the slides which is as a result of human error; each participant manually applied the force throughout the stroke whilst referencing a guide line on the computer interface as a target load to achieve. However, despite these small fluctuations there was not a big impact on the CoF, see Figure 3.10, as stability was maintained at approximately 0.7 throughout the duration of the 2-seconds sliding windows of each stroke. In the scientific community the mechanism and validity of Amontons' law are still widely discussed and researched [19, 20].

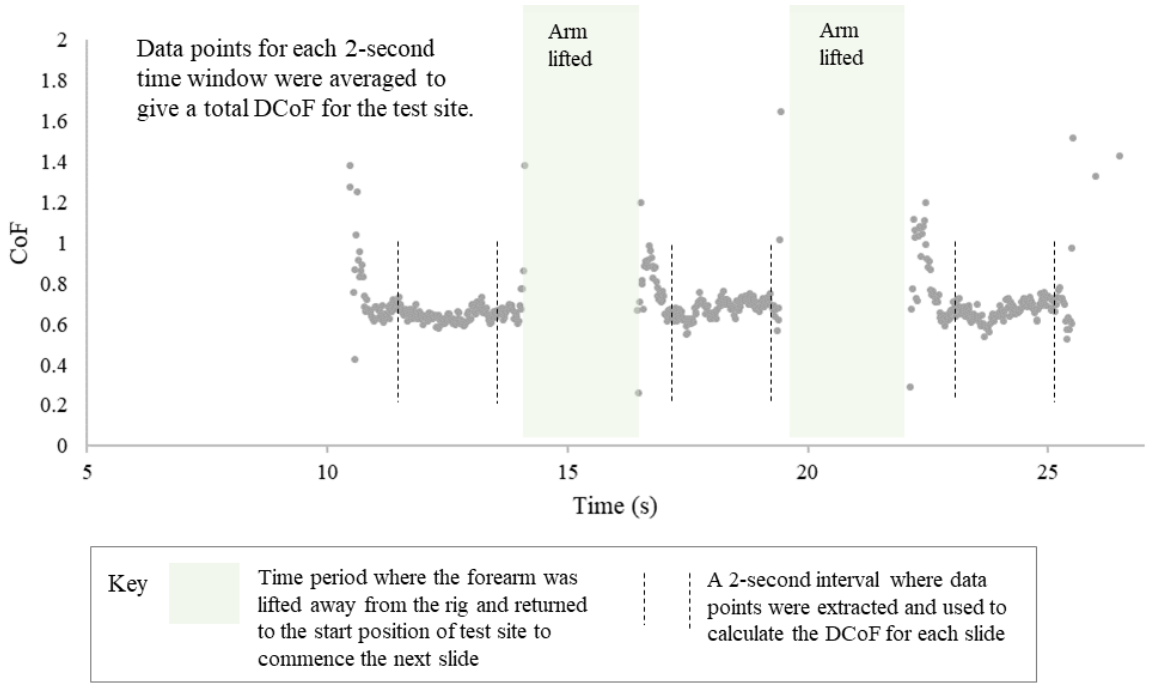


*Figure 3.10 - The data analysis technique used to calculate the CoF.*

The findings of this study therefore demonstrated that the friction rig setup and protocols are able to produce a consistent CoF between the two surfaces. Therefore, the equipment and selected tribosystem input parameters and protocol were chosen to carry forward into the final protocol.

### 3.5.3 Optical Coherence Tomography Data Analysis Protocol

Before scan images could be processed, a selection criteria needed to be established to filter out any images of lower quality which could cause errors in the analytical process. The clarity of the skin layers depends on the probe distance from the skin along with the steadiness of the hand of the operator, as well as the Fitzpatrick skin type of the participant. The selection criteria were as follows:

- Due to the probe being handheld, some of the images are of poorer quality with low quality skin layer detection. Therefore, only the non-blurred images should be selected from each sequence to take forward for analysis.
- Ensure there are no visible vellus hairs on the images as they can cause errors in the SC detection.
- Select images which have close proximity of the probe to skin, this can be noted by the very small distance between the SC surface and the top of the image, Figure 3.11 (a).

To analyse the surface roughness data from the OCT on each skin site, five image sequences were taken, with fifty images in each, and from these sequences fifteen raw images in total were selected ready to be processed. An example of a raw image and the steps to analyse the images is shown in Figure 3.11. Images were converted to TIFF file format using ImageJ image processing software. An edge filter was applied to indicate the boundary line between the air and SC. Figure 3.11 a) shows the SC was easily visible on the image; appearing as a thin bright white line on along the top surface. The highlighted yellow line in image Figure 3.11 b) displays the detected surface profile of the SC and this was identified using a Matlab algorithm developed by Maiti *et al.* [21]. The steps of the analytical process followed by the algorithm involved calculating the roughness by fitting a polynomial to the SC, see Figure 3.11 c), followed by d) normalising the SC data so that arithmetic average ($R_a$), root mean squared ($R_{rms}$), and maximum peak to valley height of a given sequence ($R_z$) could be calculated.

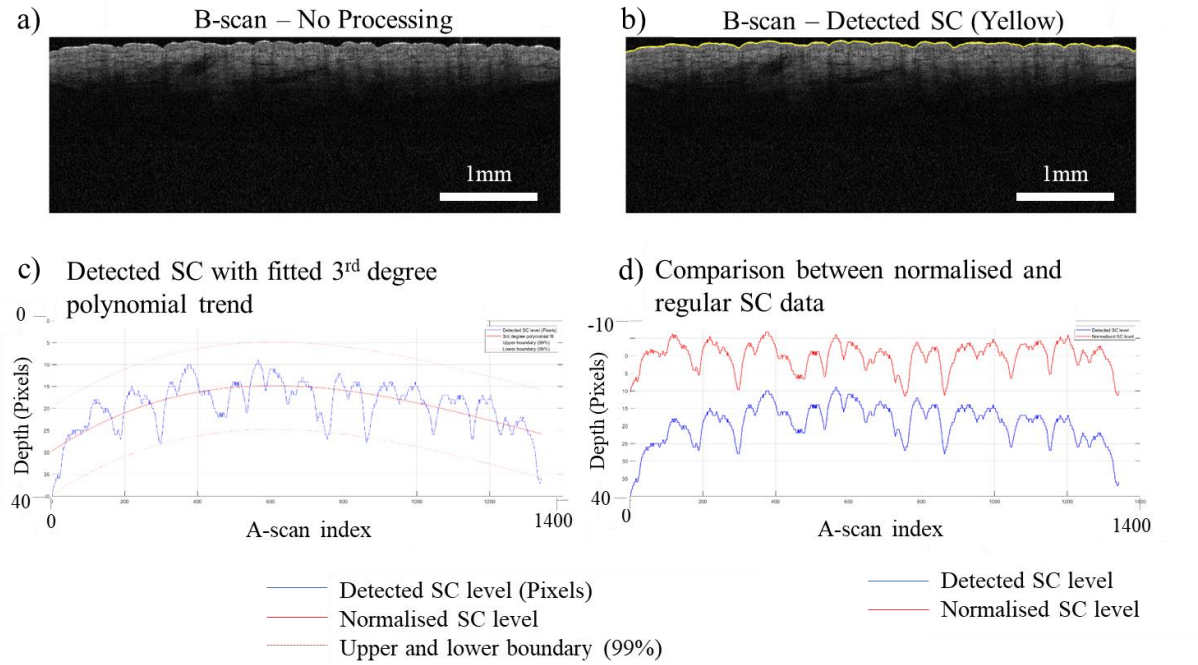


*Figure 3.11 - Extracting the surface roughness (red line) from the VivoSight raw image topographical skin profile (blue line). (a) raw image of a cross-section of the volar forearm. (b) Stratum corneum detection, yellow line, (c) Fitting a 3rd degree polynomial to the detected line (d) normalised data of the roughness profile in order to extract $R_a$, $R_{rms}$ and $R_z$ values. Image taken from the P1 control site.*

After images were selected, compiled, and processed the roughness data was then extracted. In total 15 images were selected from each site giving 15 roughness values which could be averaged to give one Ra value per site.

## 3.6 Treatments and Application

### 3.6.1 Selected Treatments

Three skin treatments were selected for the experiment: a 10% glycerol solution, *Cavilon*, and *Vaseline*. All chosen treatments have very different chemical compositions and fall into different treatment categories. Glycerol is a common active ingredient within healing skin treatments and moisturisers, and its humectant qualities draw moisture into the top layers of the skin, plumping it up and temporarily reducing signs of ageing, creating a smoother and more radiant appearance. *Vaseline* is occlusive emollient meaning it moisturises and softens the skin by preventing moisture from leaving the skin by reducing TEWL. When skin is exposed to excess moisture, as is the case with IAD, it becomes overhydrated which can lead to tissue maceration and raised levels of TEWL. High TEWL can result in a compromised skin barrier, increased vulnerability of the skin to mechanical forces of friction and shear, and increased risk of infection [22]. *Vaseline* was chosen due to its popularity as an occlusive

treatment for barrier protection within both medical and community settings. It also is marketed as a product for diaper rash, under the product name '*Vaseline® Healing Jelly Baby*', which 'locks in moisture to treat and prevent chafed skin from diaper rash' [23]. This product has the same formulation as *Vaseline* other than the addition of a mild scent. *Cavilon* was selected for the experiment due to its performance as an effective topical treatment to protect and repair the skin of those suffering with IAD. It is more of a complex treatment in that it contains a vast array of ingredients, including occlusive and humectant agents. The active ingredient with the formula of *Cavilon* is dimethicone; an emollient which is known to increase the skins flexibility and retain moisture within the skin. One of the unique features of this formulation is the polymer ingredient, which allows bandages to be applied on top of the treatment.

### 3.6.2 Treatment Application

Each participant was provided with an individually allotted treatment application sheet similar to the boxes shown in Figure 3.12 a), which indicated which site to apply each treatment for the duration of the study. Each participant was also provided with a CE marked skin-safe marker pen and dots were applied to identify the boundaries of each test site, as shown in Figure 3.12 b). Each skin site had a width of 15mm and a length of 50mm.

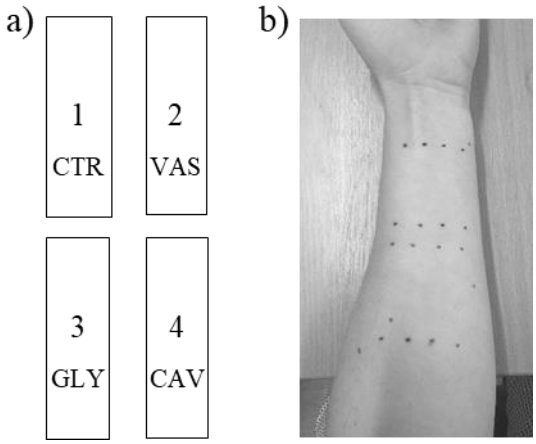


*Figure 3.12 – An example of a) the treatment application sheet given to a participant showing the corresponding test sites to which they should be applied within b) the test site markings on the forearm.*

Participants were instructed to avoid scrubbing or cleansing the skin with any skin products throughout the study for the reason that detergents and topical creams are known to alter skin properties. The participants were asked to apply the treatments on their respective treatment sites in the morning 4-hours before their scheduled test session.

The location site of application was selected at random using a research randomiser tool for each treatment so that no bias was introduced. Treatment locations for each participant have been presented in Table 3.2. One of the sites acted as a control (CTR), and the other three sites were allocated for the treatments: *Vaseline* (VAS), 10 % glycerol solution (GLY), and *Cavilon* (CAV).

*Table 3.2 - The treatment allocation assignment for each test participant.*

| Participant Number | L1 | L2 | L3 | L4 |
|---|---|---|---|---|
| P1 | CTR | VAS | GLY | CAV |
| P2 | CTR | GLY | VAS | CAV |
| P3 | VAS | CAV | CTR | GLY |
| P4 | CAV | CTR | GLY | VAS |
| P5 | GLY | CTR | CAV | VAS |

Prior to the application of skin treatments, the skin was tested during Test Session 1 (TS1) to reveal the baseline properties of the natural untreated skin. These baseline results were the benchmark with which to compare how skin changes with the presence of skin treatments. The subsequent set of tests was Test Session 2 (TS2), to investigate the effects of treatments on the skin after they had been on the skin for a 4-hour period of time. One of the considerations in the protocol which influenced the time-window between treatment application and testing was that the *Corneometer* and *Cutometer* could not be used when a layer of treatment was present on the skin. For example, a layer of *Vaseline* is an occlusive barrier and would therefore prevent any moisture readings being taken from the skin. The *Cutometer* also cannot be used where a visible layer of treatment is present due to the risk of it travelling up the aperture when the negative pressure is applied. A time period of 4-hours was deemed suitable to investigate the effects of the treatments because treatments were by then not visibly present on the skin, and no residue remained.

## 3.7 Finalised Experiment Protocol

The fully developed protocol is shown in Figure 3.13. Before any testing occurred, a participant information sheet was developed, along with a consent form. Ethical approval was given by the University of Sheffield Ethics Committee to conduct the skin characterisation tests and friction tests set out in the developed protocol (Ethics Number 007424), see Appendix D. The main test location was the Dermatology Research Department at the Royal Hallamshire Hospital, Sheffield Teaching Hospital.

Pilot tests were carried out in the Human Interaction Group Lab in the George Porter Building at the University of Sheffield. In the flowchart shown in Figure 3.13, Steps 1-3 were conducted during TS1, Steps 4-5 were conducted in the intermediary between TS1 and TS2, and the remainder of the steps were carried out in TS2.

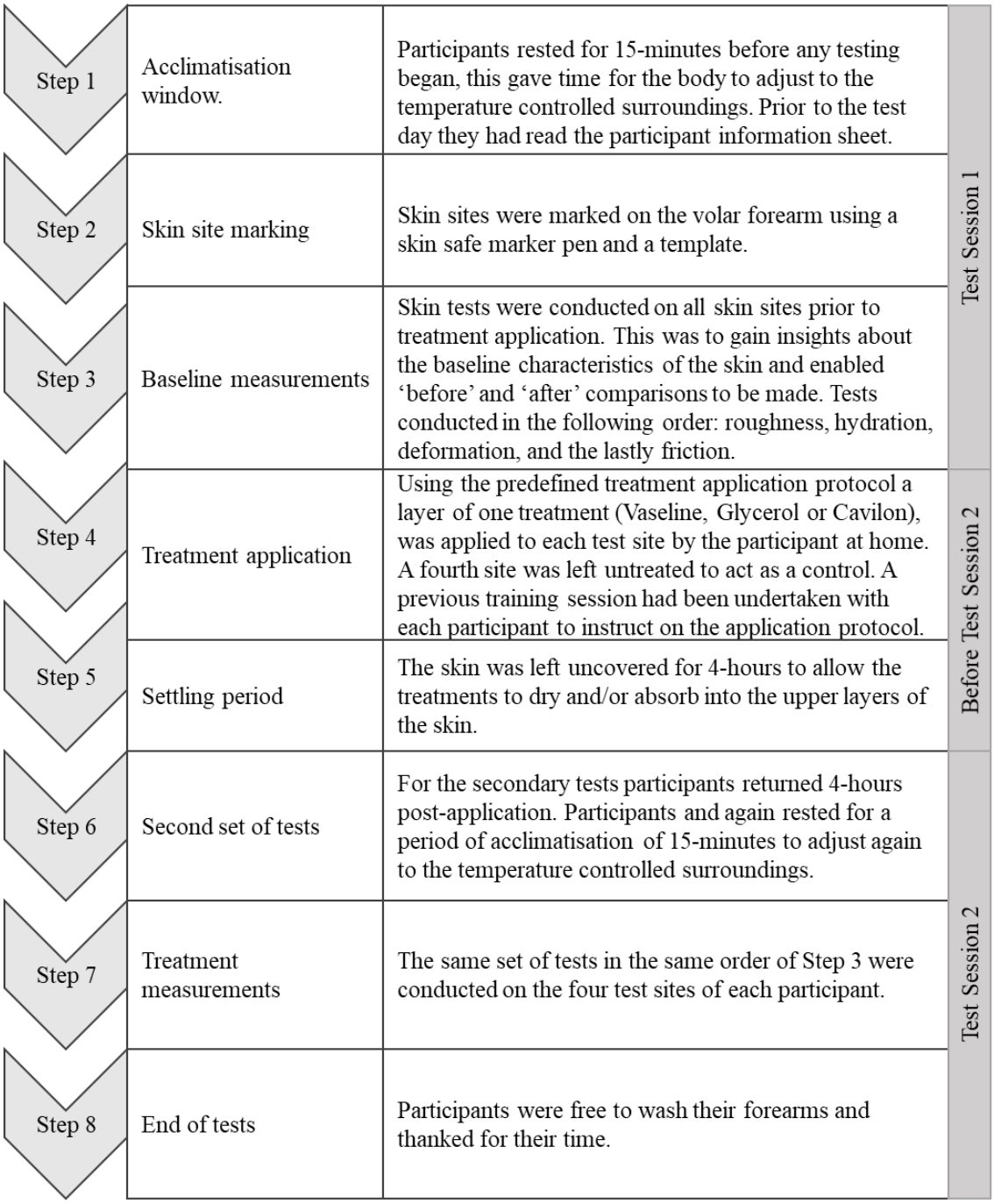


*Figure 3.13- Flowchart of the steps of the experimental protocol.*

All tests were conducted in climate controlled conditions, 20-22 °C and a relative humidity of between 40-60% humidity. Before testing, each participant acclimatised for fifteen minutes to the conditions of the climate-controlled room; it is a well-accepted practice during human participant testing to allow time for acclimatisation [24]. This period gave the body a chance to adapt to the resting conditions of the room, and for TEWL and skin moisture to stabilise.

The tests were carried out in the following order: optical imaging, hydration tests, deformation tests, and finally the skin friction tests. See Figure 3.14 for the location of tests conducted on each skin site. The order for conducting the skin tests was very important to minimise disruption of the natural skin properties for subsequent tests. The small dots show locations of the moisture tests, the central large dot was the test site for the deformation test, surface roughness tests were taken at five intervals within each test site, and the friction test was taken lengthways across the test sites from elbow to wrist, as indicated by the dashed line.

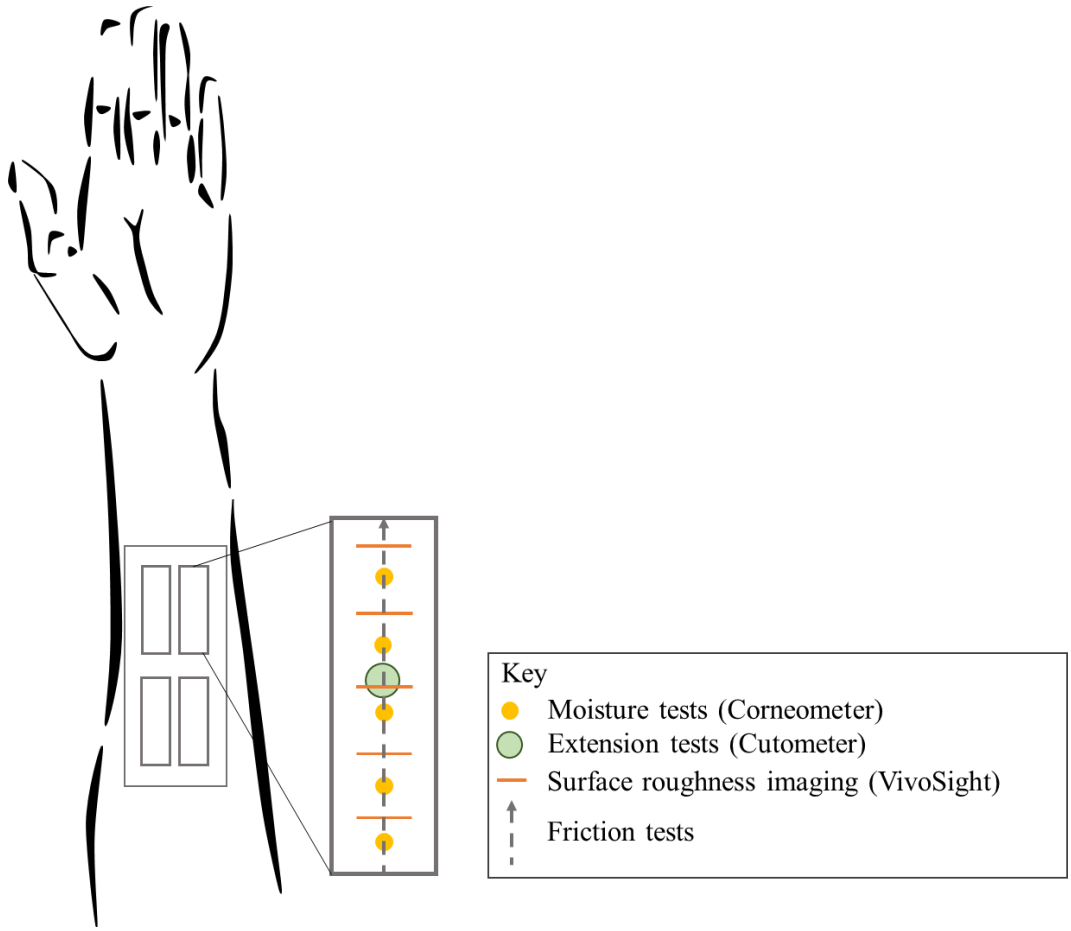


*Figure 3.14 - Diagram highlighting the number and location of tests conducted on each skin site. The small dots indicate moisture tests, the large dot indicates a deformation test, the horizontal lines indicate the roughness tests, and the vertical dashed line represents the location and direction of the friction tests.*

Roughness measurements were completed first as they had the advantage of being a non-contact method, so little (if any) disruption occurs. The next stage was the hydration measurements using the *Corneometer*, these measurements required light pressure across the surface of the test site. The third measurement looking at the maximum extension of the skin under a negative pressure was decidedly a more disruptive test due to the stretching of the skin. This was only a very minimal stretch and only slightly noticeable by participants. The final test conducted was the friction tests, this type of test was considered as more disruptive to the skin due to the low load contact that the surfaces had. There was potential for this type of test to minimally disrupt the SC by increasing the temperature and introducing shear loading.

## 3.8 Conclusions

This chapter outlined a series of protocols that were developed in order to measure the effects of treatments on the moisture, roughness, deformation, and friction of skin. Protocols were established for each piece of equipment, as well as acclimatisation, and treatment application. This chapter has also explained the analytical methods that were devised to reliably extract data for the friction coefficient and surface roughness. The results of the skin tests and treatment effects are displayed and discussed in Chapter 4. The protocols developed in this chapter show potential for use in future PhD studies, as well as forming the foundation for experiments later carried out later in the thesis, the results of which can be seen in Chapter 7.

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# 4 Influence of Topical Treatments on Skin Moisture, Roughness, Deformation, and Dynamic Coefficient of Friction

## 4.1 Introduction

The aim of this study was to investigate the influence of topical treatments on skin, and measure the relationships between the properties of skin in its natural state. Alongside investigating effects of treatments, it was important to test the protocols that were discussed in Chapter 3 to determine elements to be taken forward into future experimental work, as well as to inspire any protocol improvements.

This chapter presents the key skin characterisation findings alongside results of how skin responds to topical treatments after a 4-hr interval post-application. Section 4.2 titled 'Test Session 1' (TS1) presents the findings from the baseline skin characteristics tests where measurements from each of the four test sites (L1, L2, L3 and L4) were taken, without the presence of treatments; these measurements are referred to as the 'baseline characteristics' of the skin. Section 4.3 titled 'Test Session 2' (TS2) presents the data collected from each skin site after treatments of glycerol (GLY), Vaseline (VAS), and Cavilon (CAV) had been present on the skin for 4-hours. The key measurements taken in both test sessions were of the skin roughness, deformation, coefficient of friction and capacitance (moisture levels).

*Statistical analysis*

Where scatter graphs are presented, the Pearson's correlation coefficient, *r*, and the probability of error, the *p* value, are included. The *r* values can range from -1 to +1 where -1 indicates a perfect negative correlation, +1 perfect positive correlation, and 0 indicates that no relationship was found. For the full spread of the given classification boundaries for *r* see Table 4.1. Where error bars are present on figures they show the standard deviation (SD).

*Table 4.1 - Classification of boundaries for the Pearson's Correlation Coefficient, r. [1]*

| Strength of correlation | *r* value |
|---|---|
| Perfect | ±1 |
| Very high degree | ±0.9, ±0.8 |
| High degree | ±0.7, ±0.6 |
| Moderate degree | ±0.3, ±0.4, ±0.5 |
| Low degree | ±0.2, ±0.1 |
| None | 0 |

For the comparisons of the effects of treatments on the skin and the changes that occurred from baseline the statistical significance was tested using the two-tailed Student's t-test for paired data. A *p* value less than 0.05 was considered to be significant. Before conducting the t-tests the Shapiro-Wilk test was used to confirm that data sets were normally distributed. A significance level of *p* value of greater than 0.05 indicates a normal distribution, whereas a *p* value of less than 0.05 means data is not normally distributed.

## 4.2 Test Session 1: Characterising Skin

In total, five healthy participants were tested, three males and two females, all aged 24-29 years, without any indications of cutaneous conditions, visible damage, or inflammation. The participants are referred to in this chapter as P1, P2, P3, and so on. As the chapter progresses, the relationships between the skin parameters and friction are investigated and explored in greater depth.

### 4.2.1 Overview of Baseline Characteristics

The TS1 results displayed in Figure 4.1 and Table 4.2 summarise how participant skin behaved when no treatment was present. Performing this 'before' test was important in understanding the skin in its natural state as well as measuring differences between individuals. These initial tests also gave a benchmark, or control, with which to later compare the effects of treatment on the skin. Table 4.2 contains data to describe each participant's volar skin properties by providing mean and SD values for moisture, dynamic coefficient of friction (DCoF), deformation, and roughness. All of the devices used (the *Corneometer*®, *Cutometer*®, *VivoSight*® Optical Coherence Tomography (OCT) laser system, and Friction Rig) are discussed in detail in Chapter 3. The deformation behaviour reported was the maximum extension of the skin in millimetres into the probe when suction was applied; this measure reflects the skin flexibility.

Figure 4.1 summaries measurements collected in TS1, and the corresponding data is shown in Table 4.2. Each bubble is labelled with the participant reference number and shows their overall baseline skin moisture, roughness, deformation, and CoF, averaged across the four different skin sites on each of their forearms.

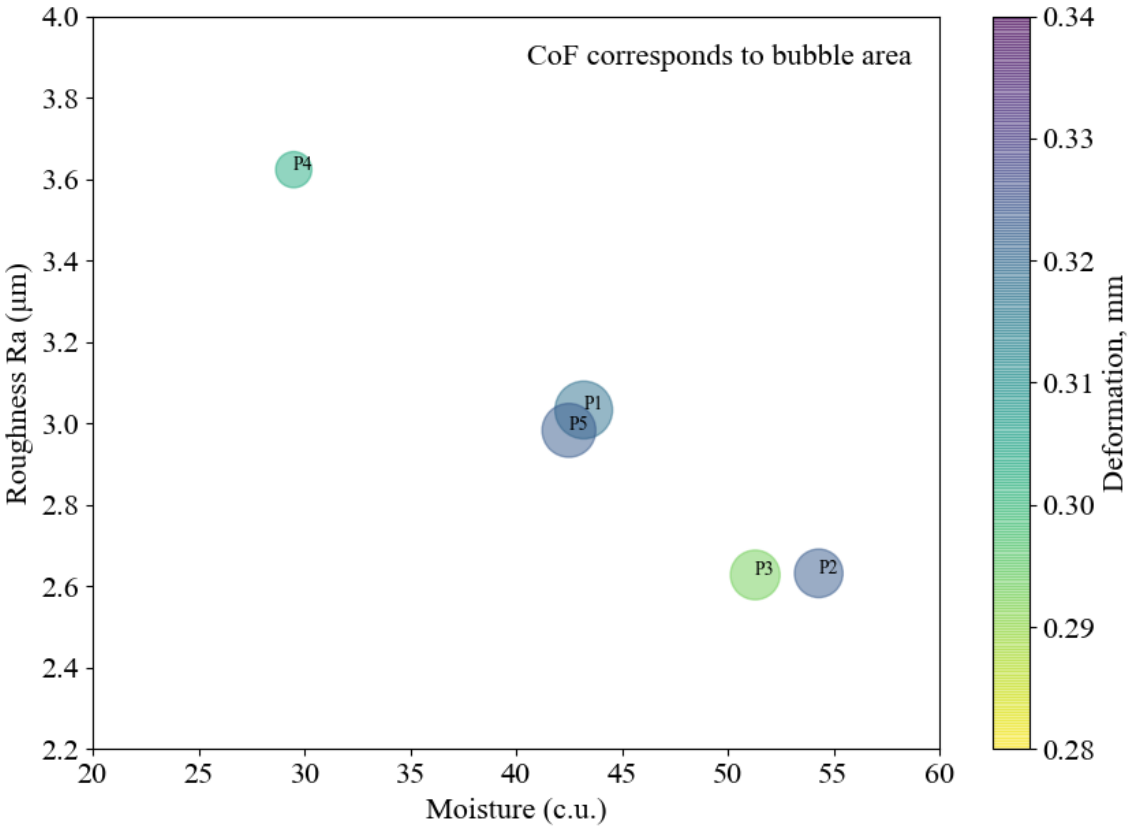


*Figure 4.1 - Bubble chart showing the mean volar forearm moisture, roughness, deformation, and dynamic friction coefficient for each participant. The bubble area corresponds to the coefficient of friction, where a larger CoF translates to a greater bubble area. CoF P1 ≈ 0.92 and P4 ≈ 0.36.*

*Table 4.2 - Summary of participant information and the baseline properties for each participant's natural skin averaged across the four skin sites.*

| Participant Number | Age | Sex | Moisture (c.u.) | DCoF | Deformation (mm) | $R_a$ (µm) |
|---|---|---|---|---|---|---|
| P1 | 28 | F | 43.2 ± 2.5 | 0.92 ± 0.25 | 0.32 ± 0.06 | 3.03 ± 0.22 |
| P2 | 24 | M | 54.3 ± 4.4 | 0.67 ± 0.17 | 0.32 ± 0.03 | 2.63 ± 0.41 |
| P3 | 26 | M | 51.3 ± 4.5 | 0.71 ± 0.13 | 0.29 ± 0.29 | 2.63 ± 0.06 |
| P4 | 29 | F | 29.5 ± 3.7 | 0.36 ± 0.19 | 0.30 ± 0.01 | 3.62 ± 0.46 |
| P5 | 24 | M | 42.5 ± 3.3 | 0.82 ± 0.23 | 0.32 ± 0.01 | 2.98 ± 0.27 |

There was a high degree of variability amongst participants, especially in the friction coefficient (0.36 - 0.92) and moisture levels (29.5 – 54.3 c.u.); in both cases the extremes of the ranges belonged to P4 and P1, respectively. The results for the DCoF were within the range of friction coefficients stated by Derler and Gerhardt *et al*. [2] in their comprehensive review paper which encompassed a large catalogue of skin friction literature. The range of volar forearm roughness was found to be 2.63 – 3.62 µm, consistent with roughness findings of ~ 3 µm by Maiti *et al*. [3]. In Figure 4.1 the relationship that immediately presents itself is the strong negative correlation between the moisture and roughness of skin ($r$ = -0.98, $p$ = 0.001); as skin becomes more hydrated, the roughness of the surface layer decreases. This correlation is explored in greater detail in Section 4.2.5.

### 4.2.2 Natural Hydration of the Skin

Natural skin moisture levels can greatly influence the way the skin responds to topical treatments, therefore it was important to assess and present results separately according to the hydration categories of the participants. Table 4.3 provides the capacitance classification for the *Corneometer* measurements. This classification system was developed by Heinrich *et al.* [4] and was used in this work to categorise four of the five participants (P1, P2, P3 and P5) as being in the same category having 'normal' skin hydration. However, it was found that P4 had a mean skin hydration level of 29.5 c.u., which was much lower than the other participants, which placed this participant on the boundary of the 'dry'/ 'very dry' category.

*Table 4.3 - Skin hydration classification, developed by [4]*

| Classification | Corneometer units for hydration (c.u.) |
|---|---|
| Very dry | < 30 |
| Dry | 30-40 |
| Normal | > 40 |

Due to the naturally lower skin moisture of P4 the decision was taken to present the P4 TS2 results separately, see Section 4.3, because it was found that the treatments had very different effects on this participants 'dry' skin, and compiling P4 in the analysis would have skewed the measured percentage changes in skin properties that occurred from TS1 to TS2.

### 4.2.3 Moisture and Friction Coefficient Relationship

Results displayed in Figure 4.2 show that baseline skin hydration has an influence on the skin friction coefficient. It is well accepted in skin friction literature that as moisture increases so does the coefficient of friction [5], [6], [7], [8]. This relationship is usually deemed to be either linear or a quadratic depending on the protocol of the test, and whether skin remains untreated or hydrated with water or treatments [2]. Much research regarding skin moisture has involved the addition of water to the skin [9] ; [8, 10, 11] [12], whereas data from TS1 is looking at the natural hydration of the SC and whether this influences the CoF.

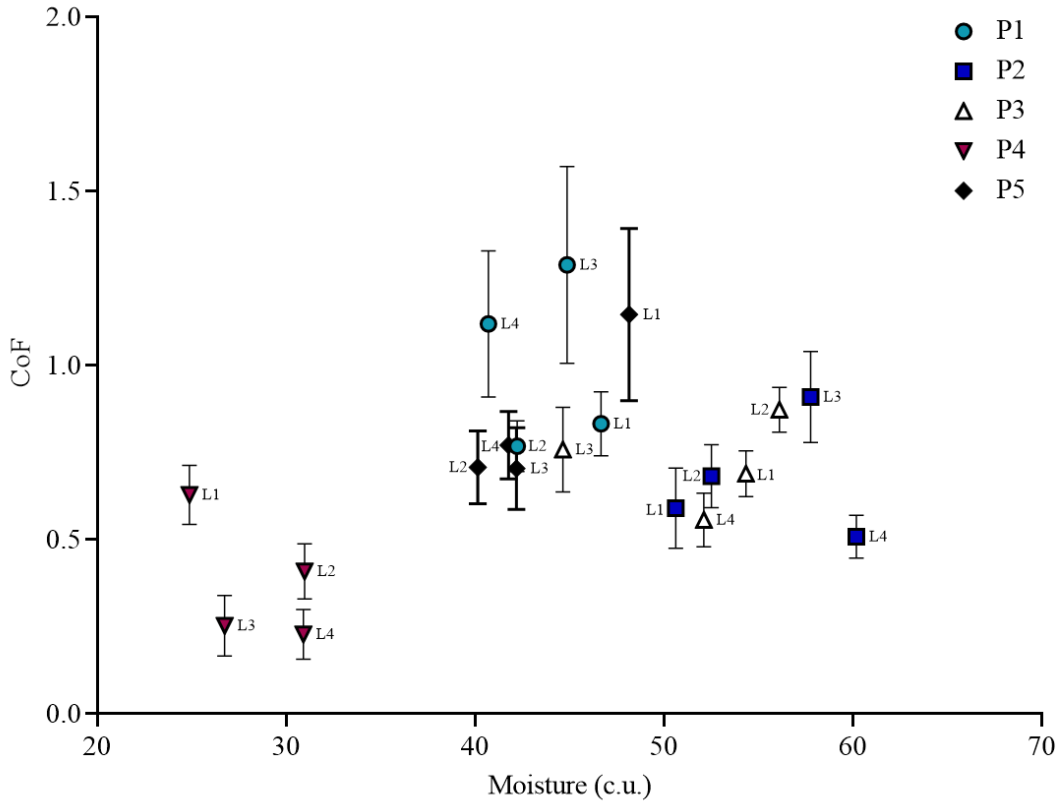


*Figure 4.2 – The dynamic friction coefficient of each skin site plotted against moisture readings. Pearson's correlation coefficient r = 0.38 and p = 0.11, indicating a moderate strength linear relationship with no statistical significance.*

This research confirms that as natural skin hydration increases then the CoF also increases. This relationship is thought to arise because the increased skin hydration, softens and smooths the skin, and provides a greater real contact area resulting in greater adhesion between the sliding surfaces, giving an increased CoF. This concurs with findings by Dabrowska *et al*. [13] where through addition of water the hydrated skin was indeed smoother and displayed higher real contact area values.

The moisture-CoF relationship could be viewed in two ways, either linear or as a bell-shaped curve, see Figure 4.3. In literature the bell-shaped curve has been previously discussed [2, 14], but as far as the researcher is aware this relationship has only been attained via the addition of liquid films to the skin rather than across the varying natural moisture levels of skin.

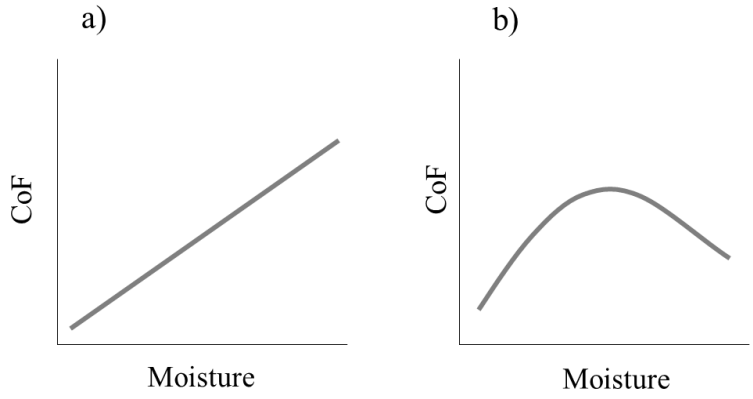


*Figure 4.3 - A proposal of two different graphs to explain the skin moisture and friction relationship for skin on the volar forearm (a) linear and (b) bell-shaped curve.*

The presence of a bell-shaped curve is possible; the explanation being that with the addition of water the CoF increases up to a certain point, and this is because the SC moisture increases which in turn results in a smoother topography. It also increases the microscopic contact area between the surfaces because moist skin conforms more easily over the asperities of the contacting material (in this case the steel probe), which increases the CoF [14]. With further addition of water, the CoF begins to fall as a liquid film forms. *In vivo* experiments by Tomlinson [15], involving a finger sliding over a force plate, displayed the beginnings of a similar shaped curve with the application of thin water films. The tribological mechanisms at play are likely in most scenarios to be very different between naturally hydrated skin versus water films, therefore drawing comparisons with this small data set has great limitations. Hendriks and Franklin [7] found that in a humid climate, skin becomes hydrated and the friction is twice as high compared to a dry environment, which could be likened to the 'dry' to 'normal' skin friction difference seen in Figure 4.2. Determining whether there is a predictable relationship, beyond dry skin having a lower CoF than wet skin, is difficult with the number of data points available in this experiment.

For any given individual the skin hydration ranged by approximately 10 c.u. across the four forearm sites, this was true for all five participants, and the interparticipant moisture level variation was also quite high. This variation between participants arises due to the SC having a range of water retaining capacities depending on an individual's genetics, the special arrangement of corneocytes, their composition, and the presence of natural moisturising factors [16].

Additionally, the CoF of natural skin in its untreated state varied by approximately 0.5 across the sites of the volar forearm for each participant. This natural variation could be attributed to a multitude of factors, particularly skin biomechanics, orientation of Langer's lines, subsurface features, and differences in skin moisture.

### 4.2.4 Friction and Deformation

Figure 4.4 shows the deformation of the forearm test sites and the corresponding mean DCoF. Where extension values are closer to zero this is an indicator of firmer skin.

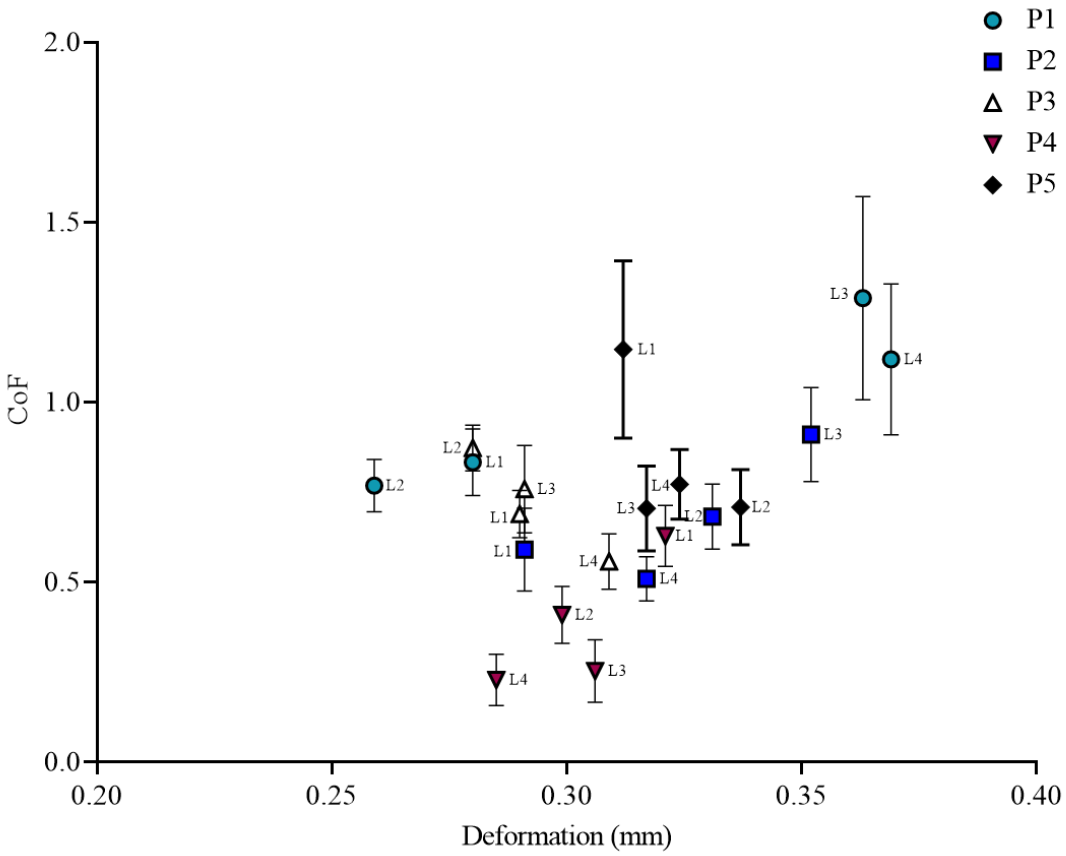


*Figure 4.4 - A scatter plot showing the maximum extension of the skin under a set negative pressure, plotted against the dynamic friction coefficient, r= 0.46, p = 0.039, showing statistical significance.*

A key observation from Figure 4.4 is that more deformable skin has a higher CoF. This positive correlation was found to be statistically significant $p = 0.039$, with a moderate strength correlation coefficient, $r = 0.46$. The skin deformation for each participant varied greatly depending on the test site on the forearm, these variations arose most likely due to diverse sub-surface features such as fat volume, muscle, fascia, and Langer's lines, which in turn can affect the reported CoF. Skin that is more flexible can deform more around the probe, hence increasing the contact area, which in turn results in a higher CoF.

### 4.2.5 Moisture and Roughness of Untreated Skin

Skin morphology, in relation to the moisture levels of the volar forearm, was measured using OCT, and the results are displayed in Figure 4.5. Values of moisture and roughness ($R_a$ values) for each TS1 test site are plotted, and for the sites with the highest and lowest $R_a$ values image scans are shown to give an example of the observable cross-sectional differences between rough and smooth skin.

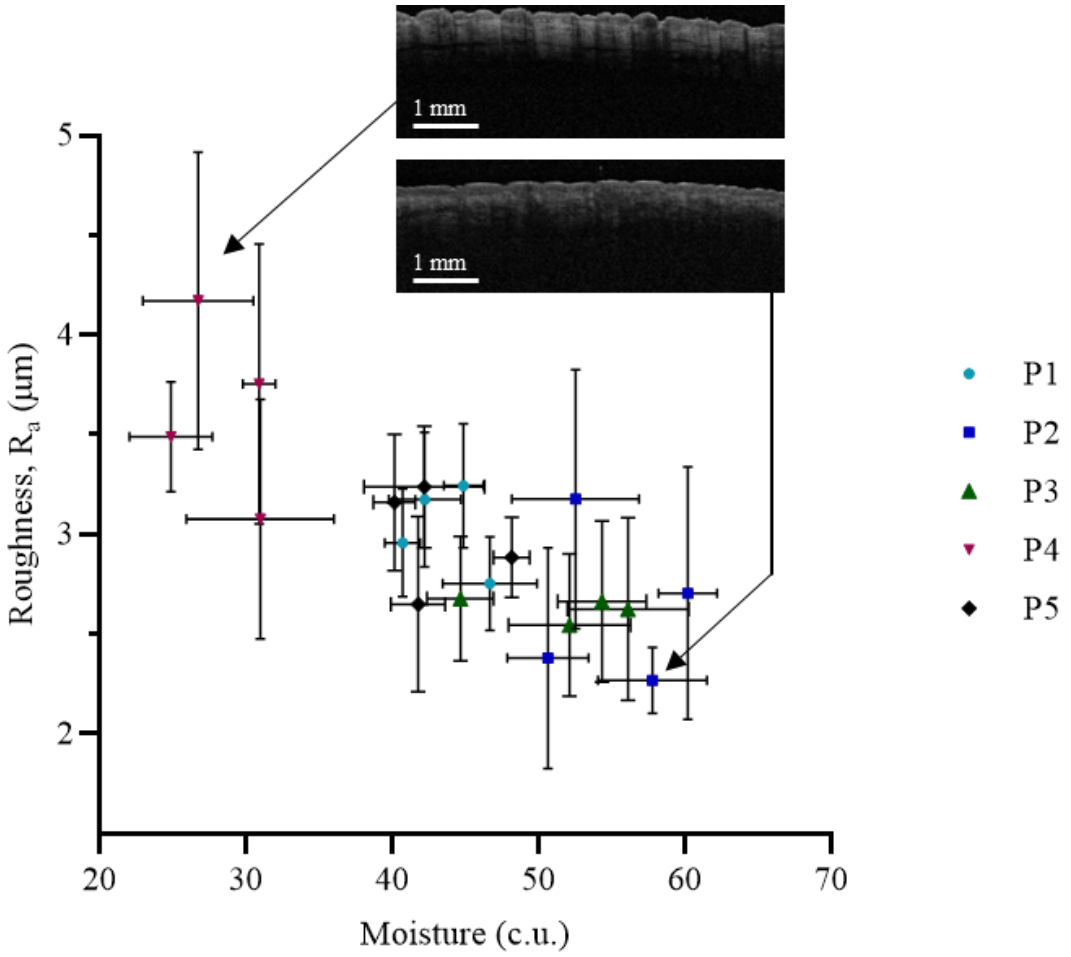


*Figure 4.5 - A scatterplot showing the linear relationship between moisture and roughness of untreated skin. OCT VivoSight 2D scans are shown alongside P2-L3 (lowest Ra value) and P4-L3 (highest Ra value) to show the visual roughness of these two sites. r = -0.79, p<0.0001.*

This moisture-roughness relationship is often discussed in literature, with the general rhetoric being that a site with lower moisture levels is associated with a higher skin roughness profile. As the hydration levels increase more moisture is retained within the skin, and the surface profile becomes smoother due to the corneocytes on the skin surface swelling [6, 9]. As far as the author is aware the detection of this relationship in untreated skin of participants with healthy skin has not been proven or measured before.

The detected correlation evidences this association, and highlights that the *VivoSight* device and analysis protocol has the required resolution and capability to output to a high level of detail; enough so to extract SC roughness on the microscale to relate to the hydration levels of the skin. Therefore, in applications where insights into skin roughness are needed there is scope for moisture measurements to be used in linear models to predict and categorise SC roughness without the need for the roughness measurements which require time-intensive analysis.

From the established strong negative correlation between moisture and roughness, Model 1 was developed, shown in Figure 1.4.6.

$$y = \beta 0 + \beta 1 * x \qquad \text{Equation 4}$$

Where,

$x$ is the moisture reading value,

the intercept $\beta 0 = 4.597$,

the moisture component $\beta 1 = -0.0364$,

and y is the calculated roughness value.

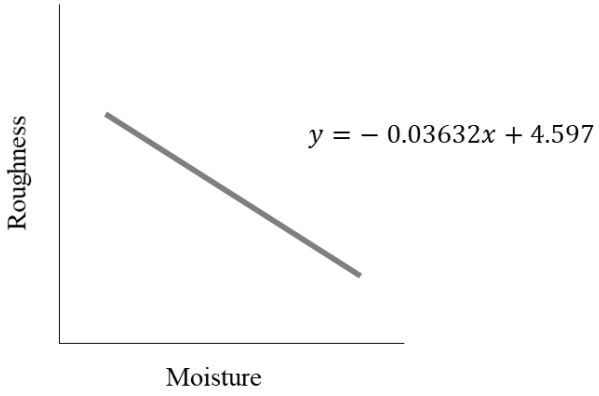


*Figure 1.4.6 - A proposed linear model for the moisture-roughness relationship of human volar forearm skin.*

A healthy skin barrier is one which maintains hydration and regulates the moisture properly; participant P4 likely has low-level impaired barrier function due to an inability to regulate the moisture which has led to the skin being rougher than the other participants. The scatterplot shows a strong statistically significant 'high degree' negative linear correlation between skin moisture and roughness, r = -0.79, $p$ <0.0001. The analysis also was conducted with P4 excluded from this dataset, and the linear relationship remained significant with $r$ = -0.59 and $p$ = 0.0161. Conducting this analysis proved that higher skin hydration is associated with a smoother surface profile and these results are visible on a microscale. This strong correlation of moisture and roughness indicates moisture can be used to obtain or even

predict information about skin roughness. Moisture has been found to effect the skin morphology, which in turn could impact the friction. These findings confirm the pre-existing assumptions that SC water content plays a crucial part in skin roughness [17-19]. Additionally, the findings confirm that using *VivoSight* and the MATLAB algorithm is a suitable non-invasive tool to assess skin roughness and changes in skin roughness over time.

As far as the author is aware this is the first time the roughness-moisture relationship has been shown of skin in a population of individuals with healthy untreated skin. In other research differences in skin roughness caused by treatments, surfactants, or medical conditions such as eczema or psoriasis have been studied and reported [20-22]. Later in the chapter, a scatter plot shows the moisture-roughness relationship of treated skin from TS2, see Figure 4.14.

### 4.2.6 Unrelated Properties of Baseline Skin Tests

The tests also revealed that no relationships were found between a few of the measures: hydration-deformation, CoF-roughness, and roughness-deformation. See Figure 4.7, Figure 4.8, and Figure 4.9 for more information.

*Hydration and deformation*

For untreated skin no relationship was found between skin hydration and deformation values, with a very low regression coefficient of $r = 0.034$, see Figure 4.7. The Young's modulus of skin has been found in literature to reduce with the addition of water, meaning it becomes more flexible, however, in the case of untreated natural skin in this experiment, higher natural skin hydration did not exhibit distinctly different extension compared to the dry skin sites. This result is surprising because the water content of the SC is very important in maintaining flexibility, and a lack of water can result in hard skin prone to flaking, splitting, and cracking. The Cutometer precision may be the cause of not detecting this relationship, or simply the location on the body studied was not distinctly different across participants. Measurements conducted on the heel of the foot or fingertips could prove to be better locations for investigating moisture-deformation relationships due to the thicker SC.

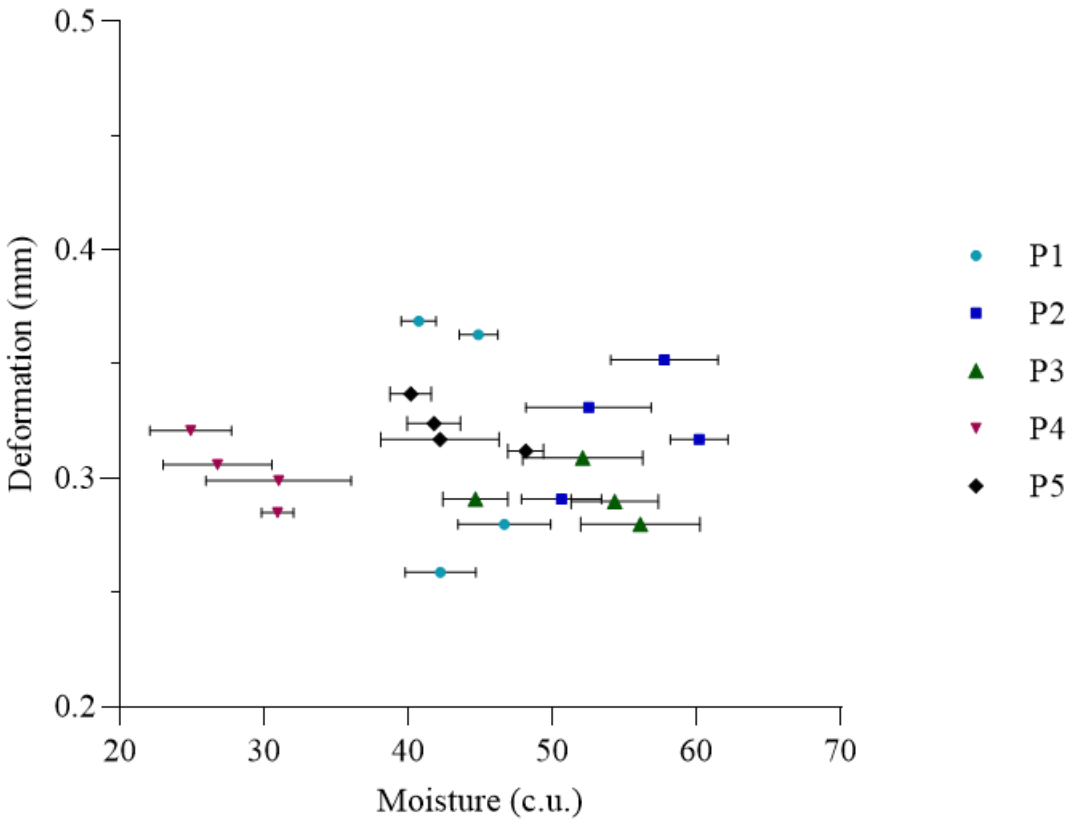


*Figure 4.7 - Moisture plotted against the deformation for each skin site of each participant in TS1, r = 0.034, p = 0.885*

*Friction coefficient and SC roughness*

The results showed there was no relationship found between the DCoF and SC roughness, with a regression coefficient of $r$ = -0.007 and $p$ = 0.979, see Figure 4.8. Other skin properties of moisture and deformation were instead found to be the dominating components which directly impacted the friction coefficient. Klaassen *et al*. [23] found that soft materials exhibit only minor CoF change in response to surface roughness due to the easy compressibility of the asperities. Egawa *et al*. [24] also showed skin surface roughness of the volar forearm did not directly correlate with CoF

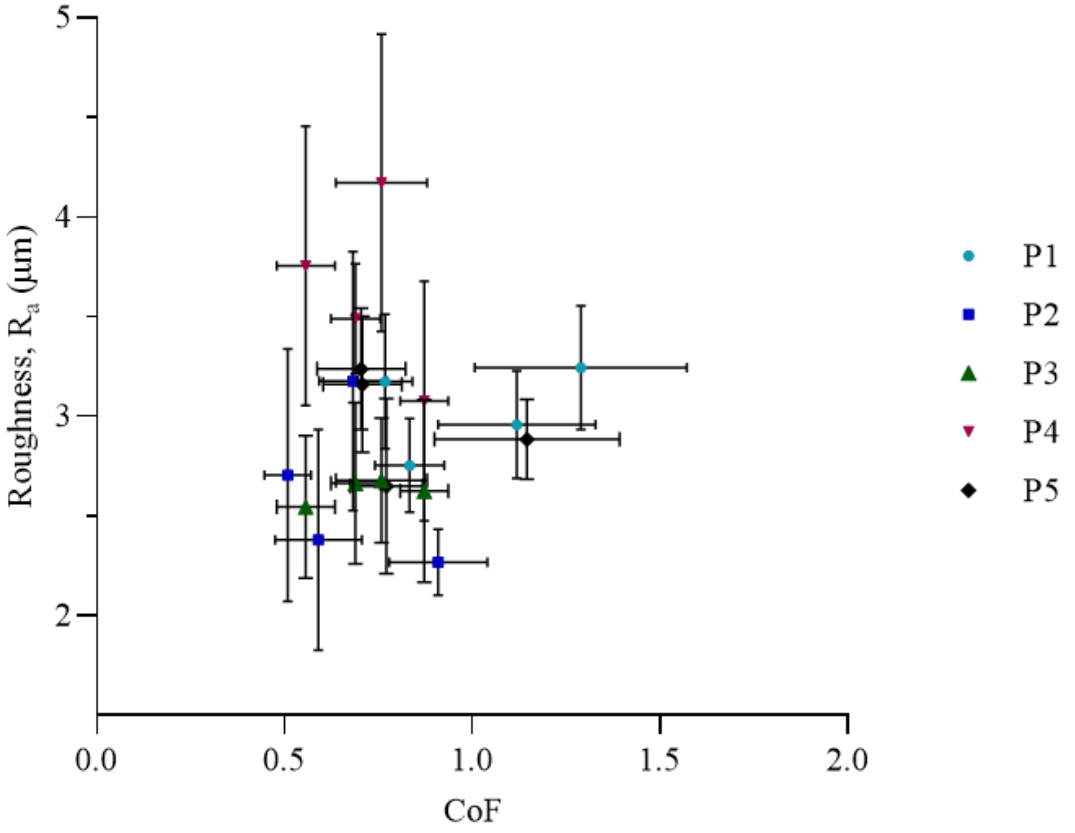


*Figure 4.8 - CoF plotted against roughness for each skin site of TS1, r = - 0.0065, p=0.979.*

*Roughness and deformation*

For untreated skin, no relationship was found between the skin roughness and the deformation values, $r = 0.0052$, and $p = 0.987$, see Figure 4.9. This finding may hold true, or other possible explanations for this result are that not enough measures were taken for determining the deformability of each skin site, or the *Cutometer* was not a sensitive enough device to gather truly representative data.

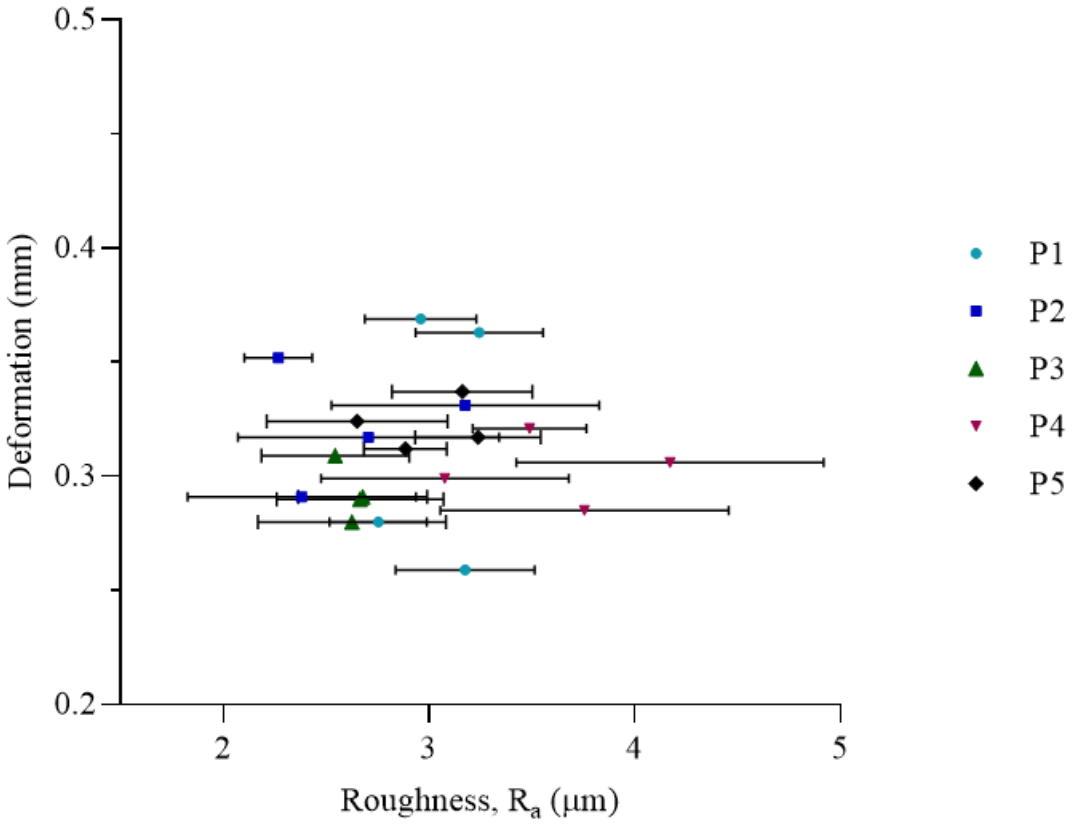


*Figure 4.9 - Deformation plotted against roughness for each skin site of TS1, r = -0.0052, p = 0.987.*

## 4.3 Test Session 2: Skin Treatments Results

This section evaluates the effects of topical treatments on the volar forearm roughness, moisture, CoF, and deformation. When analysing changes in the skin due to the application of treatments, the participant results were separated into two groups, 'dry' and 'normal', based on the natural skin hydration levels reported in the test session. This is because the participant with drier skin was found to respond differently to the treatments, for example, they displayed exaggerated percentage increases in hydration and friction following the application of glycerol. Each figure presented within Sections 4.3.1 to 4.3.4 is composed of four graphs, those marked a) and b) show floating bar charts, where each box indicates the range, and the horizontal bar within the box denotes the mean. This type of graph has been used to display data for the four participants ($n$ = 4) with 'normal' skin hydration. The bar charts in Figure 4.10 labelled c) and d) show the mean data for P4 with drier skin. The skin measurements presented in Figure 4.10 a) and c) show the mean experimental values, and b) and d) show the mean percentage changes that occurred from baseline levels in TS1 to those taken in TS2 where different topical treatments had been on the skin for 4-hours.

### 4.3.1 Changes in Skin Topography Following the Application of Treatments.

The roughness ($R_a$) values are presented in Figure 4.10 a) and c). In total 200 images per skin site were taken, and 15 good quality images per site were processed using the MATLAB code to provide average $R_a$ values for site roughness. Figure 4.10 b) and d) shows the SC roughness percentage change for each treatment.

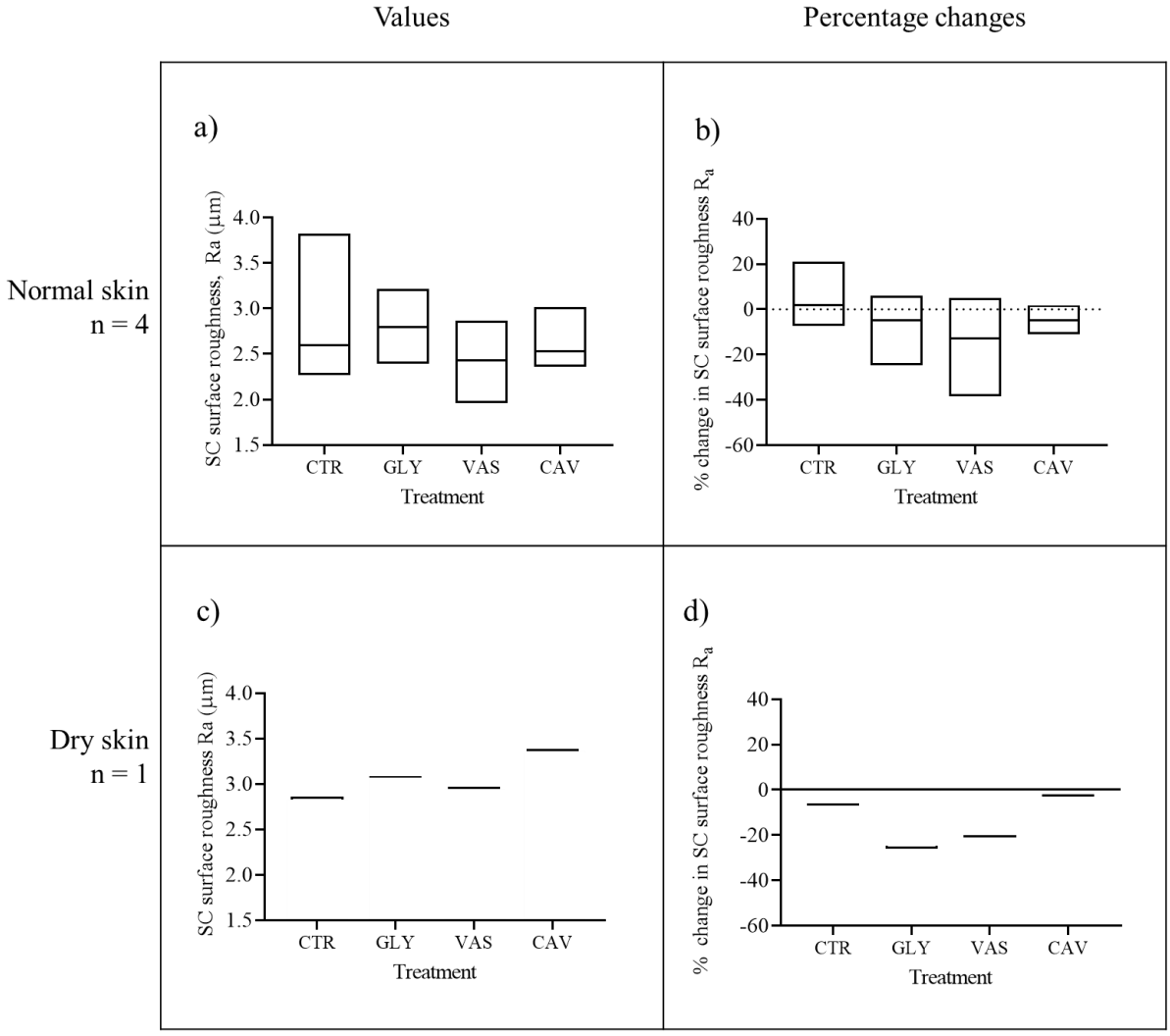


*Figure 4.10 - The $R_a$ values and changes for roughness across five participants. Boxes a) and b) present floating bar graphs for four of the participants with 'normal' skin hydration. The range of values is represented by the height of each of the bars, with the mean being shown by the horizontal line across each of the bars. c) and d) both show data from the single participant (P4) with 'dry' skin. a) and c) show the surface roughness values, b) and d) show the change in surface roughness as a percentage from the initial baseline tests, t-tests showed no statistically significant changes occurred for any of the treatments.*

In Figure 4.10 b) the application of *Vaseline* caused a varied response in participants in the percentage change of surface roughness between TS1 and TS2. This was indicated by the large height of the floating bar, known as the interquartile range. *Cavilon* had the effect of retaining the skin close to its

baseline state of roughness, as shown by the small range and a low mean percentage change in roughness, see Figure 4.10 b) and d). This finding could be due to *Cavilon* having no hydrating effect on the skin, an effect later discussed in Section 4.3.2. As *Cavilon* did not provide additional hydration then the roughness would also not be expected to reduce, according to the strong correlation between moisture and roughness found previously in Figure 4.5.

The results in Figure 4.10 b) indicate that on average the application of *Vaseline* smoothed the skin more than any other treatment. All treatments were found on average to reduce the skin site roughness values between TS1 and TS2; however, no statistically significant changes were detected in two-tailed t-tests. The percentage changes shown in Figure 4.10 b) and d) show that for both normal and dry skin the glycerol and *Vaseline* on average decreased skin roughness and had a particularly strong effect on some individuals.

Figure 4.10 c) shows that for P4 the *Cavilon* site had a higher roughness value than any other treatment site, however as we can see from Figure 4.10 d) there was very little change in roughness from baseline conditions, indicating that it was a naturally rougher site of skin on this participant rather than it being rougher due to application of a treatment. Figure 4.10 d) shows that the glycerol site of P4 had the highest percentage decrease in roughness, followed by the *Vaseline* site, whereas the control and *Cavilon* sites remained much unchanged. For 'normal' skin *Vaseline* reduced the roughness the most, followed by glycerol. For P4 all of the treatments reduced roughness; this is most likely due to dry skin responding in a more exaggerated way to treatments.

Glycerol is a very effective and widely used humectant used to hydrate skin, which operates by attracting environmental water vapour into the uppermost skin layers, and endogenous glycerol also attracts water into the upper layers of the skin as it migrates towards the surface [25]. Occlusive treatments like *Vaseline* allow more moisture to be retained in the SC because they reduce transepidermal water loss. Instead of water evaporating from the SC to the environment, it is retained and continually replenished by the deeply skin layers. Structurally, the higher water content achieved through application of moisturisers therefore causes the resulting plumping and smoothing of the surface profile of the SC.

### 4.3.2 Changes in Moisture Following the Application of Treatments.

Figure 4.11 a) shows that the inter-participant control site moisture level readings had a higher range than those of any of the sites containing treatments. The comparably smaller range of moisture values within the treatment sites of TS2 indicated that the application of treatments may have balanced the skin to a more predictable level, despite the differences between participants in their initial skin moisture levels. This finding is useful because it indicates that applying a treatment is more likely to result in set

window or category of moisture in which the majority of people fall, compared to leaving a skin untreated. For the participant with 'dry' skin, see Figure 4.11 d), the application of glycerol and *Vaseline* elevated sites into a 'normal' skin hydration category. Both the control and *Cavilon* sites remained within the dry categories.

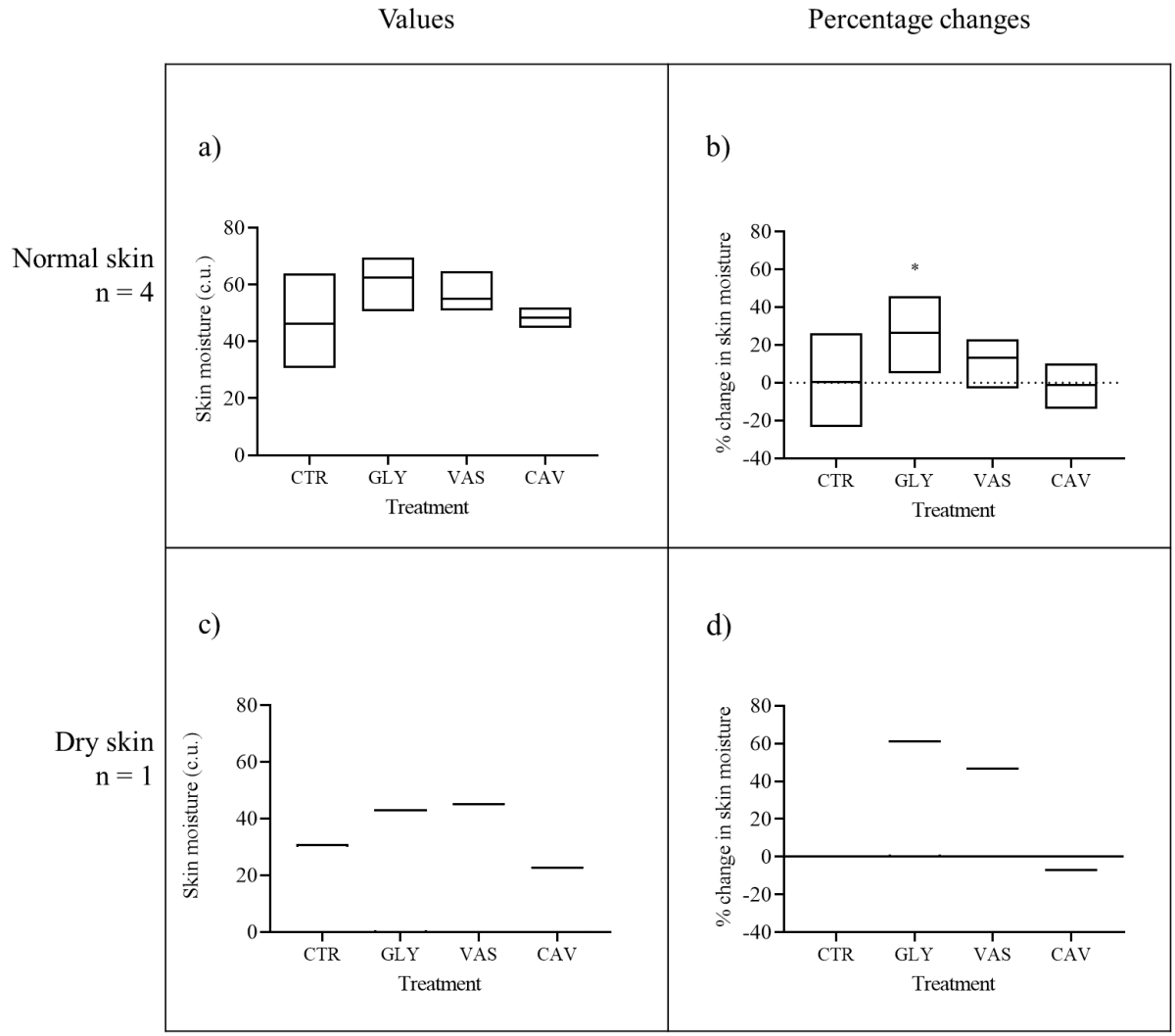


*Figure 4.11 - Figure showing the values and changes for skin moisture levels across five participants Boxes a) and b) present floating bar graphs for four of the participants with 'normal' skin hydration. The range of values is represented by the height of each of the bars, with the mean being shown by the horizontal line across each of the bars. c) and d) both show data from the single participant (P4) with dry skin. Boxes a) and c) show the moisture values in c.u ,and b) and d) show the change in skin moisture as a percentage change from the initial baseline tests. In d) the control site percentage change was 0.016 % therefore the bar is not visible on the chart. Notation of an asterisk * indicates statistical significance, $p<0.05$ for a two-tailed t-test.*

The only treatment that had a statistically significant effect on the skin moisture was glycerol, as seen in Figure 4.11 b). All participants experienced an increase in moisture levels on the skin sites containing this solution. Other studies have found glycerol to have a hydrating effect, Fluhr *et al*. [26] and Chrit *et al*. [27] found that glycerol increased the hydration throughout the entire thickness of the SC. The

improvement in skin hydration with glycerol, as seen in Figure 4.11 b) and d), is one of the desirable effects achieved through the application of moisturisers for cosmetic purposes. However, for a skin-pad relationship increased moisture may be undesirable, as it causes intracellular expansion of the corneocytes and intercellular expansion between the corneocytes, an effect known as 'bulking' [25]. With this excess hydration beyond a natural state the 'bulking' effect could cause the friction coefficient in the interface to rise, giving way to greater shear loading of the skin. In the skin-pad interface this could be the difference between an individual suffering from mild IAD symptoms or potentially having more severe symptom develop.

Application of *Vaseline* on average increased skin hydration, but to a lesser extent than glycerol. Similarly, Dobrev [28] found glycerol to show the most pronounced changes compared to the other moisturising treatments applied to the skin (including petrolatum). The TS2 control site showed great variation in moisture percentage changes from TS1, although the mean levels remained largely unchanged. The finding that half of the participants experienced a decrease in the control site moisture levels and the other half an increase shows how much skin moisture levels can change on a given individual's skin, even without the presence of treatments.

For the participant with 'dry' skin (P4), see Figure 4.11 c), the application of glycerol and Vaseline raised the moisture levels of the sites so that the skin categorisation changed from 'very dry' to 'normal'. The *Cavilon* site remained in the 'very dry' classification category. The results in Figure 4.11 d) show glycerol increased the moisture levels by ~60%, *Vaseline* by over ~50%, and *Cavilon* was shown to cause a slight decrease in moisture levels of ~10%. These 'dry' skin findings were in agreement to the pattern found in 'normal' skin, where glycerol hydrated the skin the most, followed by *Vaseline*, and then *Cavilon* treated sites on average had decreased moisture levels compared to TS1.

It could be expected that in the period of time post-application of a substance to the skin that contains humectants and/or occlusives, that the result would be increased hydration. However, as observed in Figure 4.11, it can be seen on average there was no change for *Cavilon* sites from the baseline moisture levels taken in TS1 despite the complex formulation of *Cavilon* containing both glycerol and petrolatum.

These results suggest that the moisture levels of skin become more predictable once a treatment has been applied, so therefore friction and roughness behaviours could in theory become more predictable, due to their intrinsic relationship with moisture. If skin characteristics across a population becomes less varied around a mean moisture level, then a tribosystem behaviour may become more consistent and predictable leading to more sophisticated tribological models being developed, especially useful for the development of skin treatments or selecting constituent ingredients.

Application of *Cavilon* resulted in the smallest range of inter-participant hydration levels, between 44-52 c.u.. This small range of moisture levels found across the *Cavilon* sites is quite remarkable given the

control site range was a lot larger (30-64 c.u.). Control sites also had a greater percentage change than the *Cavilon* sites between TS1 and TS2, see Figure 4.11 b). This finding could be due to *Cavilon* providing a barrier of protection against environmental conditions, e.g. humidity, or perhaps interfering with the endogenous glycerol mechanisms. *Cavilon* is a widely used and clinically approved barrier treatment; the finding that it has measureable differences in effects on hydration when compared to glycerol, *Vaseline*, and the control sites, shows that the protective mechanism of the complex formulation might arise partly due to the effect on the skins hydration when the treatment is applied. Application of *Cavilon* gave skin an average moisture of 47 c.u. which could be an optimum skin moisture level benchmark to maintain skin integrity in the skin-pad interface. For a pre-clinical assessment any newly developed treatment could undergo small scale testing to determine its suitability in terms of maintaining stable hydration levels. If hydration were to vary greatly across a group of people, then it could be predicted that the treatment would not perform optimally in the skin-pad interface to reduce or prevent IAD.

Interestingly, as well as being a barrier treatment for incontinence, *Cavilon* is also listed as being a moisturiser for severely dry skin [29], however results in this work show it was not found to have a moisturising effect, and for the participant with very dry skin the moisture levels of the *Cavilon* treated site decreased.

### 4.3.3 Changes in Friction Coefficient Following the Application of Treatments.

The application of skin treatments demonstrated an ability to alter the tribological properties of the skin, as shown in Figure 4.12. A multitude of other research studies involving human skin and other surfaces and treatments have revealed the extent to which skin interfaces can be altered [30-34]. In this study, the skin treatment sites had higher dynamic friction coefficients than the control sites. Treated sites also experienced a greater percentage increase in friction coefficients on average than the control sites. In terms of a percentage change from the baseline, Figure 4.12 b) shows that application of glycerol and *Vaseline* resulted in a statistically significant increase in CoF for all participants.

*Cavilon* application also increased the average CoF, however with a more varied response as shown by the high range of the data. The y-axis of Figure 4.12 d) is on a different scale to Figure 4.12 b) because the percentage change in the CoF of the glycerol site was greater that a 400% increase for P4. Figure 4.12 a) shows the control sites for all four participants had friction coefficients below 1.0, but with the treatments applied the CoF on average was greater than 1.0. The mean of the glycerol treatment sites CoF was also higher that both the control site and the other two treatment sites. Again, in dry skin the glycerol test site exhibited a far greater CoF than all three other sites. *Vaseline* only had a slightly higher

CoF than the control site, so it is difficult to say whether it had an overall effect as the small change could possibly have been due to the natural properties of the skin.

The glycerol values were found to not overlap the control site values, as seen in Figure 4.12 a), so glycerol can be seen to have raised the dynamic friction coefficient beyond what would typically be experienced on untreated skin. Glycerol increased the friction coefficient from baseline levels, see Figure 4.12 a), and the mechanism by which this happened could have arisen from physiological changes, such as 'bulking', or possibly due to a residue residing on the skin in a very thin film which could cause changes in the interface. Glycerol is a very sticky sugar substance, and when mixed with water into a dilute 10% solution it is easily applied to the skin. Post-application the water evaporates, and a film of glycerol remains. This is not visible to the naked eye 4-hrs after application; however, if it does remain on the skin then it could be a contributor to the higher CoF.

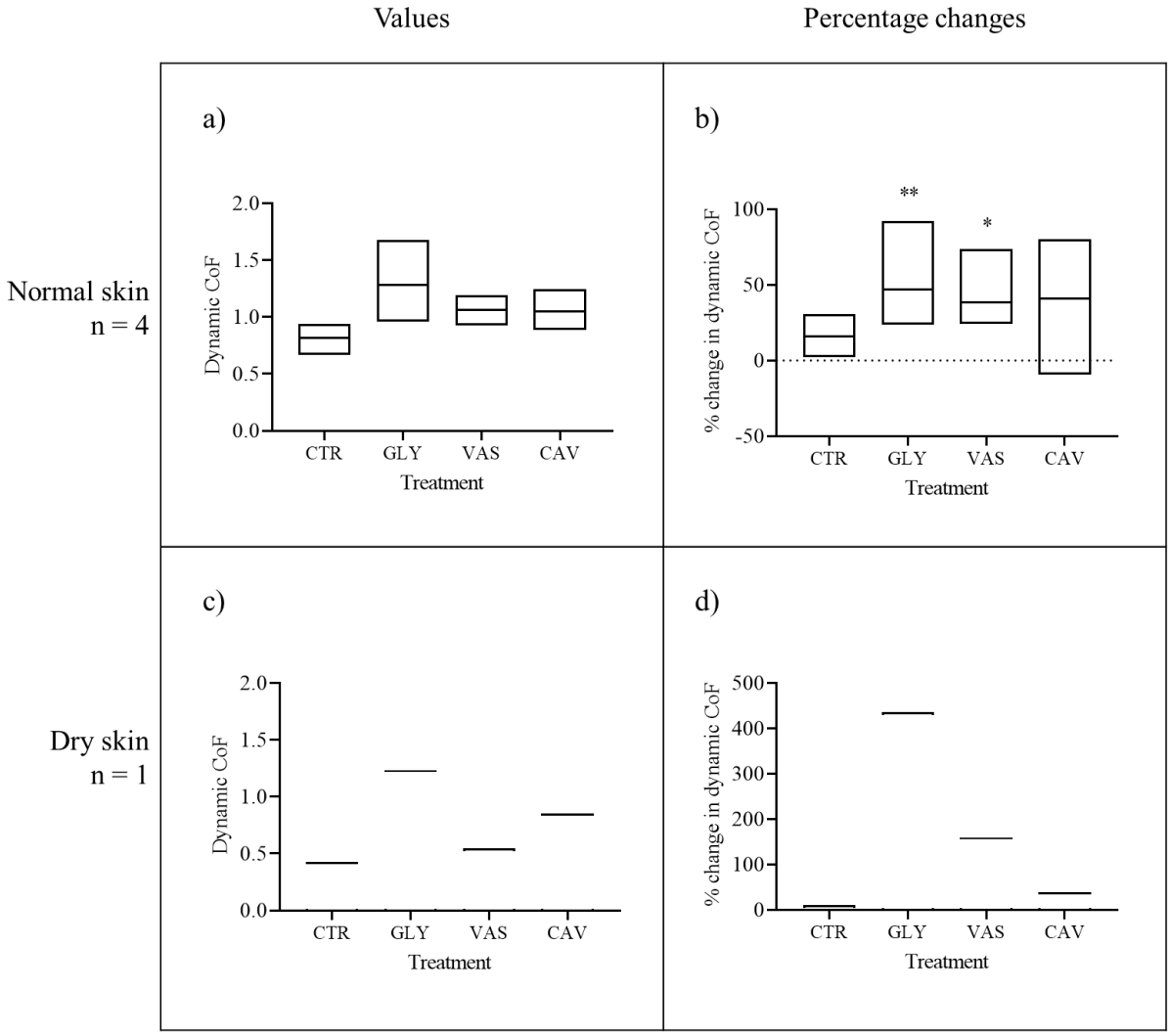


*Figure 4.12 - Figure showing the values and changes for dynamic friction coefficient across five participants. a) and b) present floating bar graphs across four of the participants with 'normal' skin hydration. The range of values is represented by the height of each of the bars, with the mean being shown by the horizontal line across each of the bars. c) and d) both show data from the single participant (P4) with dry skin. Again a) and c) show the value of the friction coefficient, b) and d) show the change in CoF as a percentage change from the initial*

*baseline tests. Notation of an asterisk * indicates statistical significance, p<0.05 for a two-tailed t-test and ** where p<0.0001. Note: b) and d) are on different scales because the application of treatment to dry skin caused significant changes to the CoF from the baseline friction coefficient levels.*

The glycerol and *Vaseline* sites increased in CoF by a statistically significant amount. The increase in CoF 4-hours after application of *Vaseline* is in agreement with Nacht *et al.* [33] who found that petrolatum initially provided a lowered friction response due to the lubricating properties, but after 1-3 hours these effects wore off which is when the CoF increased past a normal level, indicative of a higher moisture content. The change of friction properties in the short-term application of treatments poses questions into the suitable reapplication time of skin treatments used to treat incontinence-associated dermatitis. Barrier preparations used to manage skin damage have different reapplication guidelines depending on the individual manufacturer's guidelines, for example in the case of *Cavilon* it is recommended to be applied every 48 to 72 hours, or every 12 to 24 hours for severe incontinence or broken skin.

The CoF of the control sites increased slightly from TS1 to TS2, which is challenging to explain based on the other parameter findings. For example, from baseline levels the average percentage change in moisture of the control sites was close to zero, and the percentage change in deformation was lower; both measures of which were found to be positively correlated with CoF in TS1 results. However, the percentage change in the control site CoF values was much lower that of the other treatment sites, so this variation in the control sites could be down to natural variations of skin, e.g. climatic conditions outside of the laboratory environment, or even levels of physical activity of each of the participants prior to the test sessions.

The mean friction coefficient of the *Cavilon* site also increased, however the range of values was so large across the four participants that the results were not statistically significant. Why *Cavilon* produced such a varied friction response is difficult to explain, but perhaps because the formulation is complex then the constituent ingredients caused a varied response depending on the individual that the product was applied to. Certain constituent ingredients interact differently with the surface and top layers of the skin, making it difficult to determine what part of the formulation is having an effect. For this very reason topical skin formulations are very successful in achieving their purposes of hydration, reducing fine lines, softening, and firming in some individuals, yet provide little to no benefits in others. The wide range of ingredients make it difficult to distinguish which ingredients are beneficial, explaining why a trial and error is often an approach for individual consumers to find the right skincare products.

From this experiment it can be seen that glycerol increased the moisture and friction coefficient, so there is potential that if this substance was solely applied to the skin then it would cause excessive shear due to the increased friction. However, in the skin-pad interface of incontinence sufferers these

circumstances are unlikely to occur as it is not recommended that a 10% glycerol solution be applied by itself to the skin. Humectants are a common ingredient in many skin treatments, so if a barrier product were to be selected in wound management, based specifically on these results, then a treatment with a lower percentage of humectant levels would be advised. This research is not representative of all skin types, and is not condemning the addition of humectants to treatments; they are a very important ingredient in skin care products for use on the body and face due to their ability to hydrate, soften, and smooth the skin, an important factor in their widespread use for beauty purposes. Though, products in the beauty skin care industry serve a different purpose and require different functionality to those of medical purposes. In light of the Covid-19 pandemic the issue of commercial moisturising cream usage with PPE face masks has been investigated for their impact on skin health. Creams are designed to not leave a greasy residue leading to no lubricating effect and instead high shear due to softening and plasticisation, resulting in an increased contact area [35], causing high friction and in turn high shear forces to develop. PPE-related skin damage is common and therefore guidelines are needed on recommended topical treatments which are able to be worn during PPE wear without causing skin injury.

### 4.3.4 Skin Deformation Changes Following the Application of Treatments

The maximum extension of skin under a set negative pressure was investigated and the results are shown in Figure 4.13. The maximum extension of the skin is an indicator of the skin's firmness; a value close to 0 mm indicates firmer skin.

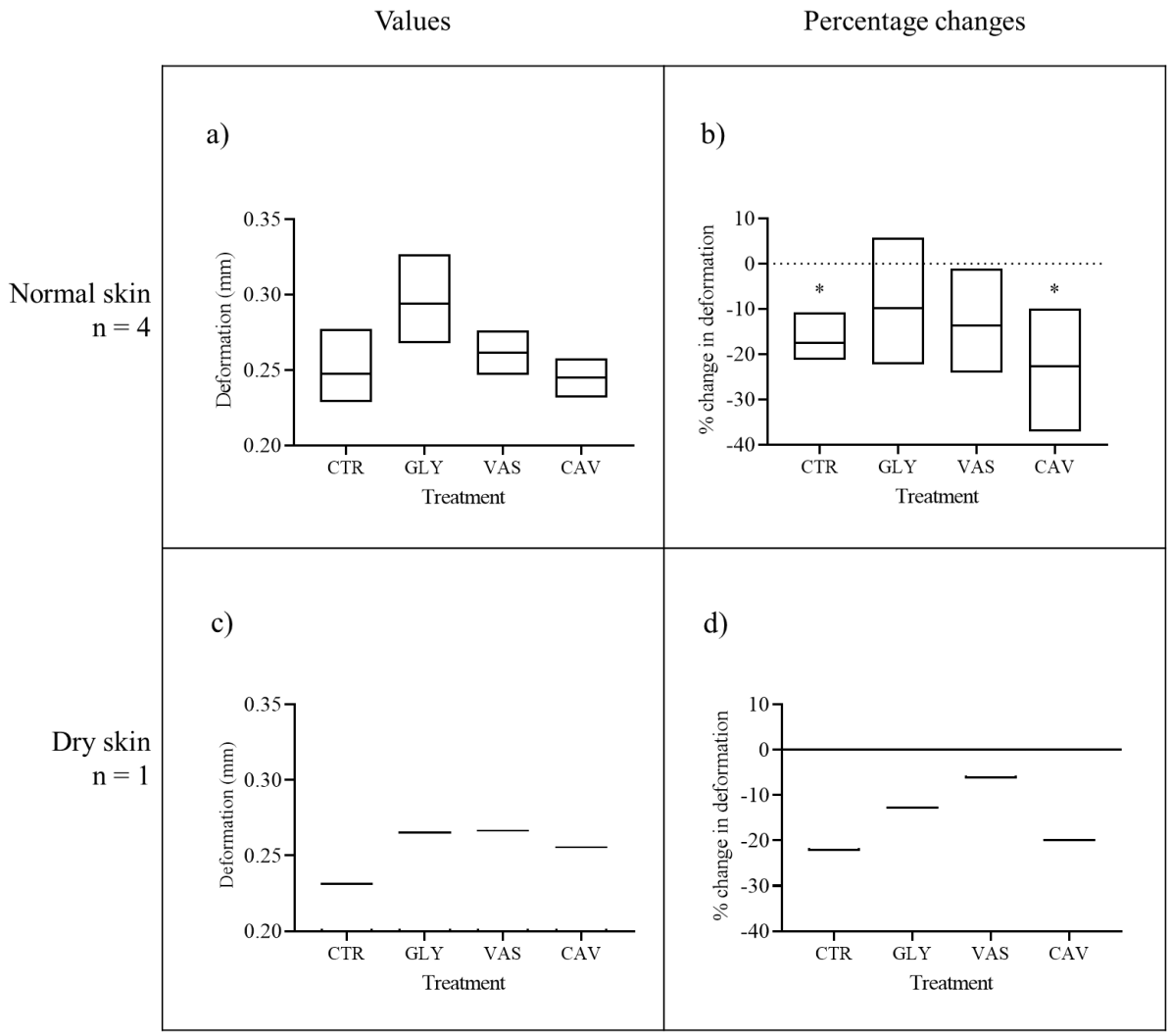


*Figure 4.13 - The values and percentage changes for deformation (extension) across five participants. a) and b) present a floating bar graph across four of the participants with 'normal skin' hydration. The range of values is represented by the height of each of the bars, with the mean being shown by the horizontal line across each of the bars. c) and d) both show data from the single participant (P4) with dry skin. Where a) and c) show the deformation values, and b) and d) show the change in extension as a percentage change from the initial baseline tests. Notation of an asterisk * indicates statistical significance, $p<0.05$ for a two-tailed t-test.*

For participants with normal skin hydration, see Figure 4.13 a), the glycerol site had greater extension on average than other sites. The mean deformation of the glycerol sites was 0.294 mm, whereas the control, *Vaseline*, and *Cavilon* sites had mean deformation values of 0.247, 0.261 and 0.245 mm, respectively. Mechanical properties of the skin have been shown to change with application of glycerol in several studies, and the mechanical properties of the SC are widely reported to be mainly influenced by hydration, whereas the underlying layers tend to maintain comparatively stable levels of hydration. Due to the ability of a topical treatment to alter hydration levels, this in turn has an influence on the mechanical properties and the friction of the skin. Pedersen and Jemec [36] found that the immediate effects of both water and glycerol exposure on the volar forearm were found to increase the deformability of skin both 3-minutes and 15-minutes after exposure. The results in this study found that

the glycerol test sites in TS2 had the highest average values of extension compared to the other skin sites. *Vaseline* and *Cavilon* application resulted in participant skin deformation values that were closely clustered together about the mean, indicated by the smaller box heights (i.e. lower standard deviation), showing that the application of these treatments could result in skin having a more predictable biomechanical response to the application of negative pressure.

Figure 4.13 b) shows that the maximum deformation of the sites (including the control site) reduced between TS1 to TS2. All participants showed a 10-20% decrease in extension on the control sites, which may have been in response to activity levels, deeper tissue hydration levels, or a multitude of other factors that could have impacted the biophysical properties of the skin between the two test sessions. The variability of the percentage change in extension from TS1 to TS2 was far greater sites containing treatments compared to the control sites, indicated by the height of the bars. This is a reminder increases or decreases in skin property measures in response to adding a treatment can be more amplified depending on the individual that they are applied to. The control and *Cavilon* sites both had a statistically significant decrease in deformation, as shown in Figure 4.13 b), highlighting again that the application of *Cavilon* has retained the similar characteristics to the untreated skin, which was found to also be the case with the hydration and SC roughness. The range of the percentage change in deformation values when skin sites were treated with *Cavilon* was large (i.e. a large spread of the participant data points), and all four participants experienced a percentage decrease in the maximum extension of the skin.

Figure 4.13 c) demonstrates that deformation values for dry skin respond in a similar way to normal skin; where glycerol and *Vaseline* sites extended more than the other sites. Figure 4.13 d) also shows similar results to b) where the control and *Cavilon* sites both were firmer in TS2 than in the baseline tests. Both Figure 4.13 b) and d) suggest that the application of glycerol and *Vaseline* encourage skin to retain a higher level of deformability beyond which it would naturally have without treatment. Application of glycerol and *Vaseline* were also both found to increase hydration, see Figure 4.11 b), and reduce roughness, see Figure 4.10 b). The increase in moisture and flexibility of skin agrees with previous literature findings that the Young's modulus of skin reduces with the addition of water [28, 37-39].

Overall looking at a) and c) the glycerol and *Vaseline* sites were found to have higher amounts of deformability relative to the control site, and *Cavilon* sites on average did not behave much differently to the control. The changes in deformability that the skin undergoes in response to treatments are important because they can have implications on the friction mechanisms that occur in the skin-pad interface. Skin that is better able to deform is likely to also undergo greater shear, and exhibit more stick-slip behaviour than firm skin, which in a skin-pad environment is undesirable as it puts skin at

greater risk of becoming damaged. *Cavilon* could act in a protective way, partly by preventing skin deformation by having a firming effect on the epidermis. In states of hyperhydration, like exposure to urine, the skin is potentially more likely to retain its baseline mechanical properties if *Cavilon* were to be applied to the skin.

## 4.4 Test Session 2: Other Findings

This section describes additional findings from the experiments conducted in TS2 and examines whether linear relationships exist between the properties measured on each skin site in the presence of the different skin treatments.

### 4.4.1 Moisture and Roughness

After treatments were applied to the skin, the negative correlation between skin roughness and moisture still resided though the correlation coefficient was lower, indicating a slightly weaker linear relationship than that of untreated skin, results are shown in Figure 4.14.

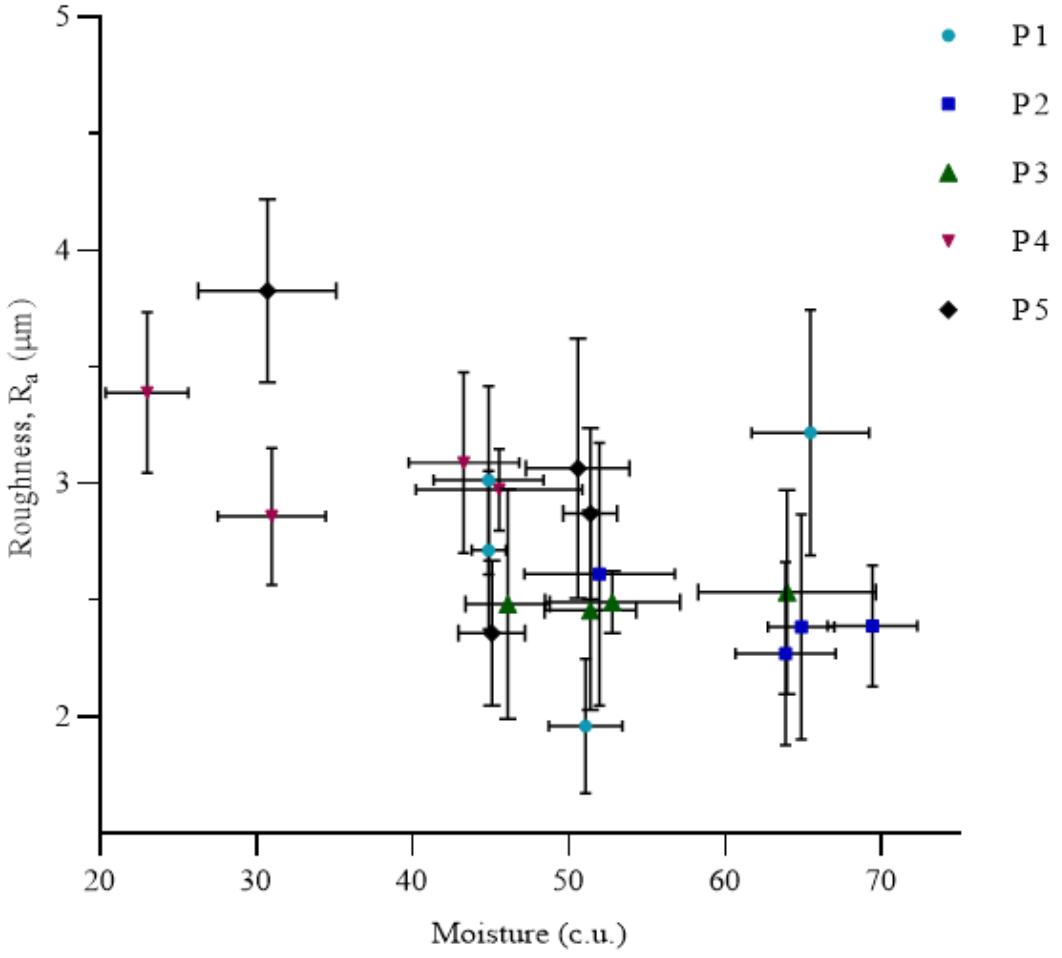


*Figure 4.14 – Plot of moisture against roughness for TS2, r = -0.57 p = 0.009.*

### 4.4.2 Moisture and Friction Coefficient

Figure 4.15 shows a moderate degree of positive correlation between moisture and friction when treatment was applied to the skin, and it was a similar correlation coefficient to that reported in the baseline tests where $r = 0.38$. This may be because when treatments are added, in most cases they increased skin moisture and friction for each person, and in this case they changed proportionally together giving rise to a similar linear relationship.

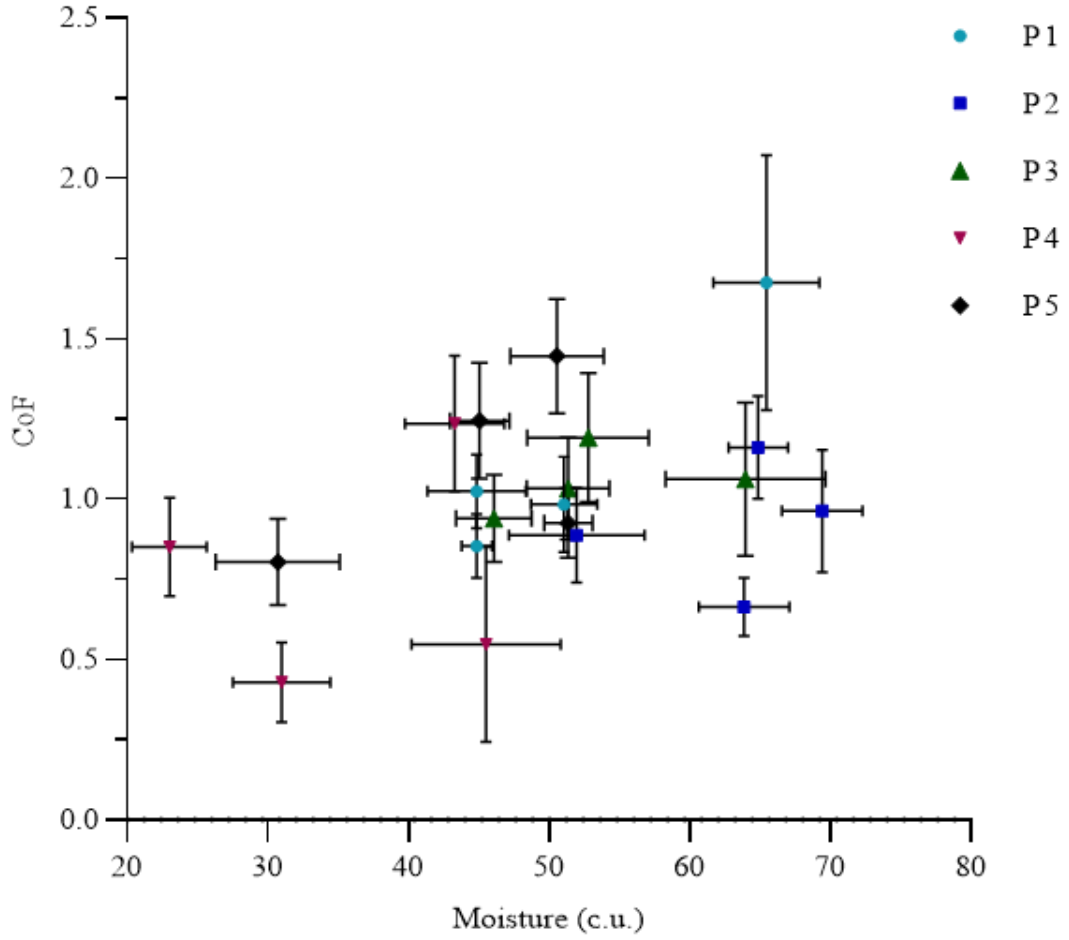


*Figure 4.15 – Plot of friction coefficient against moisture readings for TS2, r = 0.41 p = 0.070.*

Figure 4.15 shows a moderate strength correlation between skin moisture and CoF, though the relationship was not statistically significant ($p > 0.05$). When comparing this figure with Figure 4.2 from TS1, it can be seen that the participant whose skin experienced the greatest friction changes between sessions with the addition of treatments was P4.

### 4.4.3 Deformation and Friction Coefficient

Figure 4.16 shows a moderate degree of positive correlation between deformability of skin and friction when treatment was applied, though not statistically significant. The regression coefficient *r* was lower to that reported in the baseline tests where $r = 0.46$, $p < 0.05$. As an overview, it appears that when treatments are added to the skin then changes in conformability are likely to have an impact on the recorded CoF, to a similar extent those of the natural untreated skin states of the five participants.

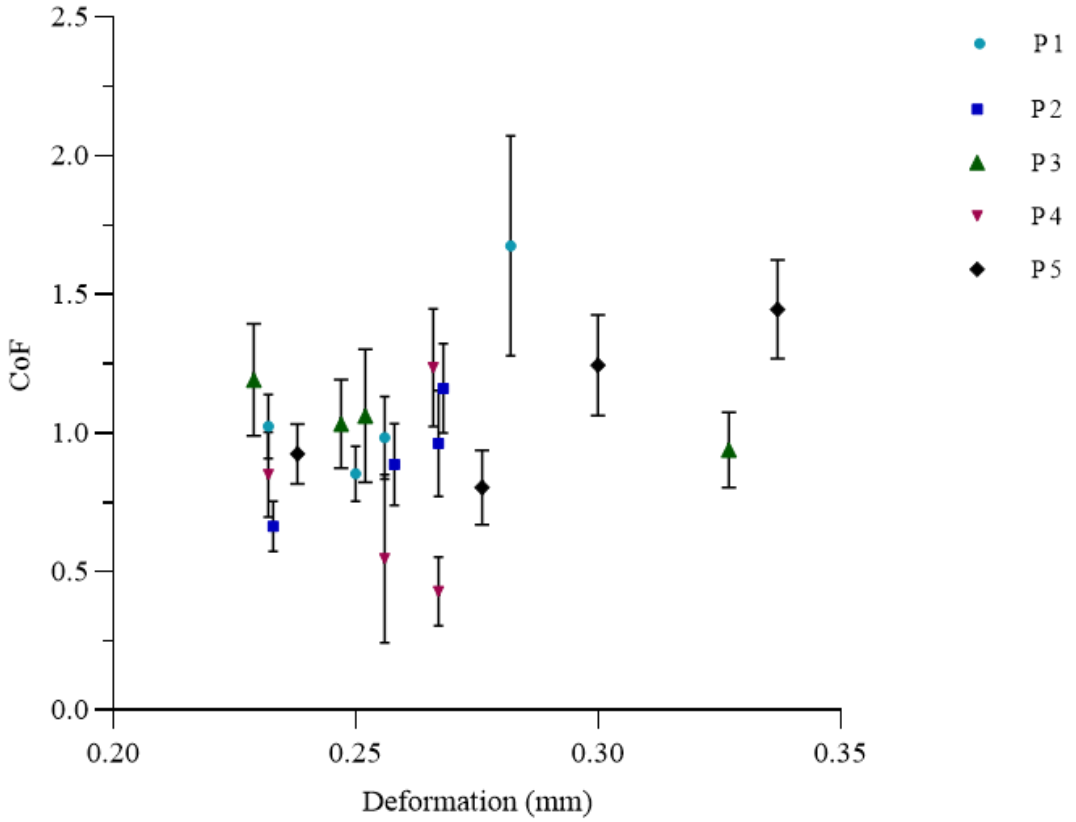


*Figure 4.16 – Plot of friction coefficient against skin deformation for TS2, r = 0.389, p = 0.090.*

### 4.4.4 Deformation and SC Roughness

Figure 4.17 shows a moderate degree of positive correlation ( $p < 0.05$) between the deformability of skin and SC roughness when treatments were applied. This indicates that a relationship may have been ignited between roughness and deformation; an observation that did not previously exist in the natural baseline properties of untreated skin recorded in TS1.

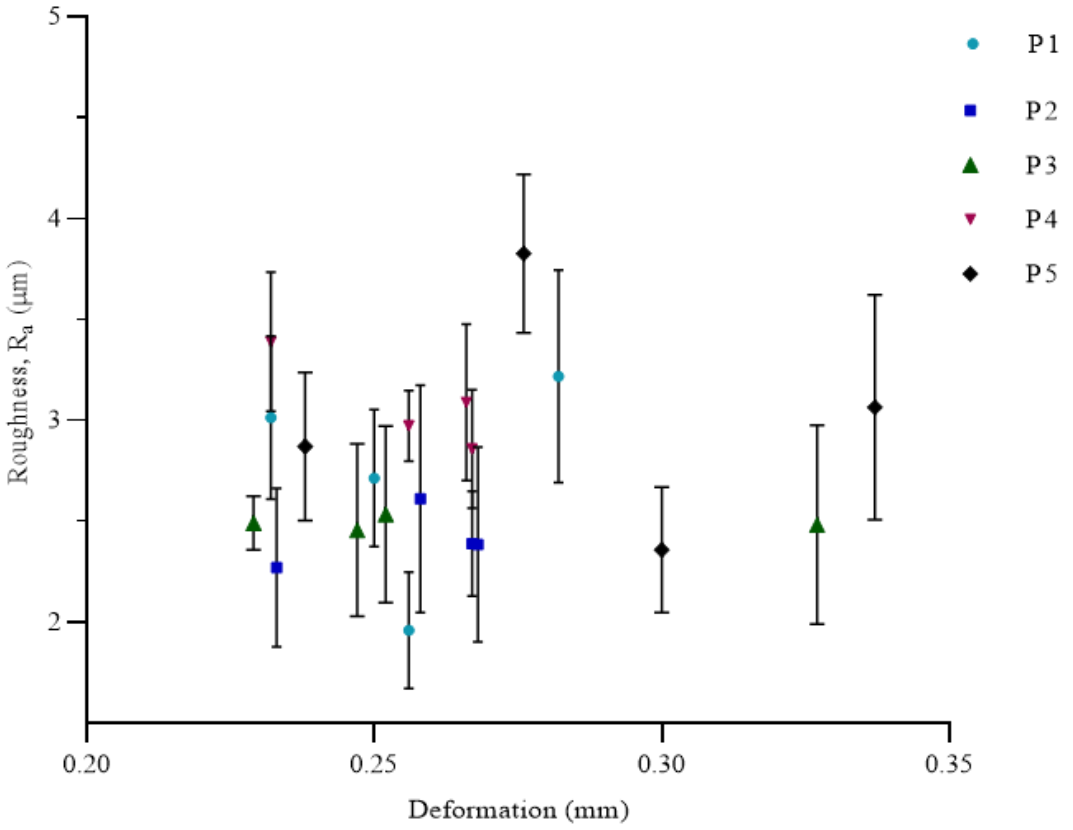


*Figure 4.17 – Plot of SC roughness against deformation for TS2, r = 0.469, p = 0.037.*

As skin deformability decreases the roughness of the skin also decreases, a relationship that naturally makes sense because more taught skin would deform less. One would expect therefore for the moisture and deformation characteristics to also be linked, since such a strong correlation was found between roughness and moisture, but this is not the case; in untreated skin it was found that the deformation-roughness relationship was not correlated.

### 4.4.5 Properties Showing No Correlation

The results also showed that when treatments had been applied to the skin there were no relationships between SC roughness and the friction coefficient ($r$ = 0.025, $p$ = 0.950), or moisture and deformation ($r$ = 0.01, $p$ = 0.966). These same properties were also found to be unrelated in untreated skin measured in TS1, see Section 4.2.6.

## 4.5 Protocol Review and Learning points

Through the course of conducting this study, the protocol was assessed to determine the suitability for future use, along with improvements identified for conducting future experiments. The following points below present a protocol review and learning points to be considered for future experimental work.

*i. Friction rig protocol*

From the data analysis conducted in Chapter 3, it can be seen that the applied normal force varied across the stroke, however the DCoF extracted from the tests was found to be consistent, deeming it a suitable method for assessing the friction between the probe and the skin. Despite this consistent CoF it was identified in this study that in order to improve aspects of the friction tests, the future tests could involve an audio cue. Additionally, in reflection, the normal force variability could be reduced by altering the protocol to reciprocate the arm rather than conducting linear sliding repeats. Removing the need to lift the forearm from the rig and reapply the load would achieve a less volatile normal force. An audio cue would therefore be necessary to align strokes to guide a consistent duration of reciprocating movement.

*ii. Optical Coherence Tomography*

The OCT protocol and analysis technique were useful to report changes in skin topography, and of particular interest was the relationship between roughness and moisture, which has not previously been seen before in literature using this imaging technique. Enough high quality images were gathered to conduct a full analysis for each skin site. The combination of the *Corneometer*, the *VivoSight* resolution, and the data analysis process were sensitive enough to conclude a strong negative correlation between moisture and roughness of the SC. A linear model, $y = -0.03632x + 4.597$, was developed which was proposed as a tool to quickly calculate roughness values ($y$) from *in vivo* moisture readings. This reduces the need for time-intensive roughness measurements to be taken and analysed. This model may be particularly useful for researchers conducting *in silico* modelling of human skin who require roughness values to input as part of their model development.

*iii. Skin deformation*

In the future when conducting experiments to assess the deformability of the skin perhaps alternative methodology or equipment could be used to assess the amount of tissue or deformability of the subsurface tissue, rather than solely measure the superficial layers of the skin.

*iv. Participants and skin hydration*

The recruitment of P4 with very dry skin highlighted that a person's natural skin hydration has an impact on the way the skin responds to treatments. It has shown the importance in future work to consider participant recruitment based on people within similar bands of hydration. On the other hand, additional

insights could be gained by recruiting participants from different skin categories of moisture, 'very dry', 'dry' and 'normal' to see whether a linear or bell-shaped curve for moisture-CoF is more predominant. Additionally, recruitment of participants with 'dry' and/or 'very dry' skin in the future would likely to highlight and reveal clearer differences in treatment performance.

*v. Skin sites*

These tests showed that each skin site behaved differently from the surrounding skin sites e.g., sites L1-L4 all have different moisture, deformation, roughness, and friction measures, despite being skin from the arm of one individual. Therefore, when testing the effects of skin treatments, it is advised to study individual sites using before and after tests rather than having a control site versus a treatment site to compare against.

*vi. Interface conditions*

This experimental work studied skin changes in an ambient environment, rather than skin exposed to high humidity or immersed in water. It is not yet clear how products would perform if an artificial urine were to be introduced in the interface. This scenario is analysed later in Chapter 7 of the thesis, using an absorbent pad as the contact surface. Therefore, in future work the inclusion of artificial urine alongside treatment application could provide greater findings which are more significant and relevant to the skin-pad environment.

## 4.6 Conclusions

The frictional behaviour of the volar forearm against a steel probe in the presence of topical treatments was studied to provide a better understanding of the ways in which treatments alter skin properties, and how these relate to changes in the CoF. Participants were found to have inherently different baseline skin properties from one another, but despite these interparticipant differences, the individual treatments showed evidence of commonality in the way they altered the properties and tribological characteristics of the skin. A protocol was established for measuring forearm friction alongside other skin properties, and these were proven to successfully produce data and provide evidence for relationships that exist in untreated and treated skin. The findings are summarised below.

*Baseline untreated skin*

The developed protocols were successful in uncovering and providing evidence for relationships that exist between moisture, roughness, deformation, and the friction coefficient of skin. Some important findings were:

- Statistically significant relationships in untreated skin were found between deformation and CoF (positive correlation), and moisture and roughness (negative correlation).

- Untreated skin tests showed a moderate degree of positive correlation between moisture and CoF, though not statistically significant.

*Effects of skin treatments*

As a result of the application of skin treatments some important findings were:

- Glycerol significantly increased the skin moisture.
- Application of glycerol and *Vaseline* both resulted in a significant increase in CoF between the probe and the skin.
- After treatments were applied, the moisture-roughness relationship remained in agreement with the baseline findings of a statistically significant negative correlation. Also, the moisture-CoF relationship and deformation-friction relationship remained consistent with baseline tests, showing a moderate strength correlation coefficient after the application of treatments.
- In contrast to untreated skin, treated skin gave rise to a moderate degree positive correlation between deformation and SC roughness,
- Application of *Cavilon* made the skin of all participants behave in a more similar way to untreated skin i.e., it reduced the interparticipant variation in the skin properties evidenced by the narrowing range of the results. These findings have interesting implications for model development because by applying certain treatments, it could enable skin to behave in a more predictable manner in the skin-pad interface. More work needs to be done in this area to look at different barrier creams to see if they perform in a similar way to *Cavilon*.
- After drawing comparisons against glycerol, *Vaseline*, and *Cavilon*, it could be concluded that the use of glycerol could have a negative impact on skin integrity if applied on its own to the skin in a skin-surface tribological environment. However, in a typical cosmetic moisturising skin care application this it may not be an issue, so long as the skin was not coming into close and prolonged contact with a surface, e.g. the skin-pad environment, or facial PPE masks.
- The experimental findings show that the developed protocols show potential for use in future experimental work in this thesis based on their ability to establish differences between the treatments and their effects on the skin properties and tribosystem.

The developed protocols were successful in discovering the effects of skin treatments on skin friction, moisture, deformation, and roughness. Critique and future improvements to the protocols have been identified with a view to make necessary changes in order to improve future skin friction experiments. The results have provided confidence in the modified rig and friction protocol to take forward into the skin-pad tests, and have delivered insights into the behaviour of skin with and without treatments applied.

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# 5 Questionnaire Design and Development

## 5.1 Introduction

The purpose of conducting the questionnaire was to enrich the current experimental and medical understanding of the skin-pad interface by talking to users of incontinence products and skin treatments. The varied and harsh environmental conditions which surround the skin can lead to people with incontinence developing symptoms of incontinence-associated dermatitis (IAD), such as redness, blistering, and skin erosion. Information surrounding condition management decisions, such as pad choice and skin treatments used, along with IAD symptoms and personal insights, are all relevant data which together can give a better indication of the principle contributors to the development of IAD.

Experimental work forms the majority of this thesis, so connecting the research to users of pads and skin treatments was fundamental to gain a greater insight into lived experiences of incontinence and IAD. The findings will be used to supplement the development of future experimental work, as well as provide a greater depth of discussion. This combination of experimental work and social studies is often described as a patient-led approach; regularly a neglected aspect of lab-based investigations. The design phase of the questionnaire was an important element of this work, which is why an entire chapter is dedicated to the process. The results are presented in Chapter 6, and for reference throughout this chapter the finalised version of the questionnaire can be found in Appendix A.

## 5.2 Aims and Objectives

The aim of the questionnaire was to build an understanding of incontinence and IAD in a community-living population, and this was to be achieved by designing and formulating a series of structured questions to be distributed online. The questionnaire findings aimed to provide a greater understanding of tribology in the skin-pad interface, the risk factors, absorbent product usage, and skin treatments commonly used by people to manage and treat IAD.

Objectives:

1. Research, design, and develop a preliminary draft of the online questionnaire.
2. Secure ethical approval from the University of Sheffield Ethics Committee in order to conduct the interviews and questionnaire.
3. Research and prepare for individual participant interviews.
4. Conduct individual interviews and acquire feedback on the preliminary draft.
5. Refine the questions and format of the online questionnaire based on the individual interview feedback.
6. Conduct a final testing stage, and make further amendments where necessary.
7. Open the questionnaire online to the community to collect responses.
8. Draw conclusions based on the questionnaire data to build a picture of the current situation of condition management and severity of IAD in this relatively unstudied population.

## 5.3 Questionnaire Development

Figure 5.2 highlights the key stages, Steps 1 to 12, which were necessary in order to prepare the questionnaire ready to gather relevant data from the population of people living with incontinence within the community.

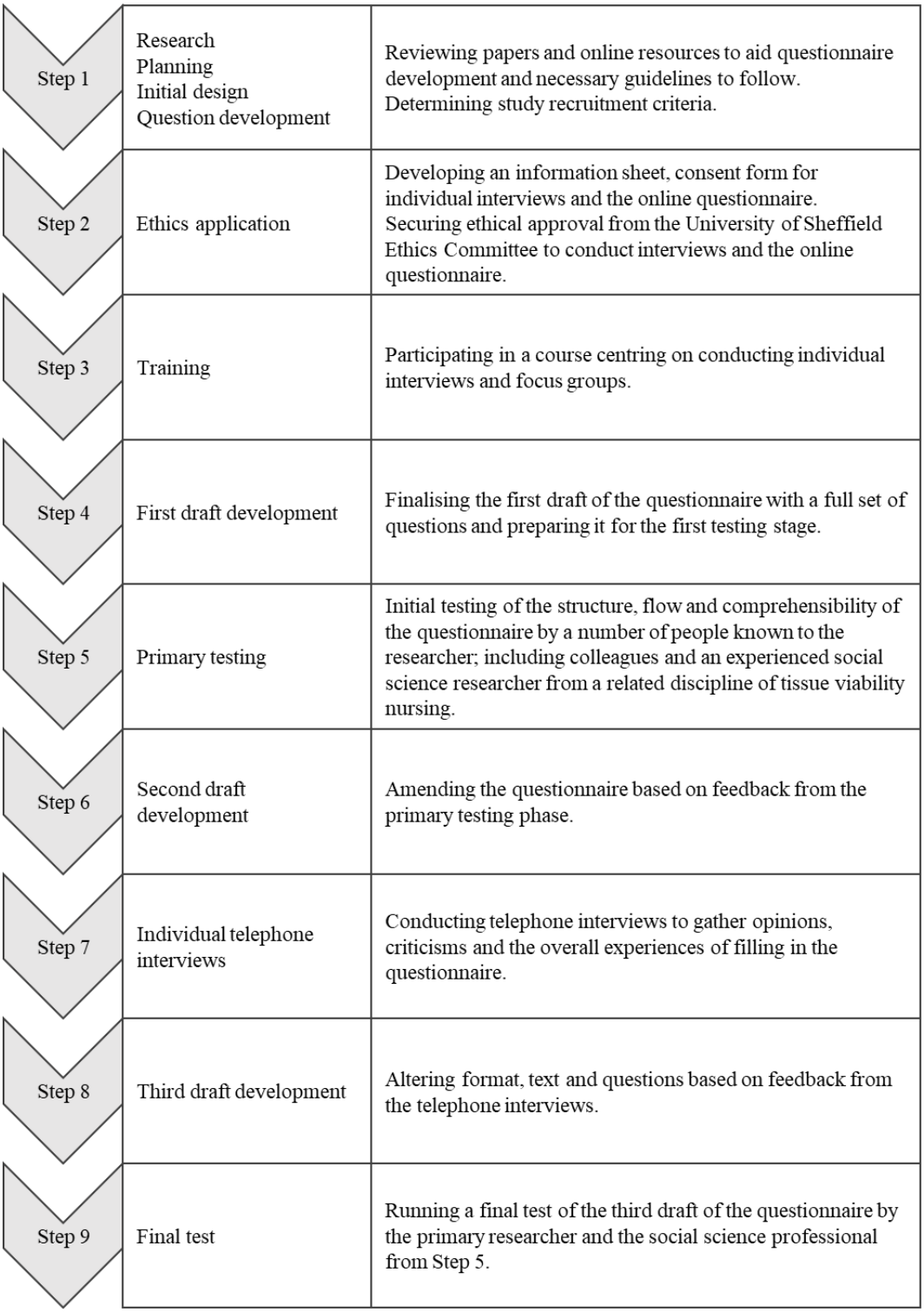


*Figure 5.1 - Steps 1-12 of the development of the questionnaire (Stages 1 – 12), from the initial research stage, through to testing and reiterations, and finally the distribution of the questionnaire. See steps 10 - 12 on the following page.*

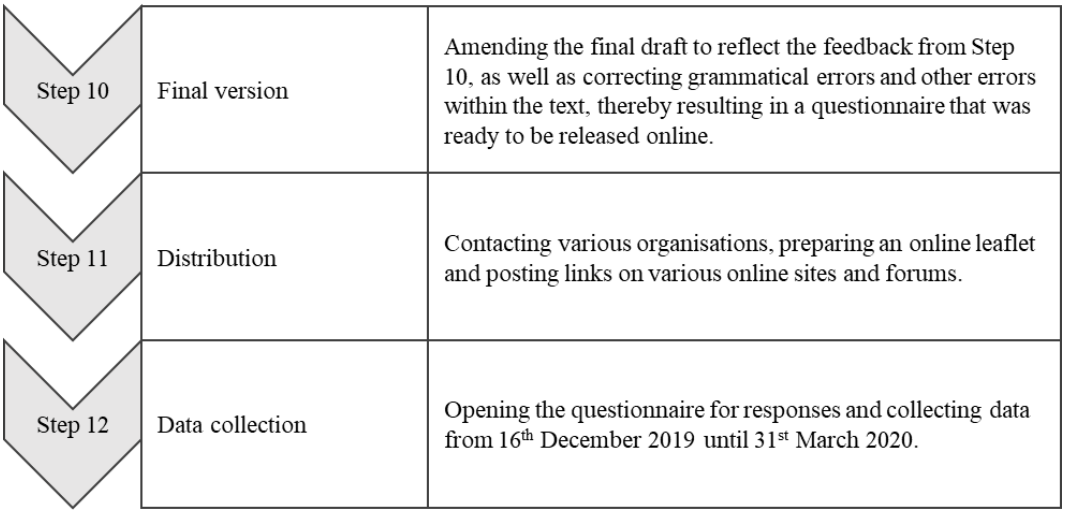


*Figure 5.2 - Steps 1-12 of the development of the questionnaire (Stages 1 – 12), from the initial research stage, through to testing and reiterations, and finally the distribution of the questionnaire. See steps 1 - 9 on the previous page.*

### 5.3.1 Selection Criteria

A number of factors were considered in the recruitment criteria to provide boundaries to the research, such as age range, gender, type of incontinence, whether participants would be living in a medical based setting or community living, and whether people must have had experience of IAD. The selection criteria and justifications are as follows:

*Living arrangements*

The survey was specifically not to be completed by those in care homes or hospitals, as this cohort would be less mobile and more likely bed bound. The target population were those living in relatively normal day-to-day circumstances so that the data could be reflective of a community-based cohort of incontinence sufferers.

*Medical help*

There were no boundaries in terms of whether somebody could be (or in the past) receiving medical help for incontinence or IAD. The only stipulating criteria was that they were living within the community and not living within a medical setting. This was to gain an understanding of contact and skin damage during a normal active lifestyle.

*Age*

A wide age range of 20 – 80 years old was chosen because incontinence affects all ages of people and the incidence of people with UI tends to increase from 20-years old upwards with parity of women.

The over 80s population were excluded to prevent some potentially vulnerable members of the community participating and to ensure that those participating were more likely to be living a mobile lifestyle.

*Sex*

The questionnaire was open to males and females because the findings from both sexes would be interesting to compare, especially in terms of bodily locations affected by IAD.

*Type of incontinence*

Although one of the experimental studies in this thesis looks at UI (with artificial urine added to a pad, see Chapter 8), inclusivity of those with faecal incontinence (FI) and double incontinence was deemed appropriate, fair, and relevant. Seeing as the primary interest is tribological relationships between the skin and pad, participation across all incontinence categories was valuable.

*Incontinence-associated dermatitis*

Anybody could participate in the study whether or they had ever experienced IAD. This was in order to gain a better understanding of whether there are certain differences between people who do and do not develop IAD.

*Exclusion criteria*

The exclusion criteria were as follows:

- Anybody not living independently, i.e. those in care homes.
- Vulnerable adults
- People under the age of 20 and over the age of 80.

### 5.3.2 Risks

The following risks and mitigations for carrying out the questionnaire were identified, see Table 5.1.

*Table 5.1 – Risks of conducting the questionnaire, and mitigation strategies.*

| Risk | Mitigations |
|---|---|
| Risk 1: Questions causing offence | Scrutiny of the wording by a medical professional and participant telephone interviews. |
| Risk 2: Lack of in person guidance from researcher | Ensure a clear information sheet is provided and design unambiguous questions. Test the questionnaire thoroughly before online release. Provide a point of contact on the information sheet should there be any questions. |
| Risk 3: Questionnaire might not be relevant to a community population resulting in a limited response. | Connect with members of the community to discuss their issues, and research online forums, support networks, and advice resources to gauge incidence. |
| Risk 4: A participant may not feel like questions are relevant whilst completing the questionnaire. | Talk to community-living incontinence sufferers before and during questionnaire development, to establish any potential points of contention.<br><br>Do not make all of the questions compulsory; only set some of the most important questions as required to avoid people giving up mid-questionnaire and valuable data being lost. |
| Risk 5: Questions being biased. | Special attention must be given to the question wording along with presenting all of the relevant answers for a multiple choice or checkbox style question. To ensure bias is eliminated include options of 'Not Applicable', 'Unsure' or 'Other' for answers that required it. |
| In terms of minimising risk, the ethics approval process also ensured that risks were considered, and the relevant mitigations put in place. | |

In Table 5.1, Risk 3 regarding the relevance of the questionnaire arose because during the early development stage of the questionnaire, a medical professional expressed the opinion that there likely would not be many responses to the questionnaire as IAD isn't a common enough condition in the community. They advised the study to be opened to care homes, patients, and carers. Though unnerving, this conversation did not act as a research deterrent because prior to this there were many discussions with active community members who did suffer, and still suffer with IAD. Knowing that potentially a large group of people was unacknowledged was a compelling reason to push ahead with the survey and the existing recruitment criteria.

### 5.3.3 Ethical Approval

The study was approved by the University of Sheffield Ethics Committee to conduct the preliminary interviews and questionnaire (Ethics Number 031334), see Appendix D. Firstly, approval was needed for conducting telephone interviews, in which people discussed the sensitive issue of their incontinence, along with providing critical feedback on the questionnaire draft pilot test. The second phase which required ethical approval was for releasing the final online questionnaire to the public. Due to the sensitive nature of the investigation, it was crucial that participants were fully aware that the questions might be challenging; this was fully disclosed in the information sheet prior to any study questions. Additionally, it was designed such that the majority of questions were optional to answer. Before consenting to be involved participants were made aware that it was completely optional to take part, responding was completely anonymous, and they could leave the questionnaire at any point. To ensure people were fully informed and happy to participate in the study they were initially presented with an information sheet to read before proceeding, which they had to confirm to having read. This page was followed by a consent form, to which they had to agree to the points before beginning the survey.

### 5.3.4 Format

The questionnaire was distributed in an online format, which was deemed the most appropriate way to collect data widely from the community. Additionally, an online format offered accessibility to everyone, and could be filled in at a most convenient time.

The chosen hosting platform was Google Forms because it is a recognised survey platform which is compatible with computers and mobiles, very user friendly, and is easy to export data in a .csv file format. It was decided that having a paper format was not necessary for a number of reasons: the long questionnaire length, the inability to easily embed multiple pathways on paper copies, and also paper formats have a limited reach. In terms of accessibility to an online format, the number of IT literate people has greatly increased in recent times. According to the government statistics website [1], internet use in the age category 65-74 increased from 52% in 2011 to 80% in 2018. Aged 75 and higher had a lower number of just 44% in 2018, but young people aged of 16-34 were at 99%. The available statistics were deemed satisfactory to distribute the questionnaire in an online format only.

The multiple pathway options that Google Forms provides are extremely useful as they enable whole sections to be skipped based on certain answers. For example, if a participant answered ‘No’ to the question ‘Do you use any skin treatments, barrier creams, moisturisers or powders to prevent or manage skin discomfort?’, then they would skip the next section all about identifying skin and rating treatments that they use. This setup made it easier for participants to navigate the questionnaire and importantly saved time by not asking them irrelevant questions.

In addition, by keeping the form online, it was more environmentally friendly; if the questionnaire were to be printed, it would need approximately 30 pieces of paper, which would be overwhelming for a participant. The questionnaire was lengthy but simplistically ordered, and the multiple choice options and checkboxes enabled simple and quick navigation for the respondents. With an online version, it was possible to have colour images of each skin treatment and pad type; people remember packaging or logos but might have found it tricky to remember just the name.

Deciding on the question categories, wording and the ordering of sections, were key elements of a well thought-out questionnaire. The importance of getting a good flowing design was the difference between a respondent filling in the whole questionnaire, and giving up halfway through. The questions at the beginning of the questionnaire were very standard openers for scientific health questionnaires, requiring people to fill in some personal health data.

The majority of the questionnaire was quantitative with the bulk of the questions being categorical yes/no answers, multiple choice, or checkboxes. The Likert scale is a spectrum rating system used in questionnaires with the principal goal to be a measurable tool to gather people's preferences, perceptions and opinions. Responses chosen for Likert scale research are generally in the form 'Slightly Agree', 'Agree' and so on. The strength of the Likert scale is that it allows assertion of responses rather than the fixed boundaries of multiple choice. For the finalised questionnaire a 5-point scale was chosen with the middle option being 'Neither agree nor disagree', which was important to include as the goal was not to bias the results by forcing a response to a question. This style of question was used in questions where people were rating the performance of pads and skin treatments.

The selection of answers provided in the questionnaire was another important consideration in formulating the questionnaire because the choice of provided answers can influence the results. Participants got to read all of the available responses before they selected their answers, so if an answer didn't match the answer they want to give then it was less likely they would select a random answer or abandon the survey altogether. Therefore 'Don't know', 'Other', and 'Neither agree nor disagree', were often provided as responses to questions to remove forced responses and allow for flexibility. Where forced responses were implemented they were critical to the questionnaire analysis such as splitting people into categories of 'Yes' or 'No' to having IAD. Without specific answers to these required questions then the missing data would have caused problems during the analysis. For the required questions participants had to choose an option from the available answers in order to progress to the next pathway in the survey.

### 5.3.5 Question Development

The full set of questions can be seen in Appendix A, and listed below are some of the key questions and categories that participants were asked to answer:

i. Background information

At the very beginning of the questionnaire, participants were asked background information, such as age, weight, height, parity and any skin conditions or allergies. See Appendix A, Section 3 for questions asked. The importance of building a basic biological passport of the participant was crucial in understanding the likelihood of skin damage but also certain risk factors. Asking such questions could appear to be meaningless in the eye of the participant and not related to the study in question; however, with any study plan it is crucial to think of a diverse set of questions needed to fully comprehend the dataset later on.

ii. Incontinence

Questions about incontinence covered the type, severity and life impact. The questions from the Sandvik Severity Index, see Table 5.2, were included so participants could be classified into severity categories of UI based on the calculated index score. It is a well-known, medically validated tool developed by Sandvik *et al.* [2]. In tribological terms, it gives better understanding of the wetness conditions of the interface, along with the frequency of exposure to urine. This index formed an important foundation for the subsequent data analysis and was the inspiration in this thesis for the development of an IAD severity scale, described in detail in Chapter 7. See Appendix A, Section 7 for the incontinence severity questions asked in the survey.

*Table 5.2 - Questions and method used to calculate the Sandvik Severity Index score*

| A) How often do you experience urinary leakage? | |
|---|---|
| Frequency | Score |
| Less than once per month | 1 |
| A few times a month | 2 |
| A few times a week | 3 |
| Every day and/or night | 4 |
| | |
| B) How much urine do you lose each time? | |
| Drops | 1 |
| Small splashes | 2 |
| More | 3 |

The total score is then found by multiplying results from questions A and B.

Categorisation of the severity is based on the following scores:

1-2 = slight

3-6 = moderate

8-9 = severe

12 = very severe

iii. Absorbent products

Questions were asked about types of absorbent products used and frequency of wear. This question was useful to establish potential links between pad type and IAD, see Appendix A, Section 9.

iv. IAD symptoms

In-depth questions were asked about symptoms of IAD, affected body locations, frequency of IAD episodes and recovery time. This enabled a new severity index to be developed for IAD. Appendix A, Section 17.

v. Skin treatments

Questions about skin treatments were asked in order to establish the range of treatments used, personal preferences and treatment effectiveness, see Appendix A, Sections 22 to 24. These questions explored how people in the community go about treating IAD.

vi. Perception questions

Obtaining insights into individual perceptions was very important because in many studies the human factor is often ignored. In order to build a more diverse data set, questions were asked such as, 'how severe do you perceive your incontinence to be?'. This was later compared with the Sandvik Severity score, providing a perception categorisation versus a medical severity categorisation. Other personal questions were included; participants were asked to rate the impact that their incontinence had on various quality of life factors such as, work, sleep, travelling and participation in sports. Additionally, on the questionnaire close, a comment box was included, which enabled participants to tell more of their story, challenges and experiences.

### 5.3.6 Understanding the Tribosystem

In order to get a better understanding of the tribosystem, questions were asked about the following categories:

i. Region of the body affected

Collecting data on body region affected provided understanding of certain anatomical features, bony prominences, presence of hair, contact pressures and shear as different contributors to the severity of IAD. IAD on the buttocks, for example involves very different contact conditions to IAD on the upper thighs. The buttocks experience significant pressure and shear throughout the day as a large amount of time is spent seated. The buttocks are also directly in contact with pads, all-in-ones, and pull-ups. Participants were also asked which contact surfaces they thought contributed to their IAD, whether skin-skin, pad-skin, or clothes-skin. See Appendix A, Section 17, to see the questions used to gather this information.

ii. Physical symptoms and sensations

Symptoms of IAD vary drastically across a cohort. It is important to record individual symptoms and perceptions in order to build a clearer picture of what could be happening in the tribosystem. Symptoms may be a result of different friction mechanisms, so having symptom data can indicate different wear mechanisms at play. See Appendix A, Section 17, for the questions used to gather the symptom information.

iii. Pad type and skin treatments

The pad is the other contact surface on the skin, therefore having an understanding of the type of absorbent product used by each person is crucial to better understanding the tribosystem, Appendix A, Sections 9-11). Application of treatments modifies the friction, slip, shear and wetness experienced by

the skin. Therefore, collecting data on treatment types used and effectiveness could provide greater insights into the usefulness of treatments in the skin-pad interface. See Appendix A, Sections 22-24, to see the questions that were used to gather information about treatments.

### 5.3.7 Individual Interviews

After designing the questionnaire, the next stage involved piloting it with the target audience. Prior to taking part in the individual interviews, the participants were provided with an information sheet about the questionnaire and upcoming interview. After signing a consent form, participants were sent the questionnaire to fill in via an online link, and a follow-up telephone interview was scheduled. Telephone interviews were an effective way of connecting with people in a place where they felt comfortable and at a time that suited them. Participants were reassured that any criticisms of the questionnaire draft were encouraged, and the purpose of the interview was to get feedback and find out about their experience of completing the survey.

The phone call was also an opportunity for participants to share their personal stories and experiences; these dialogues were later very useful in providing context in a meeting with Sheffield City Council where the committee were reviewing whether the local continence services were meeting the needs of the people. Even though the interviewees were not local to Sheffield, their thoughts and experiences were incredibly beneficial to the meeting, and it was established that many of the points raised were also echoed by those living in Sheffield. See Chapter 6, Section 6.13 for more details about the impact of this work.

Some key changes to the questionnaire were made because of the following learning points from telephone interviews. The feedback points discussed in this section are not inclusive or all of the feedback received, however they are indicative of some most important changes that were made in order to improve the participant experience, and data collection.

Feedback 1: Simplify the information sheet because it is too lengthy and there is some terminology that may be confusing for participants.

> Corrections: Paragraph sizes were reduced and condensed as much as possible to ensure that information was quick to read and easy to understand. Where necessary wording was put into layman's terms.

Feedback 2: Shorten certain sections.

> Corrections: Questions were removed if deemed non-essential, and where sections seemed too heavy, questions were moved onto new pages.

Feedback 3: Put more disclaimer declarations throughout the questionnaire because all the treatment questions are a bit like company market research.

> Corrections: After this test feedback, another important disclaimer was added to the questionnaire on the information sheet and all relevant sections stating ‘This research is not funded by any product manufacturers and will not be used for any marketing or commercial purposes’.

Feedback 4: People are unlikely to ‘Strongly Agree’ or ‘Strongly Disagree’ with some of the product statements and that it would be best to look at using ‘Agree’ and ‘Disagree’ at the far ends of the scale.

> Corrections: The Likert Scale questions were shortened from a 7-point to a 5-point scale.

Feedback 5: Include a text box section where people can input their thoughts, opinions and experiences.

> Corrections: At the end of the questionnaire, a text box was included for people to write as many words as desired about their experiences.

The feedback received throughout the questionnaire design and development stages provided valuable perspectives and therefore iterations could be produced before reaching the improved finalised version. A copy of the full finalised version of the questionnaire can be found in Appendix A.

### 5.3.8 Distribution

The questionnaire was constructed and distributed to target community-living people in order to provide new insights into the skin-pad interface from an active population perspective rather than those in a care setting. In order to recruit the participant’s various organisations were contacted to arrange online distribution, including charities, support networks, people, and organisations with an online presence. A digital leaflet was developed to make it easier to distribute the questionnaire online, see Figure 5.3.

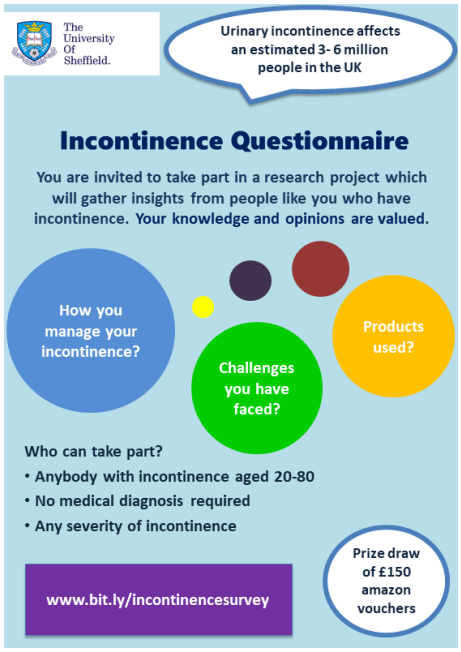


*Figure 5.3 - Digital leaflet used to advertise the questionnaire.*

Connecting with the right organisations to advertise the questionnaire was a challenge and sometimes a barrier to collecting results. The following list shows the organisations and people that helped with distribution of the questionnaire:

- Bowel and Bladder Community
- Bladder and Bowel UK
- Mumsnet
- Tissue Viability Society
- IMechE - Incontinence the Engineering Challenge conference list
- The link to the survey was also distributed via email and online platforms such as Facebook and Twitter.

Keeping the process online allowed complete anonymity and privacy which was especially helpful when dealing with this topic of a sensitive nature. There was no requirement for interaction with any people, and the survey required no personal identifiable data. This setup was an important factor in the questionnaire design, and it was set out this way in order to gather honest data whilst removing the sense of embarrassment.

## 5.4 Conclusions

A carefully formulated and thought-provoking series of questions was compiled to extract the necessary information from individuals living with incontinence in order to supplement and better inform the experimental research into the tribosystem of the skin-pad interface. With thorough preparation, design, and multiple testing stages, a methodical questionnaire was constructed to allow the necessary research questions to be answered, as well as new discoveries to be made along the way, the results of which are presented and discussed in Chapter 6.

References

[1] C. Prescott. "Office for National Statistics, Internet users, UK,". https://www.ons.gov.uk/businessindustryandtrade/itandinternetindustry/bulletins/internetusers/2018. (Accessed: July 21, 2019)

[2] H. Sandvik, A. Seim, A. Vanvik, and S. Hunskaar, “A severity index for epidemiological surveys of female urinary incontinence: Comparison with 48-hour pad-weighing tests,” *Neurourology and Urodynamics*, vol. 19, no. 2, pp. 137-145, 2000.

# Results of a Questionnaire to Investigate Incontinence and Incontinence-Associated Dermatitis in the Community

# 6

## 6.1 Introduction

The questionnaire discussed in this chapter was developed with the aim of providing an overview of ways in which people manage their own incontinence across a wide spectrum of ages in a non-medical setting, along with finding out about their individual experiences. In total there were 29 sections in the questionnaire, and the full final version can be found in Appendix A. The term 'managing incontinence' refers to the individual approach of managing the condition because people require different absorbent products, different skin treatments, and some may suffer from IAD as well as incontinence. The different management approaches can result from numerous factors: the severity of incontinence, severity of IAD, whether or not medical help is sought, individual perceptions, as well as factors such as personal preferences, and the impact on quality of life. Individuals can have very different approaches to managing both incontinence and IAD; during the time of living with the condition, people become experts through a trial and error approach of product use and different care routines. This knowledge is beneficial to research, especially within a product development context, where often there is a lack of a patient-led approach.

The majority of questions in the questionnaire in some way related to the tribological conditions experienced in the skin-pad interface. For example, requesting Body Mass Index (BMI) information can indicate that a person might have higher or lower pressure on skin, and tissue deformation on areas of skin, leading to a higher risk or severity of IAD. Similarly, questions about the type of absorbent product used can offer insights into the contact area, pressure points, and capacity for liquid absorption. In this chapter a novel IAD severity scale was created called the HIG Severity Index. It was developed to enable respondents to be categorised with 'mild', 'moderate', or 'severe' IAD. The analysis of the responses provided a deeper knowledge into the skin-pad tribosystem, body locations affected and symptoms experienced along with various contact surfaces that were identified by respondents as being suspected causes of their IAD development.

## 6.2 Study Participants

A total of 117 people participated in the questionnaire, aged 22-76 years, with a mean age of 46 years. This average age appears to be in line with what could be expected; for example Hunskaar *et al.* [1] found in their study of women with UI across four European countries that the mean age of the 17,080 respondents was 46.3 years. In this current study the percentage of respondents who fell within each age category is shown in Table 6.1, the age-range of 50-59 years made up the highest number of the respondents (30.8%).

*Table 6.1 - Percentage of participants in each age category*

| Age Category | % |
|---|---|
| 20-29 | 8.5 |
| 30-39 | 25.6 |
| 40-49 | 23.1 |
| 50-59 | 30.8 |
| 60-69 | 6.0 |
| 70-79 | 6.0 |

The findings in Table 6.1 do not necessarily mean that prevalence of incontinence across the general population is higher in this 50-59 year age category, but it does mean that in the context of this questionnaire that the reach might have been better received or more readily accessible by this group. Perhaps more of this age group engaged with the organisations and platforms that were used to help advertise the questionnaire.

Of the survey participants 77% reported to identify as female, and the remainder male. Of the female entrants, 79% had at least one child and 21% were nulliparous. Amongst both sexes, urinary incontinence (UI) was the most common form of incontinence experienced, see Figure 6.1.

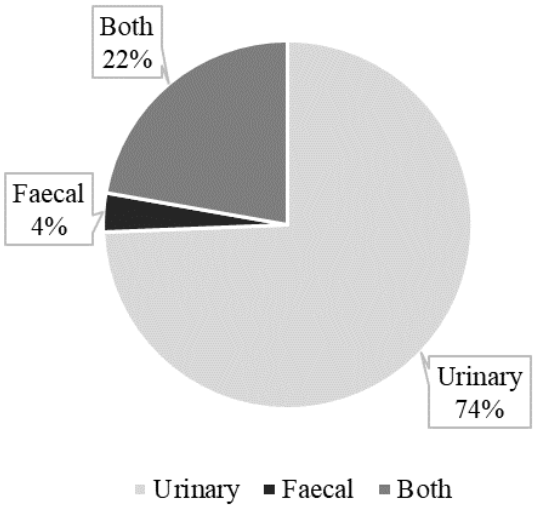


*Figure 6.1 – Percentage of respondents (n = 117) with urinary incontinence, faecal incontinence or 'both' UI and faecal incontinence..*

## 6.3 Quality of Life

People living with incontinence often find that having the condition can impact negatively on different areas of their lives. Various quality of life factors and the answers given by respondents are presented in Figure 6.2. Participants could choose from 'Yes', 'Somewhat', 'No', or could choose to not answer the question which asked 'Does having incontinence have a negative impact on some of the following areas of your life?'.

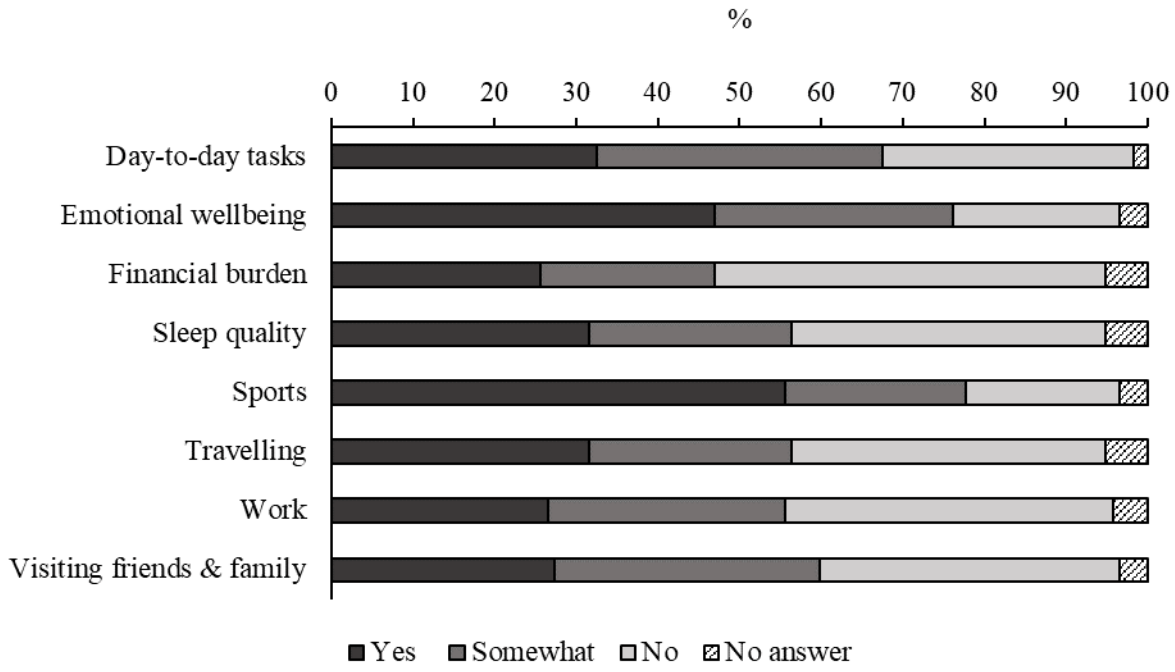


*Figure 6.2 – Percentage of respondents (n = 117) who answered 'Yes', 'Somewhat', 'No', or 'No answer' to whether having incontinence negatively impacts on certain factors of their life.*

The impact that living with the incontinence has on quality of life differs considerably from person-to-person. The categories shown in Figure 6.2 were chosen as important areas of a lifestyle which can really impact on a persons' quality of life, such as emotional wellbeing and sleep quality. The most negatively impacted areas of life quality that respondents answered 'yes' or 'somewhat' to were as follows: 77.8% of respondents said the condition negatively affects them taking part in sports, 76.1% agreed that the condition negatively affects their emotional wellbeing, and 67.5 % communicated that it affects day-to-day tasks. The impact on activity is in agreement with other studies; a largescale randomised study by DuBeau *et al.* [2] involving over 9000 women found that more than 60% of them would restrict their activities, including physical exercise, due to the possible incidence of an episode of incontinence. Further to this, in a study of 41,000 women aged 45 to 50 years in Australia, one third reported that they avoided physical activities due to fear of an episode [3].

The data analysis found that 9.4% said 'yes' to all presented factors being impacted, 3.4% said 'no' none of the lifestyle factors were impacted negatively, and 0.9% did not respond to any of the categories in the question. The majority of people have a different combination of areas of their life that they feel are negatively affected by their condition, which is to be expected because we all have different life situations such as different workplaces, family situations, travel needs, and activity levels.

## 6.4 Sandvik Severity Index

The Sandvik Severity Index scoring system, was developed in order to categorise people according to the severity of incontinence that they experience [4]. The severity index was introduced in Chapter 5, Section 6.3.5, and applying it resulted in the following scores shown in Table 6.2. The specific questions that were asked can be seen in the table, where they are labelled Question A and Question B. In total 59% of respondents with UI, or both UI and faecal incontinence, had episodes of UI every day and/or night, and 44% reported voiding amounts of more than small splashes.

*Table 6.2 – Results of the Sandvik Severity Index questions, along with n the number of participants who selected each answer for questions A and B, or fell within each index score or severity category.*

| Question A: How often do you experience urinary leakage? | |
|---|---|
| Reported frequency | *n* |
| Less than once a month | 67 |
| A few times a month | 22 |
| A few times a week | 19 |
| Every day and/or night | 5 |
| **Question B: How much urine do you lose each time?** | |
| Reported amount | *n* |
| Drops | 23 |
| Small splashes | 40 |
| More | 50 |
| Total index score (a result of multiplying participants' answer to Question A score by their score from Question B). | *n* |
| 1 | 2 |
| 2 | 8 |
| 3 | 7 |
| 4 | 18 |
| 6 | 16 |
| 8 | 17 |
| 9 | 4 |
| 12 | 41 |
| Sandvik Severity Index categorisation result (where index scores are split into categories of 1-2 = slight, 3-6 = moderate, 8-9 = severe, and 12 = very severe. | *n* |
| Slight | 10 |
| Moderate | 41 |
| Severe | 21 |
| Very severe | 41 |

Note: There were 113 responses to the questions, not 117, because this question related only to those who experienced UI. 4 respondents identified as solely experiencing faecal incontinence so they were not required to answer the questions.

The percentage of respondents in each index category is expressed in Figure 6.3. Of the 113 respondents who had UI all completed the full set of Sandvik Severity Index questions enabling all to be categorised into their corresponding severity groups. Those who experienced solely faecal incontinence were instructed not to complete the questions because they were only applicable for people with UI. 8.8% were found to have 'slight' incontinence, 36.3% 'moderate', 18.6% 'severe', and 36.3% were classified as 'very severe' according to the Sandvik Severity Index.

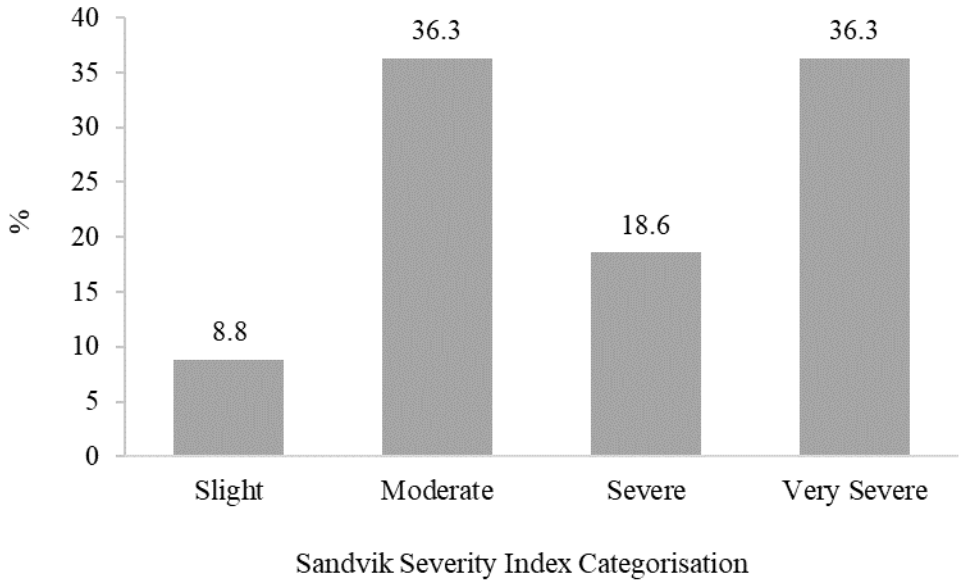


*Figure 6.3 – The percentage of respondents with UI (n = 113) who fell into each Sandvik Severity Category.*

The high percentage presenting with 'very severe' incontinence could be due to the sources of recruitment. For example, the survey link was advertised by specific incontinence charities and also posted on the 'Bladder and Bowel Community' group page on Facebook, which has a very high number of members, at the time of the study there were over 16,000 members. Charity emailing lists and the Facebook group likely reached an audience with a more severe condition, such to the extent that they were already seeking community support and advice.

Of the 117 study participants, 62.4% currently or in the past had received professional medical help for incontinence, this high figure is likely due to the high percentage of respondents with 'very severe' incontinence. This percentage was far higher than many other past studies have reported, for example, some of the literature reports:

- In a community-based study of females with UI by Hannestad *et al.* [5] it was found that on average 26% had consulted a doctor about their urinary leakage. For those in the 'severe'

incontinence category the percentage of medical help seekers was higher at 54%. The severity in the study was also categorised using the Sandvik Severity Index [6]).

- A study of a population of over 40 year olds found that only one in nine of those with clinically significant symptoms of incontinence felt the need to get help [7].
- Hunskaar *et al.* [1] found that 25% of UK respondents with UI had consulted a doctor.

In this current study 46.6% of those categorised as suffering from 'very severe' incontinence had sought medical help (Figure 6.4). Those with 'slight' UI sought medical help far less often than any of the other severity categories. There are many factors which are barriers for people getting help, such as embarrassment and perceptions that incontinence (UI especially) is a normal part of the ageing process. Additionally, Sadler [8] found that 42% of woman affected by UI delayed seeking help and treatment for up to 15 years.

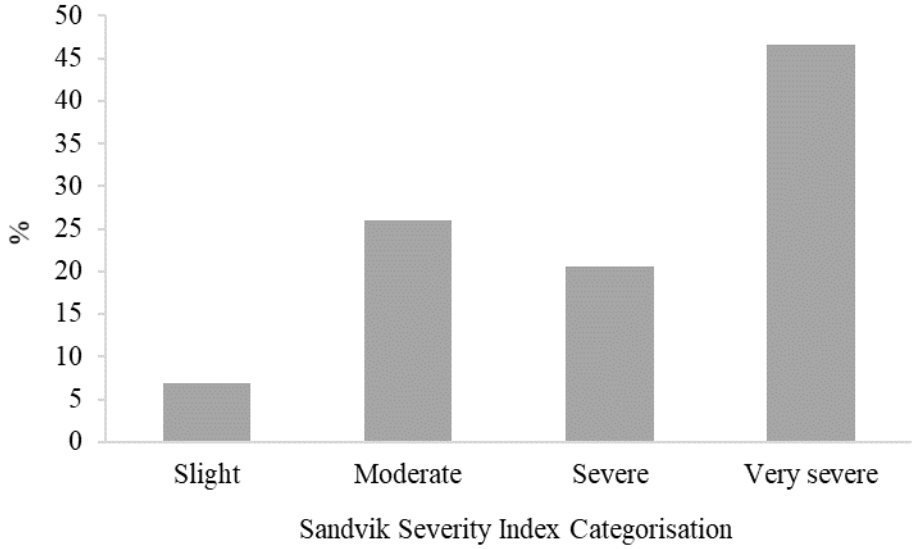


*Figure 6.4 – The percentage of people in each category of the Sandvik Severity Index who had currently or in the past sought medical help*

An additional factor which could influence a person's decision to seek medical help may be tied to personal perceptions of severity, see Figure 6.5. Severity perceptions of the respondents were shown to differ greatly from those indicated using the medically validated Sandvik Severity Index. To determine the perceived severity participants were asked 'How severe would you say your incontinence is?'. The options to choose from were 'Mild', 'Moderate', 'Severe' or 'Very severe'. The terminology adopted here for the lowest perceived severity was the word 'mild' rather than the word 'slight' which was used

in the Sandvik Severity Index. In the design phase of the questionnaire ‘mild’ was deemed a more understandable quantifiable term for respondents to identify with.

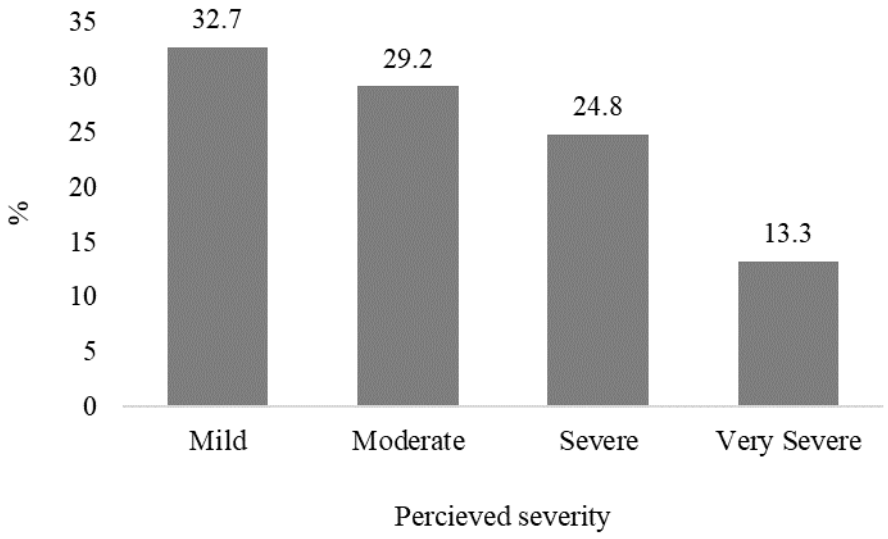


*Figure 6.5 - The percentage of respondents with UI who perceived their incontinence severity as either ‘Mild’, ‘Moderate’, ‘Severe’, or ‘Very Severe’.*

According to the Sandvik Severity Index, 36.6% of the respondents with UI were classified as having ‘very severe’ UI, which contrasted greatly with the results of the personal perception categories where only 13.3% selected they thought they had ‘very severe’ incontinence. Again looking at the lower end of the Sandvik Severity Index, 8.8% were classified as having ‘slight’ UI, whereas 32.7% of respondents self-reported as ‘mild’. This disparity could be for a number of reasons. It is perhaps a result of medical professionals underplaying the symptoms and passing them off as ‘normal’ or it could be due to self-perceptions of severe incontinence only relating to older people. The perceived severities of UI versus the Sandvik Severity Index categorisation for people can be seen in the pie-charts in Figure 6.6. Each pie-chart is representative of one UI severity category, and the individual slices represents the proportion of respondents with a certain severity perception.

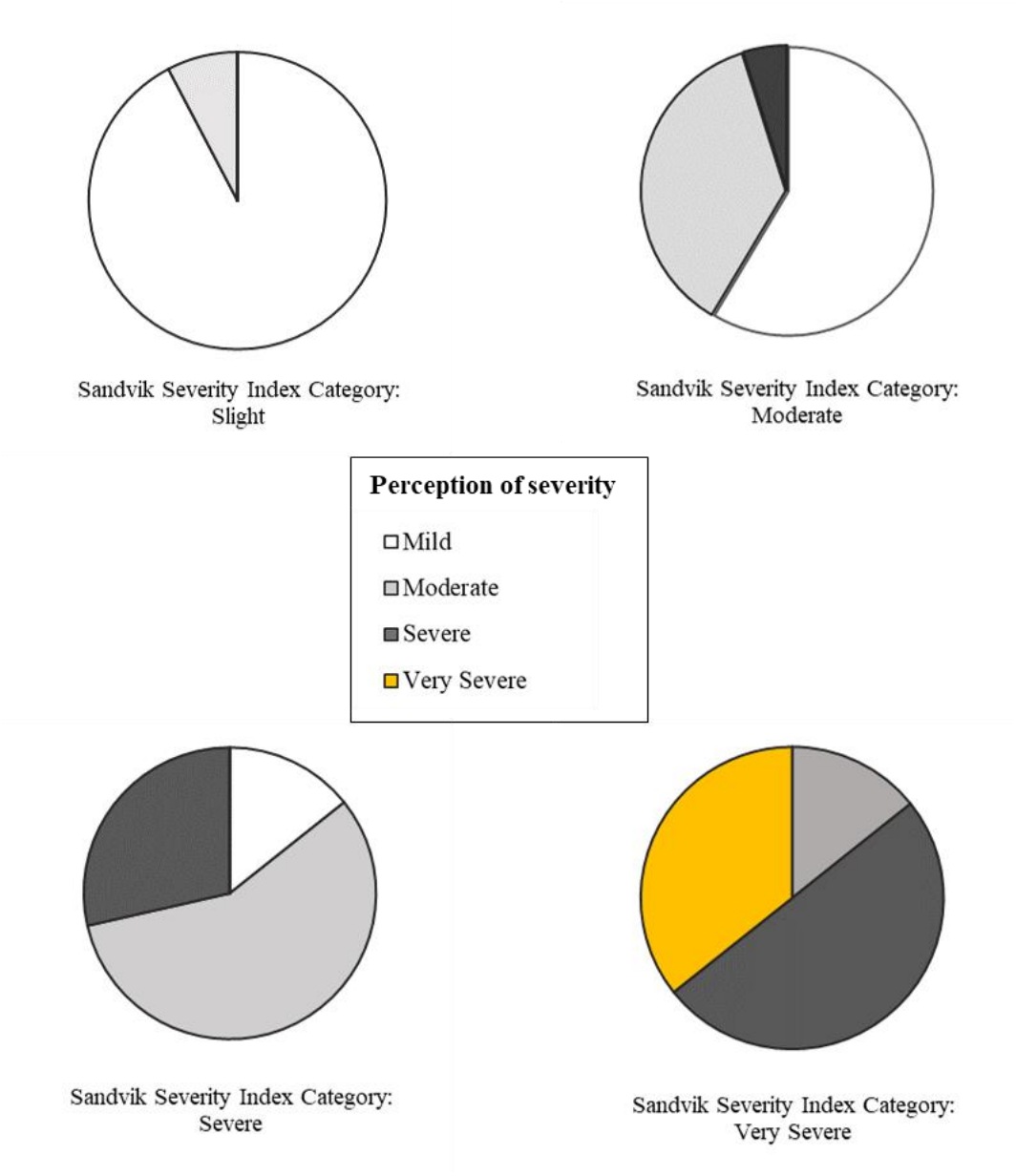


*Figure 6.6 - The perception that people had of the severity of their UI versus the Sandvik Severity Index score.*

For those with 'slight' incontinence the majority classed themselves as having 'mild' UI. For those categorised with 'moderate' severity UI, over 50% perceived themselves to have 'mild' UI, and close to a third rated themselves as having 'moderate' UI. The majority of people with 'severe' UI perceived themselves to have 'moderate' incontinence. For those categorised with 'very severe' incontinence, none perceived themselves to be of 'mild' severity, though close to 50% deemed their incontinence 'severe' rather than 'very severe'. Nobody from other categories classed themselves as having 'very severe' incontinence, and nobody with 'mild' incontinence associated themselves with having either 'severe' or 'very severe' incontinence. A study by Chiner et al. [9] found that 95% of patients with severe asthma underestimated the severity of their condition. Such an underestimation of the severity

of medical conditions may be a common phenomenon, perhaps due to personal resilience, desire to avoid clinical environments, or due to a lack of knowledge about a given condition. This highlights the disconnect between people's perspectives and severity of the condition, so it is highly likely that this could contribute to the delay of people connecting with medical help.

Of all respondents, 93% said they have accessed incontinence help and information. This information was shown to come from a variety of sources. 59.8% of people reported using three different places or more to source their information. The most common way people find their information about incontinence was through online searches (41.9% reported using this method), seeing the GP closely followed this (40.2%), and then using online forums (39.3%).

## 6.5 Sandvik Score and IAD

A higher severity score is strongly associated with having a greater risk of developing IAD (Figure 6.7); those categorised as 'very severe' were over three times more likely to be a sufferer of IAD than somebody in the 'slight' category.

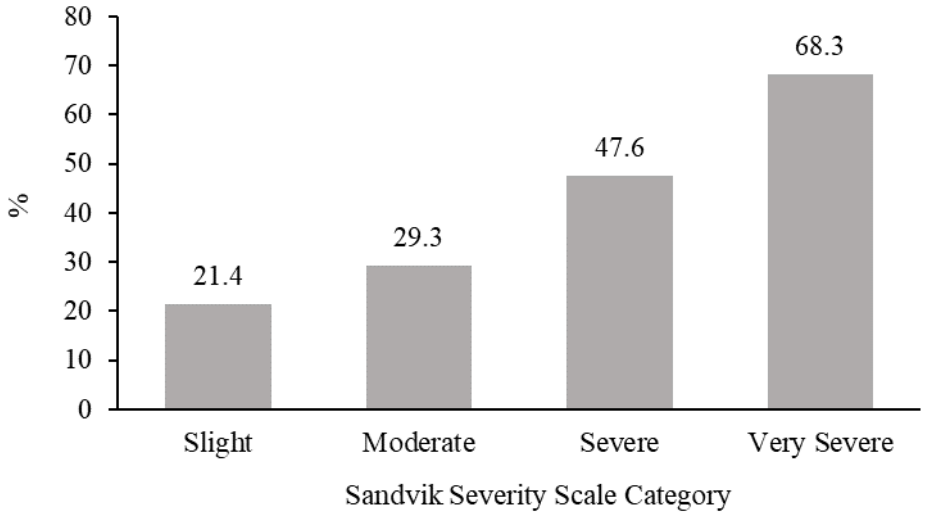


*Figure 6.7 – Percentage of respondents with IAD within each category of the Sandvik Severity Index.*

## 6.6 Incontinence-Associated Dermatitis Symptoms

In the survey of 117 respondents, it was found that 45.3 % suffered with IAD. Participants were asked whether or not they experienced any skin discomfort or damage due to incontinence and also which regions of the body were affected, see Section 16 and 17 of Appendix A. 40% of female entrants and 63% of males had experienced incontinence-associated skin problems. A study by Bliss *et al.* [10], had similar findings of 41% reporting symptoms of IAD, where the subjects assessed their skin over a time-

period of 2-months and reported symptoms of IAD such as redness, rash, fungal infections and skin loss. Of the subjects 65% had faecal incontinence and 35% had double incontinence. To determine prevalence of symptoms, the question was asked, 'What skin symptoms have you experienced?'. In order to answer this, participants were provided with a list of options to tick (see Table 6.3). The symptoms of IAD experienced were found to differ for males and females, see Table 6.3, Figure 6.8, and Figure 6.9. Of the 17 males who reported present or past experience of IAD, the most common symptoms identified were, itchiness (94.1%), followed by sores (52.9%), followed by inflammation, and pain (both 35.3%). Females reported different symptoms to males, of the 36 females with IAD, the top symptoms experienced were, itchiness (69.4%), and burning, and stinging (both 52.8%).

*Table 6.3 – Listed symptoms of IAD and the percentage of males (n = 17) and females (n = 36) who identified with having each symptom.*

| IAD Symptom | % | |
|---|---|---|
| | Males | Females |
| Bleeding | 24 | 25 |
| Blistering | 6 | 17 |
| Burning | 29 | 53 |
| Dryness | 24 | 28 |
| Inflammation | 35 | 50 |
| Itchiness | 94 | 69 |
| Lumps | 12 | 19 |
| Open wounds | 12 | 19 |
| Pain | 35 | 33 |
| Raw skin | 12 | 42 |
| Sores | 53 | 31 |
| Spots | 24 | 22 |
| Stinging | 29 | 53 |

Some of the symptoms in Table 6.3 include physical sensations, such as burning, stinging, itching and pain. Such symptoms are self-reported, perception based categories, and these non-observable symptoms are not easily comparable amongst individuals in the way that observable symptoms are. This is because different individuals tolerate and perceive physical sensations differently. The physical, observable signs and symptoms such as inflammation, raw skin, sores, bleeding, spots, lumps, open wounds, and blistering are compared in Figure 6.8.

One problem which hinders IAD diagnosis is that sometimes it can be difficult to distinguish from pressure ulcers. Specific training manuals have been developed for medical professionals which are aimed to increase knowledge and clinical management techniques [11].

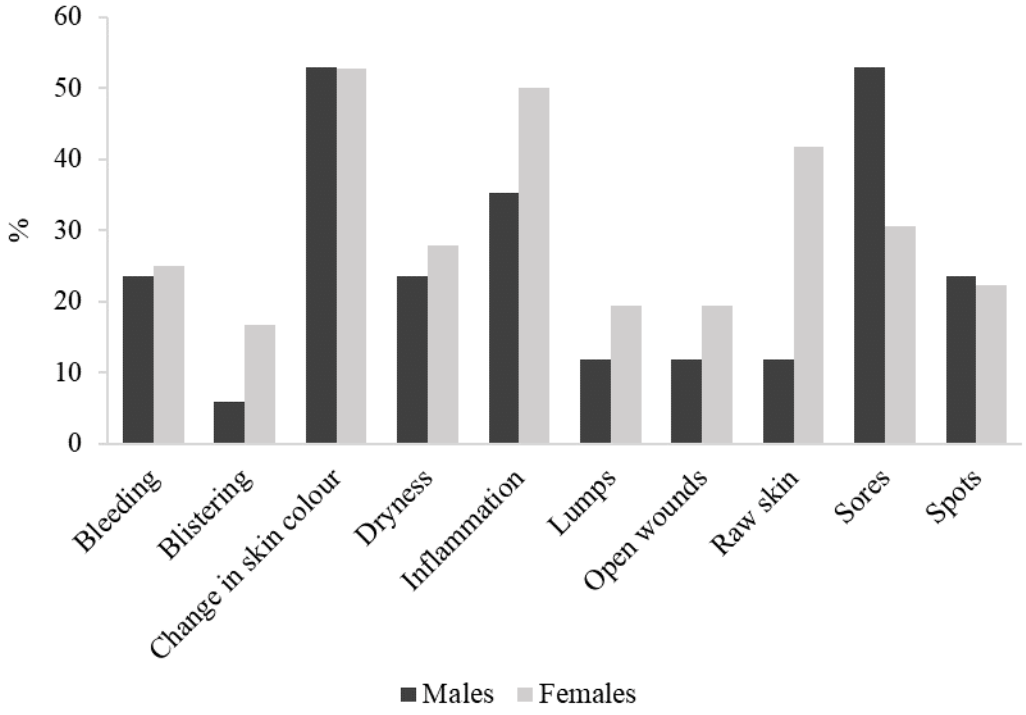


*Figure 6.8 – A comparison between the percentage of males with IAD (n = 17) versus females with IAD (n = 36) who are affected by different observable IAD symptoms.*

Of the physical signs of IAD the two most common in males were sores (52.9%) and 'change in skin colour' (52.9%), and in females the most common were 'change in skin colour' (52.8%), and raw skin (41.7%). In the study mentioned earlier by Bliss *et al.* [10], it was found that the most common signs and symptoms of IAD were 'redness' (60% of patients) and soreness (78%). In this study the term 'Change in skin colour' was adopted instead of 'redness' because people of darker skin tones often experience development of darker patches of skin of a purple, dark red or yellow colour [12]. Figure 6.9 highlights the IAD differences in physical sensations between males and females. The non-observable physical sensations that people identified with are shown in Figure 6.9.

The way friction contributes to each of these symptoms could be separated into different groups, for example, some may be caused by mechanical loading, and others may primarily be associated with moisture-associated skin damage. In mechanical loading static friction is a contributor to the symptoms of blisters, sores, and likely bleeding. Bleeding may result from skin tears due to shear, and blisters can form because of the result of greater shear forces, and generally the formation is due to a prolonged state of static friction. Spots may be a result of hair follicles getting infected, they can be seen as small

red bumps containing pus that are centred on the hair follicles. Rubbing of surfaces over the skin may exacerbate and prolong the duration of the symptom.

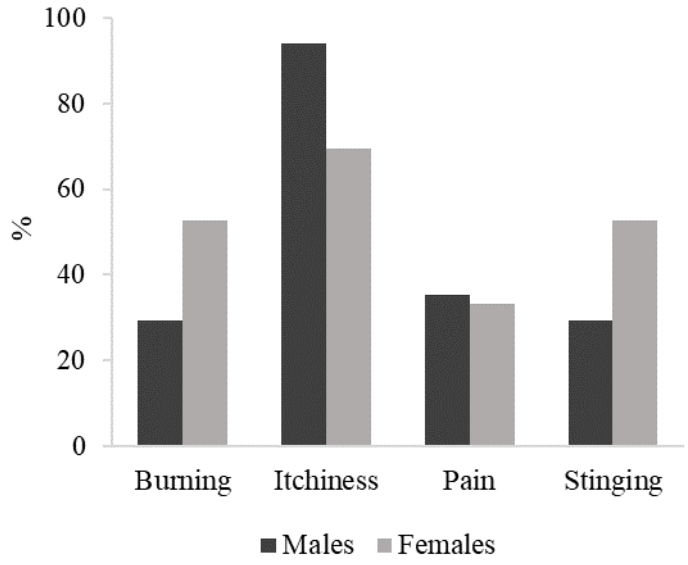


*Figure 6.9 - A comparison between the percentage of males with IAD ( n = 17) versus females with IAD (n = 36) who are affected by different physical sensations as a result of IAD.*

An almost equal percentage (~35%) of males and females reported pain as one of their IAD symptoms. The most common sensation was itchiness, with 94.1% of males and 69.4% of females reporting it. A greater percentage of female IAD sufferers reported symptoms of stinging and burning, than the males. This difference could be due to anatomical differences or due to a difference in the way sexes perceive and describe experiences of pain. Burning and itching can result from the exposure to chemical irritants like urine and/or faeces which alter the pH of skin and make it vulnerable to bacteria. Pain and stinging could be indicative that skin has been exposed to trauma, meaning that the skin integrity has been compromised due to rubbing against absorbent pads, clothes, or other skin.

## 6.7 Body Locations Affected by IAD

The region of the body which was most commonly reported being affected by IAD was the groin, followed by the buttocks, and then the inner thighs, see Figure 6.10. Of the 53 people with IAD nobody reported the lower abdomen as being an affected region, despite this being listed as one of the common areas to be affected by IAD.

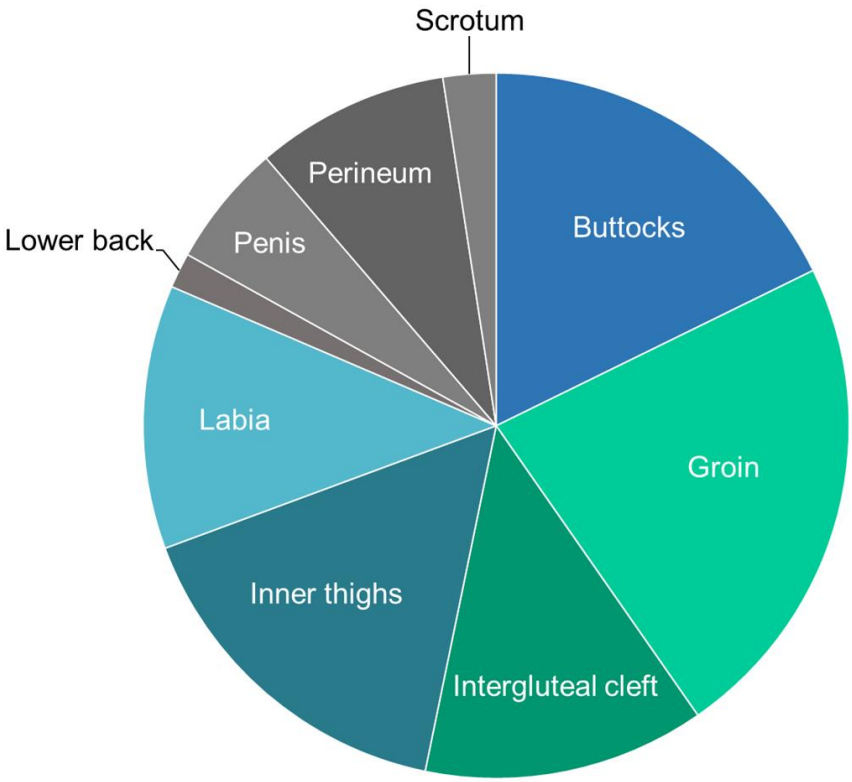


*Figure 6.10 – Regions of the body with IAD. The size of each segment is representative of the proportion of respondents who are affected in the body region.*

Skin damage is usually found in the perianal area, although it can extend farther depending on the degree of the incontinence, speed and frequency with which the contaminants are removed from the skin. The body locations affected by IAD were also found to differ for males and females, (see Figure 6.11). Of the respondents 19% experienced IAD in one body location, 26% in two locations, 25% in three locations, and 30% in four or more bodily locations. This contrasts to the findings of [10] who looked at IAD in community-dwelling individuals with faecal and double incontinence ($n$ = 98) where 85% of subjects suffered IAD in solely one location.

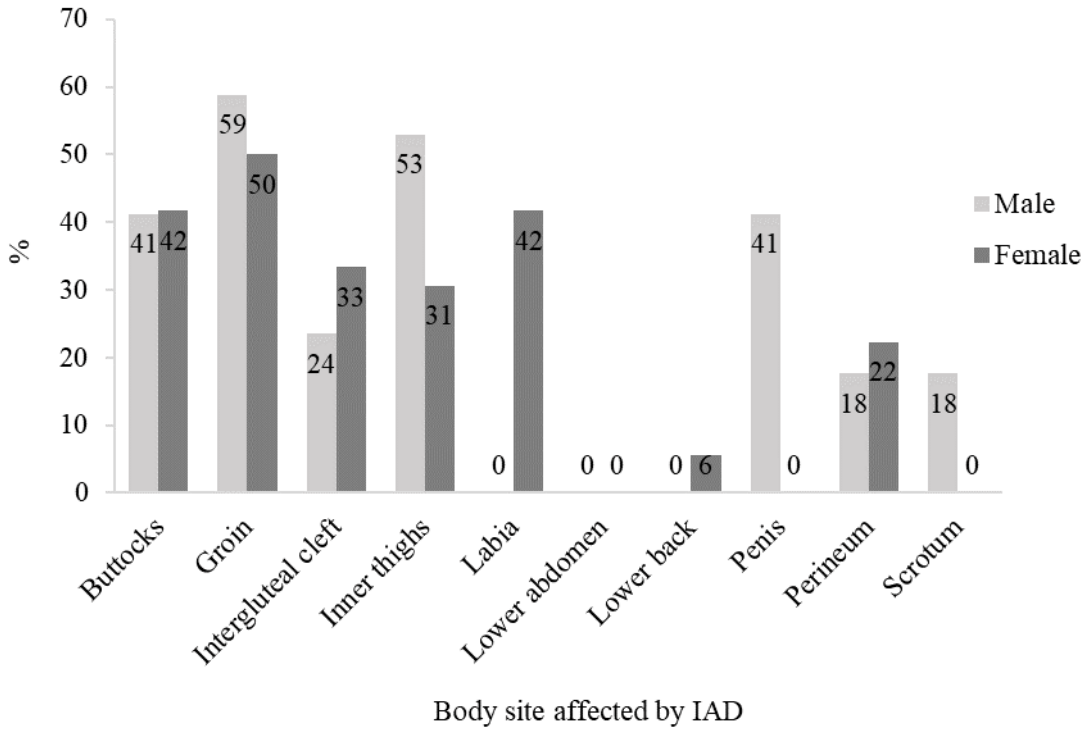


*Figure 6.11 – Percentage of males and females who identified with having IAD the different body sites. Males (n = 17) versus females (n = 36).*

The groin was the body site most commonly found to be affected by IAD in both sexes, see Figure 6.11. 52.9 % of males reported IAD on the inner thighs, whereas for females the prevalence in this body location was much lower (30.6 %). This could be due to anatomical differences such as the wider hip placement in females leading to less thigh contact and therefore less chafing. Or it could be due to women having more diverse outfits such as dresses and skirts, meaning less skin irritation from clothing for example. This final reason could potentially be ruled out, see Table 6.4, as respondents were asked what they believe contributed towards their own IAD and only 9.6% said they believed particular clothing could be a cause. A very low percentage of people reported IAD on their lower back, with just 5.6% of females and no males reporting the symptom. For both males and females, the genital areas were high prevalence body sites for IAD.

## 6.8 Contributing Factors to the Development of IAD

Shown in Table 6.4 is a list of factors which people selected as being prime contributors to the development of their own IAD, where participants were asked ‘Do any of the following contribute to your skin problems?’. The main cause of developing skin problems was selected as ‘being unable to change pads when needed’ affecting over 50% of respondents. This was followed by taking part in

particular activities (46.2%), and thirdly the rubbing of the absorbent product on the skin (40.4%). Only a small number of people found that particular clothing, pad tightness or particular skin treatments contributed to the development of IAD symptoms. There was an 'other' category for any additional comments to be made and one person responded that the net pants that they use to keep the pad in place sometimes dig into the top of their legs.

*Table 6.4 – Percentage of IAD sufferers who selected 'agree' to the listed statements being contributing factors to the development of their IAD*

| Question: 'Do any of the following contribute to your skin problems?' | % of respondents who agreed |
|---|---|
| Being unable to change garments or pads at regular intervals or soon after an episode | 53.8 |
| Particular activities e.g. walking, sports etc. | 46.2 |
| Pad rubs | 40.4 |
| Sleeping in pad | 36.5 |
| Pad not always large enough for amount of urine | 34.6 |
| Sitting for long periods of time | 34.6 |
| Pad not breathable enough | 30.8 |
| Pad leaks | 23.1 |
| Particular type or brand of pad | 17.3 |
| Pad too loose | 11.5 |
| Particular clothing | 9.6 |
| Pad too tight | 5.8 |
| Particular brand of skin treatment | 3.8 |
| None | 1.0 |

## 6.9 Contact Surfaces that Contribute to IAD Development

Due to the nature of the variety of different contact surfaces with the skin, it was important to give people the opportunity to select from various options the sort of skin-surface contacts they thought might be contributing to their IAD. Table 6.1 shows the percentage of IAD sufferers who agreed to the stated surface interaction causing their skin problems.

*Table 6.5 - The percentage of participants who selected 'agree' to different skin contacts contributing the development of their IAD.*

| Surface interaction leading to the development of IAD | % of respondents who agree |
|---|---|
| Skin on skin | 9.7 |
| Pad on skin | 74.2 |
| Standard catheter on skin | 12.9 |
| Sheath catheter on skin | 0.0 |
| Underwear on skin | 19.4 |
| Other clothing on skin | 0.0 |
| Don't know | 19.4 |

A very high percentage (74.2%) of sufferers attributed the pad on skin interaction to contribute to their skin problems occurring, followed by underwear on skin (19.4%). Of the respondents with IAD 19.4% did not know what contact surfaces contributed.

All absorbent product users were asked if they experienced IAD. The results on the bar-chart in Figure 6.12 show that 82% of all-in-one users experienced IAD. Pad users had the lowest rate of IAD with 42% having suffered from it.

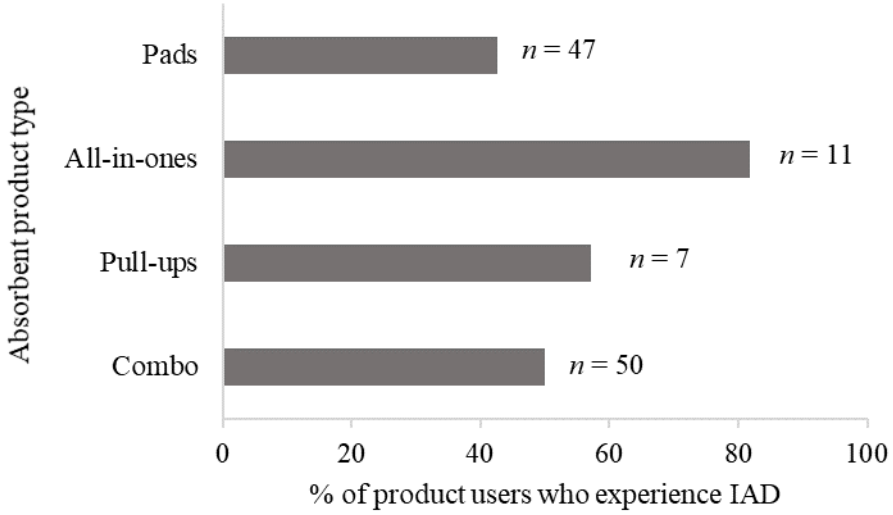


*Figure 6.12 – The percentage of number of people using each category of absorbent product who experience IAD, where 'Combo' refers to a person who uses two or more types of absorbent product.*

What is interesting here is that the all-in-one users were found to have higher reported levels of IAD, and 'combo' users were found be approximately as likely to have IAD as those who wear solely pads pull-ups. However, in Section 6.9 it is revealed there are actually some other in-depth relationships

between absorbent product types and IAD, but these relationships involve the severity of IAD experienced, rather than solely whether a person has or has not got IAD.

## 6.10 The HIG Severity Index

A novel diagnostic tool was developed to calculate IAD severity. The severity scale combines scoring of three factors to determine a severity category of either ‘mild’, ‘moderate’ or ‘severe’. This index takes into account duration, frequency of occurrence, recovery time and symptoms experienced. All of these factors are important in gauging the potential impact of the condition on the physical and psychological health of those affected.

### 6.10.1 Development of the HIG Severity Index

With inspiration from the Sandvik Severity Index [4], a new tool, the HIG Severity Index, was developed in this thesis for categorising the severity of IAD in respondents Table 6.6. In the newly developed HIG Severity Index, three key questions (labelled A, B and C in the table) were asked; firstly ‘How often is IAD experienced?’, secondly ‘How long for episode recovery?’ and a third question which takes into account the skin damage symptoms. The range of scores designated to the responses to each question are shown in Table 6.6.

The Sandvik Severity Index is different in that it determines the severity of UI that a person experiences by only asking two questions regarding the frequency of voiding and the amount people typically void. Further discussion into the Sandvik Severity Index was detailed in the questionnaire design chapter, see Chapter 5.

An important aspect of the HIG Severity Index design was to use language and descriptive words that were easy to understand, rather than using specific medical terminology, e.g. fungal infection rather than cutaneous candidiasis.

*Table 6.6 – The questions used to assess the degree of IAD severity, listed alongside the score for each selection and then lastly how the scores align with each severity category.*

A) How often do you experience IAD?

| Frequency | Score |
|---|---|
| Once or twice a year | 1 |
| A few times a year | 2 |
| Approx. once people month | 3 |
| A couple of times a month | 4 |
| Every week | 5 |

B) How long does it take to recover and heal?

| Recovery time | Score |
|---|---|
| Within 3 days | 1 |
| Within 1 week | 2 |
| 1-2 weeks | 3 |
| More than 2 weeks | 4 |
| It never properly heals | 5 |

C) Do you experience any of the following symptoms: raw skin, bleeding, open wounds, fungal infection or blistering?

| | |
|---|---|
| No | 1 |
| Yes | 2 |

The total score is found by multiplying scores from questions A, B and C together.

Categorisation of the severity is based on the following scores:

1-4 = mild

5-11 = moderate

12 and above = severe

A total index score was calculated by the multiplication of scores from questions A, B and C and the final number either fell into a category for ‘mild’, ‘moderate’, or ‘severe’ IAD.

A number of iterations of the question model were tested. Under an initial approach, just questions A and B were included, however after testing this method it became clear that accounting for frequency and recovery time alone were not enough to determine severity categories. This was because some

people slipped through the gaps and ended up being either over-rated or under-rated in severity. Question C was then added to the model, and to integrate this question into the index the most severe symptoms of IAD had to be identified, Table 6.7. Symptoms were deemed severe when they involved tissue maceration, degradation or fungal colonisation.

*Table 6.7 –Examples of IAD symptom severity*

| Examples of severe IAD signs/symptoms | Examples of less severe IAD signs/symptoms |
|---|---|
| Bleeding, blistering, fungal infection, open wounds, raw skin | Discolouration, dryness, inflammation, spots |

Symptoms of IAD manifest differently amongst individuals and can cause significant physical problems, as well as having a psychological toll and negative affect on quality of life.

*Examples of how to apply the index*

Categorisation scores greater than 12 were classed as 'severe'. A score of 12 or above can be reached in a variety of ways. Here are a couple of example scenarios below:

i) An individual who has IAD approximately once a month (score = 3) and it takes more than 2 weeks to heal (score = 4) and no experience of the listed symptoms (score = 1).

ii) An individual who has IAD a couple of times per month (score = 4) and it takes 1-2 weeks to heal (score = 3), and experiences one or more of the symptoms listed (score = 2).

iii) An individual who experiences IAD once per month (score = 3) and it heals within a week (score = 2) but also has bleeding, open wounds or fungal infection (score = 2).

Introducing the new framework for categorising IAD severity gives a greater freedom for data analysis so that new trends and patterns can emerge, as described in the next section (Section 6.10.2). Implementation of this tool in a diagnostic way should be done so as part of an ongoing assessment which could be recapped regularly, for example on a yearly basis, to ensure an individual's condition is closely monitored.

*An example of where people could fall through the gaps using the initial A*B model of the HIG Severity Index*

Somebody may have IAD approximately once per month, with healing time within one week. Under the old system this would give a categorisation of 3*2 = 6. A second person may have the same

occurrence and recovery rate however the symptoms could be totally different. Person 1 may have bleeding, itching, burning and raw skin. Whereas Person 2 may have discolouration and itching. In the old categorisation both would show up as ‘severe’.

In order to mitigate this, question C was introduced based on the symptoms that people had selected during the questionnaire, see Section 17 of Appendix A. From the selected responses it was possible to distinguish the more severe IAD signs and apply participants’ symptoms to the model. With the implementation of question C in the tool, the final result for each person was calculated using A*B*C. So in this case Person 1 with more severe symptoms ended up with an overall score of 12, categorised as ‘severe’, whereas Person 2 remained at 6, categorised as ‘moderate’. In this way both duration of suffering and symptoms experienced had an impact on the overall score and resulting categorisation. Accounting for the severity of tissue damage was a way to effectively moderate the total score and improve the model.

### 6.10.2 HIG Severity Index Results

Applying the new severity index tool led to the results tabulated in Table 6.8. The final percentage of respondents within each severity category, ‘mild’, ‘moderate’, or ‘severe’, is shown in Figure 6.13.

*Table 6.8 - Results of the HIG Severity Index, with the number (n) of respondents who chose each answer and the number within each index score and lastly the number who fell within each severity category.*

| A) Reported frequency of IAD symptoms | n |
|---|---|
| Once or twice a year | 3 |
| A few times a year | 13 |
| Approximately once a month | 8 |
| A couple of times a month | 13 |
| Every week | 14 |
| **B) Reported recovery time** | **n** |
| Within 3 days | 16 |
| Within 1 week | 17 |
| 1-2 weeks | 9 |
| More than 2 weeks | 4 |
| Never properly heals | 5 |
| **C) Severe skin symptoms reported** | **n** |
| No | 1 |
| Yes | 2 |
| **Index values** | **n** |
| 1 | 1 |
| 2 | 3 |
| 3 | 3 |
| 4 | 8 |
| 5 | 2 |
| 6 | 6 |
| 8 | 8 |
| 9 | 1 |
| 10 | 2 |
| 12 | 2 |
| 15 | 0 |
| 16 | 1 |
| 18 | 0 |
| 20 | 2 |
| 24 | 3 |
| 25 | 2 |
| 30 | 1 |
| 32 | 1 |
| 40 | 2 |
| 50 | 3 |
| **HIG Severity Index** | **n** |
| Mild | 15 |
| Moderate | 19 |
| Severe | 17 |

Note: 1 person with IAD had incomplete answers for parts of the IAD index responses, so they were not included.

The percentage of respondents within the study who were classified as having ‘mild’, ‘moderate’, or ‘severe’ IAD is shown in Figure *6.13*.

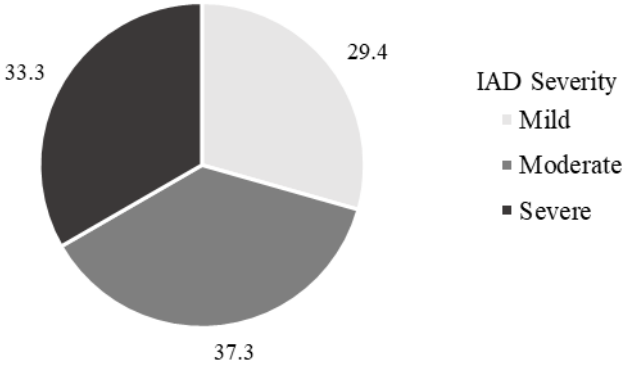


Figure 6.13 – The percentage of IAD sufferers who fall within each severity category, 'mild', 'moderate' or 'severe' according to the HIG Severity Index.

As can be seen from Figure *6.13* the proportion of people within each category is fairly evenly weighted with approximately one third of people lying within in each group. This finding may mean that the tool does a good job of separating the population i.e. not biasing towards one extreme or the other. The associations found through applying the HIG Severity Index to the analysis alongside other questionnaire data can be seen in Section 6.11.

There could be an application for the tool to be used by the general population at home as part of a knowledge advisory service, and/or the tool could have clinical applications. Some of the benefits of using and further developing this tool are:

- It could allow for better communication with a specialist by providing a quick initial assessment
- Ease of use at home without travelling to clinic
- The table and is simple and quick to calculate
- It could be turned into a simple online interface to calculate the score on behalf of the participant
- There are no distressing images and the terminology is user-friendly

## 6.11 Factors Affecting the Severity of IAD

In this section, associations and relationships between the HIG Severity Index and other data areas are examined, including its relationship with IAD severity, BMI, type of incontinence, and the choice of absorbent products used by the respondent.

### 6.11.1 Relationship between the Sandvik Severity Index and the HIG Severity Index

To determine whether or not the severity of UI impacts the severity of IAD, categories from both indices were compared (Figure 6.14).

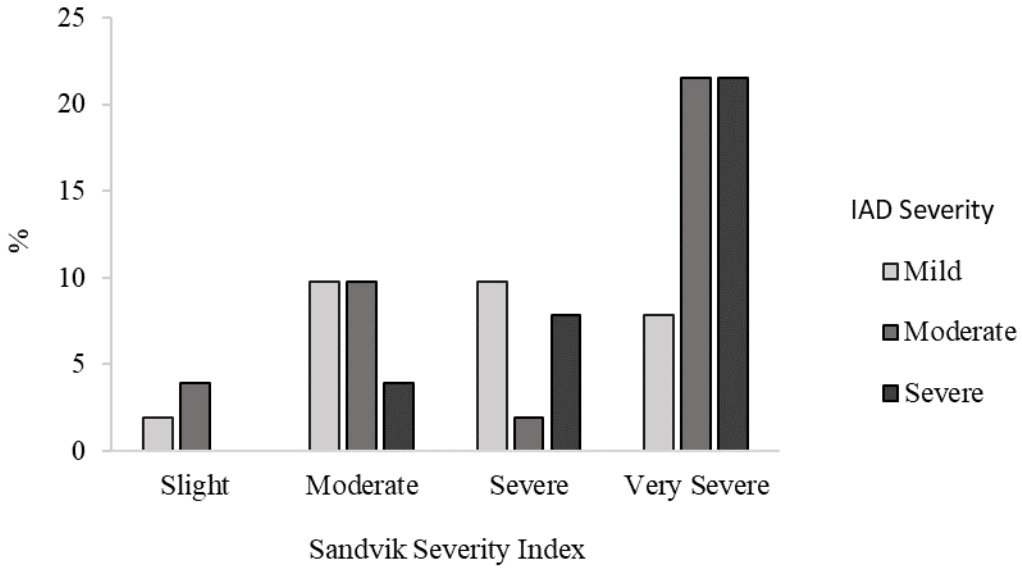


*Figure 6.14 – The percentage of respondents in each Sandvik severity category who are categorised as having 'mild', 'moderate', or 'severe' IAD. (n = 51)*

From Figure 6.14 it can be seen that as the level of severity of UI increases from 'slight' to 'very severe' the percentage of suffers with 'severe' IAD also increases. Of those with 'slight' UI there were no cases that had been categorised as having 'severe' IAD, whereas in the highest UI severity of the Sandvik Index ('very severe') there were 22% classified as having 'severe' IAD.

### 6.11.2 Relationship between BMI and the HIG Severity Index

The association between BMI and the severity of IAD was investigated. The BMI category of each respondent was compared with their calculated HIG Severity Index category, see Figure 6.15.

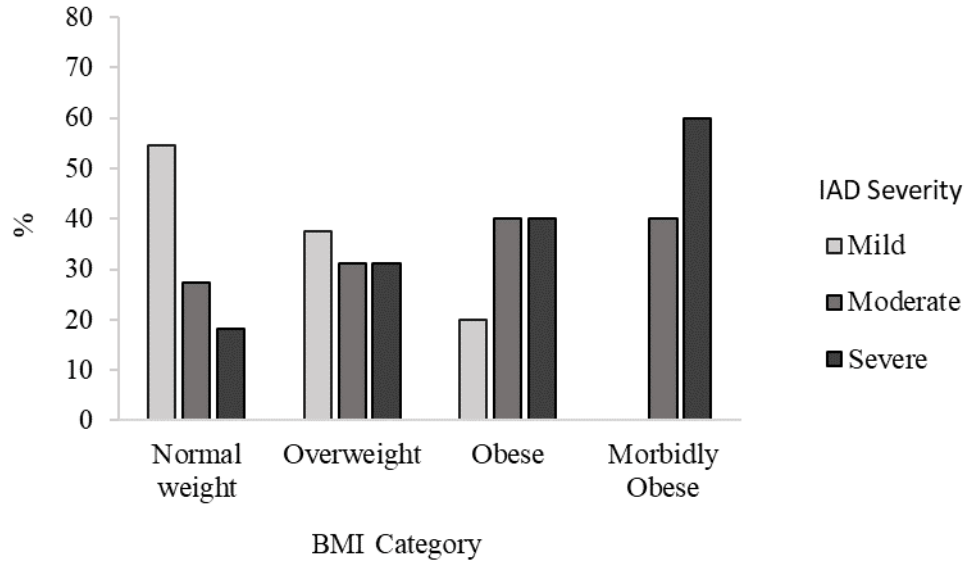


*Figure 6.15 - The percentage of respondents of each IAD severity category who lie within each BMI category.*

Within the 'normal weight' category there were a far higher percentage of people who experienced 'mild' cases of IAD. As the BMI category increased than the percentage of people suffering with 'mild' IAD decreased and instead the percentage of 'moderate' and 'severe' cases increased. Within the 'morbidly obese' category 40% of IAD sufferers had 'moderate' IAD, 60% had 'severe' IAD, and none were classified as having 'mild' cases. This shows a link between increasing BMI and increased likelihood of a person having more severe symptoms, along higher frequency and longer duration of IAD episodes. This finding supports those of Kottner *et al.* [13] who found that men with diabetes mellitus, higher BMI, and mobility issues had a statistically significantly higher prevalence of IAD.

### 6.11.3 Type of Incontinence and the HIG Severity Index

Each IAD severity category was compared against the type of incontinence that each person suffered with, see (Figure 6.16).

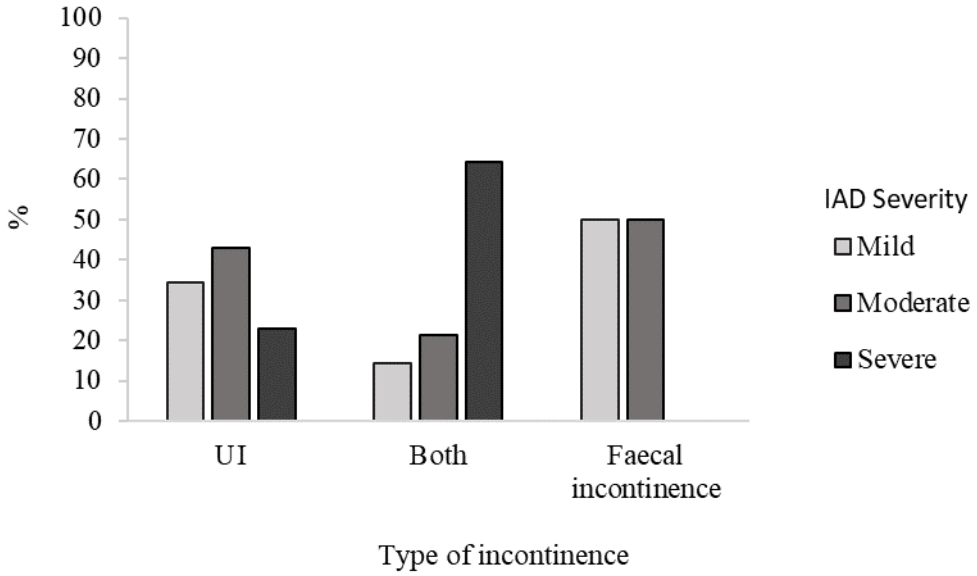


*Figure 6.16 – A chart to show the how the type of incontinence experienced (UI, faecal, or both) may have an influence on IAD severity.*

The type of incontinence has a big impact on the severity of IAD experienced. As seen in Figure 6.16 when people have double incontinence ('both' urinary and faecal), there are more cases of 'severe' IAD than if people solely suffer with UI. The presence of stools in urine has been clinically recognised as leading cause developing IAD and also giving rise to more severe cases of IAD. Browning *et al.* [14] simplified the IAD risks as liquid stools being 'very high risk', stools and urine as 'high risk', and urine 'at risk'. The results in Figure 6.17 align with others who have found that exposure to liquid stools is more damaging to skin because of the high levels of digestive enzymes present and double incontinence is more damaging than urine or faeces alone [15]. In the case of the faecal incontinence data available, in this study, there is not enough to establish possible relationships as few respondents suffered both faecal incontinence and IAD ($n$ = 2).

### 6.11.4 Type of Absorbent Product Used and the HIG Severity Index

Different absorbent products have very different design features and therefore interactions with the skin vary and result in a diverse range of contact pressures and contact sites on the body. Also, the ability to perform well varies from product to product and person to person. Figure 6.17 shows how the different

products, (pads, all-in-ones and pull-ups) may influence the likelihood of experiencing IAD within different severity categories. A 'combo of products' refers to people who use more than one type of product as a part of managing their incontinence.

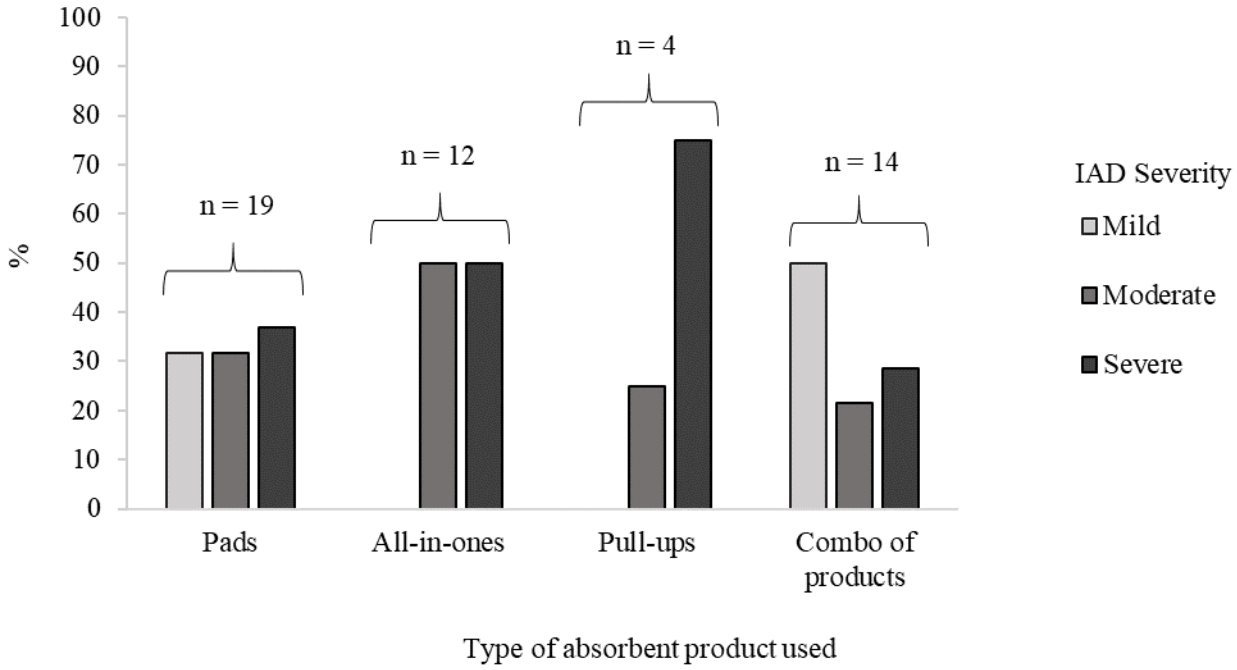


*Figure 6.17 – The percentage of people in each IAD severity category who use each category of absorbent product.*

With pad usage it was found there was an approximately equal percentage of 'mild', 'moderate', and 'severe' IAD cases. For all-in-ones, out of 12 users, none had 'mild' IAD, all had either 'moderate' (50%) or 'severe' IAD (50%) as classified using the IAD index. People using pull-ups were found to have a greater severity of IAD with 75% of users categorised with 'severe' IAD, and there were no cases of 'mild' IAD amongst those using pull-ups. The severity and type of incontinence largely contributes towards absorbent product choice, therefore the severity is also a factor to consider alongside Figure 6.17. When a combination of products was used (pads and all-in-ones, pads and pull-ups, or all-in-ones and pull-ups), there was a much higher percentage of sufferers in the 'mild' category. Of 14 people who were combo users, 50% had a 'mild' classification, 21% 'moderate' and 29% 'severe'. The low occurrence of 'severe' IAD in combo product users could be due to the alternating friction and pressure points during daily usage. So despite the finding that a higher percentage of combo users had IAD, see Figure 6.12, more of these cases were 'mild' than those of other product users. A possible explanation for this is that if an individual alternates between absorbent product types regularly, e.g. for certain activities, or wearing a different product type day to night, the skin likely

experiences different contact conditions. Therefore, this alternating pattern may relieve the skin and give a time period in which skin can recover.

### 6.11.5 Limitations of the HIG Severity Index

When assessing the suitability of this new diagnostic tool it is important to view the limitations and drawbacks of the particular approach taken. Iterations of the model have improved it, however there is still conflicting arguments as to what extent the suitability is for all cases. For example, if an individual has IAD a few times a year (score = 2) and it heals within 3 days (score = 1) and they have bleeding symptoms (score = 2), then gives a total score of 4 when all of scores are multiplied together. This example would show up as a 'mild' level of IAD. Whether or not this could be classed as a 'mild' case is questionable. Future work in the area would require a study involving medical validation. The best way to assess the suitability of the scale would be to test run it diagnostically with a medical specialist before moving on to further clinical studies.

### 6.11.6 Impact of the HIG Severity Index

The HIG Severity Index may enable people to get a better understanding of their own skin health both in and out of a medical setting by providing guidance and resources. This tool would help to quickly categorise a person, and give indication of whether or not they might require more help managing their IAD. Additionally, the index could be used to diagnose and monitor patient skin condition; asking patients the questions yearly would enable any increasing or decreasing severity levels to be recorded. Recording such data could improve patient outcome by early detection of worsening symptoms and also it could provide useful data collection provide insights into which treatment interventions are most successful. It could also be used as an ice-breaker, as many people find the topic of IAD difficult to broach with medical professionals. Many diagnostic tools are not patient friendly and require clinical knowledge to understand and implement. The HIG Severity Index has the benefit that it is very patient friendly, easy to understand and quick to calculate.

## 6.12 Skin Treatments

The questionnaire contained a section to find out the ways in which skin treatments played a role in the management of IAD within the community-living population.

### 6.12.1 Skin Treatment Usage

Usage of skin treatments was found to vary widely amongst individuals; not everybody who had IAD used treatments, and conversely some people with no skin problems used skin treatments (Table 6.9).

*Table 6.9 – The results of skin treatment usage in IAD sufferers and non-sufferers*

| IAD and treatment usage | % of people |
|---|---|
| Sufferer of IAD and uses skin treatment | 29.1 |
| Sufferer of IAD and no treatment usage | 16.2 |
| Non-sufferer of IAD and uses skin treatment | 9.4 |
| Non-sufferer of IAD and no treatment usage | 45.3 |

Of the 117 respondents 45% did not have IAD and did not use treatments, and as could be expected the highest percentage of skin treatment users were those with IAD.

Figure 6.18 shows that 29% people chose to use skin treatments to prevent the onset of symptoms, 32% use them to manage IAD when symptoms are present, and 32% of people use them to both manage and prevent IAD.

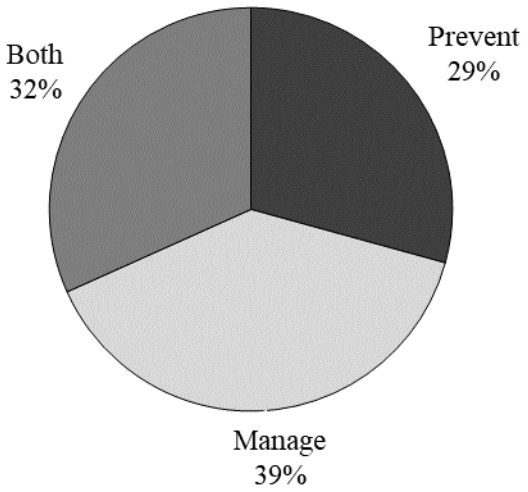


*Figure 6.18 – The percentage of treatment users who use skin treatments to either prevent onset of IAD, manage the condition when symptoms are present, or both.*

Whether or not a person had sought medical help for incontinence was found to have an effect on skin treatment usage. Of the people with IAD who had sought medical help for incontinence, 75.6% used skin treatments. Of those who had IAD but never sought medical help for incontinence only 24.4% used

skin treatments. This indicates a big disparity between the two groups, and if more people with IAD sought help for their incontinence then they would likely get help and implement treatments as part of managing their incontinence and skin health. The lack of treatment usage could be due to a lack of awareness of effective treatments, a lack of need for treatments, or a lack of medical help and advice for IAD.

### 6.12.2 Treatment Preferences and Reviews

In order to gauge the more in depth specifics of treatment usage of respondents, a series of questions were asked to determine treatments used, the least preferred and most preferred treatments, along with reviews of a treatment or treatments of their choice. The purpose was to judge the performance of each treatment in pre-defined areas of importance. The treatment users responded to a series of performance statements as either 'agree', 'disagree', 'neutral', or may have left the answer blank resulting in a 'no answer' being reported on the figure. Participants had the option of rating one or more products of their own choice. 100% of the 46 skin treatment users chose a preferred product from a list, with the option to write their own preferred product. When asked to choose a least preferred product 78% responded.

The top six preferred products were *Sudocrem* (28.3%), *Cavilon* (10.9%), *Bepanthen* (6.5%), *Cetraben* (4.3%), *Clotrimazole* (4.3%) and *Hydrocortisone* (4.3%). The top least preferred products were *Sudocrem* (8.7%), *Talcum powder* (8.7%), *Vaseline* (6.5 %), *Aloe Vera* (4.3%), *Aqueous cream* (4.3%) and *Bepanthen* (4.3%). In total 24 different products were chosen as 'preferred products' across the group of people and 18 were chosen as 'least preferred'.

The treatment rating results for the top three most rated products are shown in the following figures: Figure 6.19 (*Sudocrem*), Figure 6.20 (*Cavilon*), and Figure 6.21 (*Bepanthen*). Ratings for other treatments were collected however there was insufficient data to present given that there were only one or two ratings per treatment.

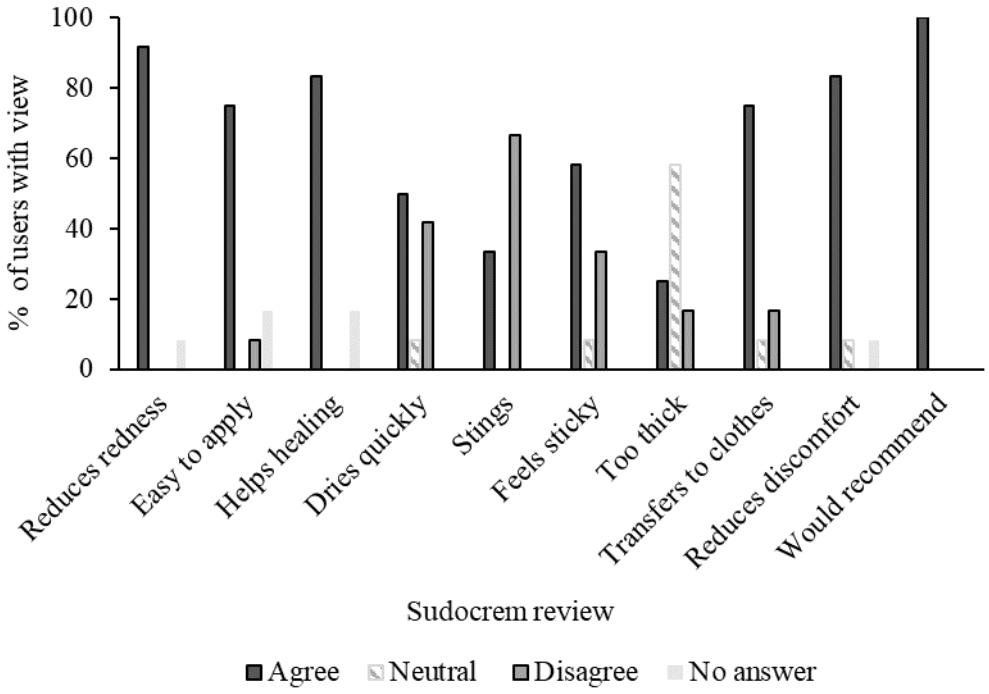


*Figure 6.19 – Reviews of Sudocrem where n = 12 people chose to rate this product.*

People who chose to rate *Sudocrem*, in general, had positive experiences with the product judging by the end result that 100% of people would recommend it. Whereas for *Cavilon* and *Bepanthen* ~20% of the people would not recommend the product. The majority of people agreed that *Sudocrem* reduces redness, is easy to apply, helps healing, feels sticky, transfers to clothes, and reduces discomfort. Approximately ~30% of those who rated *Sudocrem* agreed that it stings, compared to ~20% of the *Cavilon* and *Bepanthen* respondents. For all three treatments the majority of people agreed that the products transfer to their clothes; this is problematic because a transfer of a product from skin to clothes can indicate that a transfer may also be happening from the skin to the absorbent product, therefore blocking the moisture-wicking properties of the fabrics. People using *Cavilon* and *Bepanthen* also agreed that the product reduced redness, helps healing, and reduced discomfort. Approximately 50% of people rating *Cavilon* did not agree that the product was easy to apply, whereas for both other treatments they were rated as easy to apply by the majority of people (~80%). Participants were not asked why they did or did not find it difficult to apply products, but in the context of *Cavilon* part of the reason for the may be due to the ability to see where the product has been applied. *Cavilon* is instructed to be applied very sparingly and once rubbed into the skin it is invisible and dry except for a slight shine. Whereas, *Sudocrem*, when applied, remains as an opaque layer on the skin, so people can see that they have definitely applied the product to all of the right places. Research in future could look at product comparisons in the context of user experience to discover more about some of the perceptions recorded in the findings of the questionnaire data.

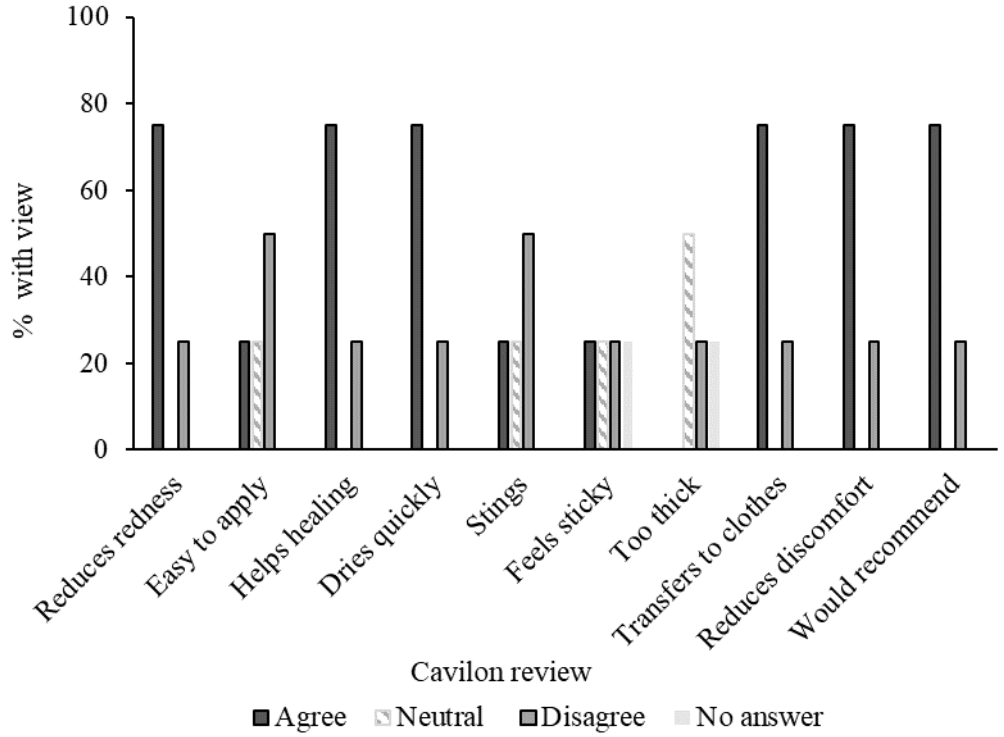


*Figure 6.20 – Reviews of Cavilon where n = 4 people chose to rate this product.*

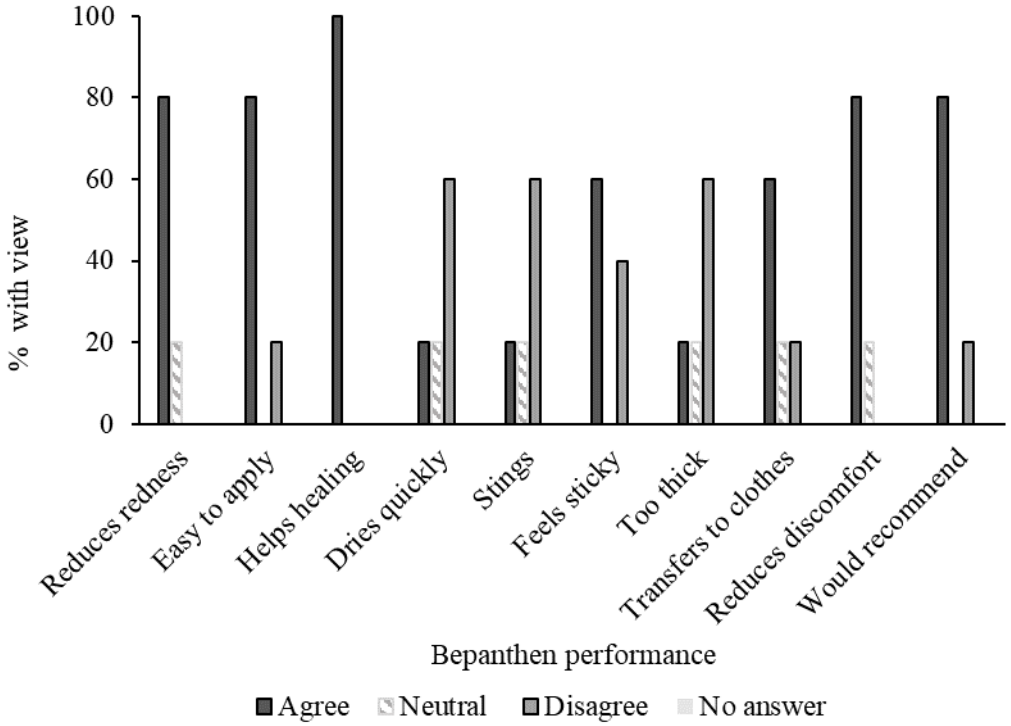


*Figure 6.21 – Reviews of Bepanthen where n = 5 people chose to rate this product.*

In general, there were very mixed opinions amongst treatment users, even of the same treatment. Due to the lack of data it is difficult to make comparisons, but the results do indicate certain elements of treatment performance, and the answers to 'Would you recommend the product?' are good indicators of satisfaction. Other limitations of product rating questions are that people may be hesitant to rate a product that they do not like, and what they currently use may be deemed to perform satisfactorily. However, if given the opportunity to try different products they may find something that suits their skin much better.

## 6.13 Absorbent Products

### 6.13.1 Pads, All-in-ones, and Pull-ups

77.8% of respondents were users of absorbent products. Figure 6.22 shows the frequency of which absorbent products were worn by users.

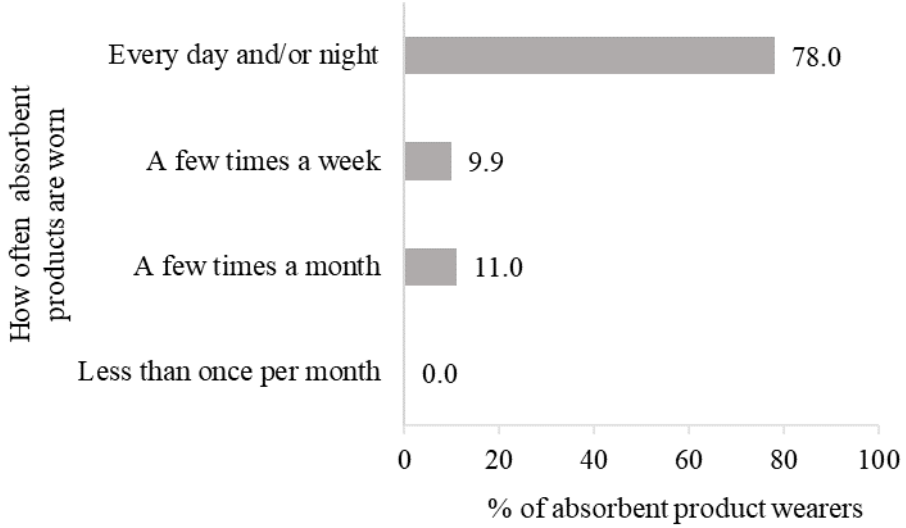


*Figure 6.22 – Chart showing the percentage of people who wear absorbent products either 'every day and/or night', 'a few times a week', 'a few times a month', or 'less than once per month'.*

The majority of absorbent product users wore them every day and/or night. The most commonly worn product was pads, with 67% opting for this choice of product. Of the respondents twenty-five used more than one type of absorbent products (e.g. either pads and pull-ups, all-in-ones and pull-ups, or pads and all-in-ones). This type of dual product use has been referred to in this chapter as a 'combo' of products. There were also respondents who reported using period underwear and panty-liners due to the embarrassment of buying incontinence pads.

### 6.13.2 Absorbent Product Reviews

The following figures compare opinions on the performance of different categories of three absorbent products: pads (Figure 6.23), all-in-ones (Figure 6.24) and pull-ups (Figure 6.25). In total 126 product ratings were completed, where 69 people rated pads, 31 people rated all-in-ones, and 26 people rated pull-ups of their choice. Some people rated more than one product.

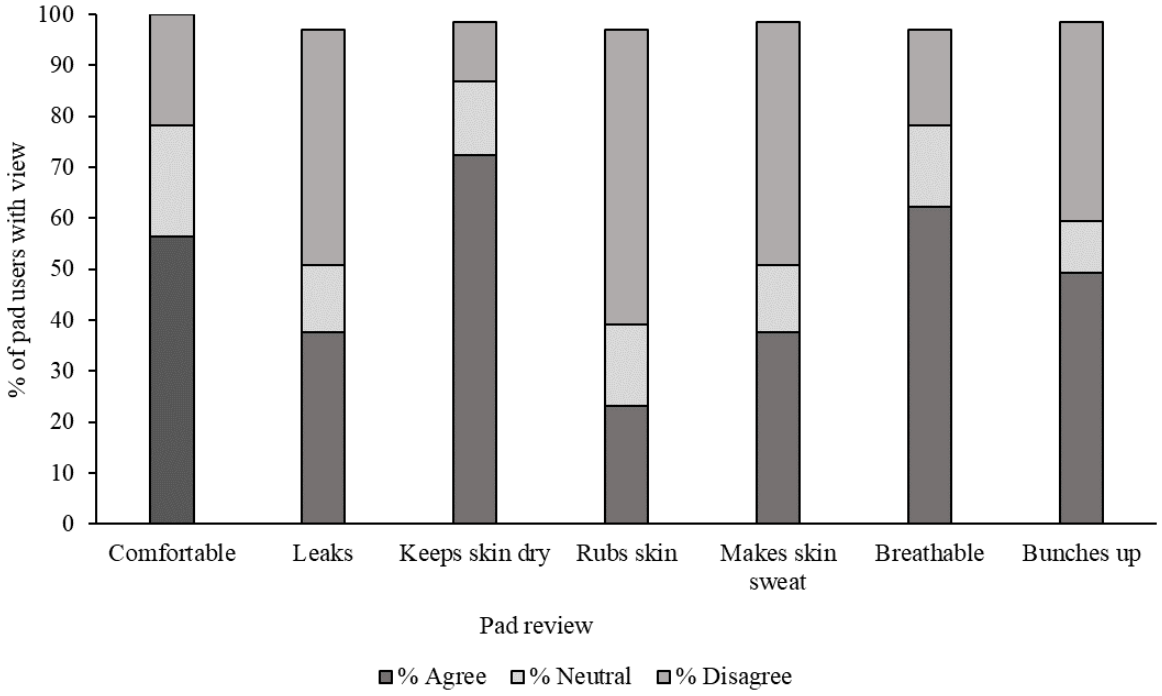


*Figure 6.23 – Pads: Chart showing the percentage of pad users who responded 'Agree', Disagree' or remained 'Neutral' about a series of statements regarding pad performance, n=69.*

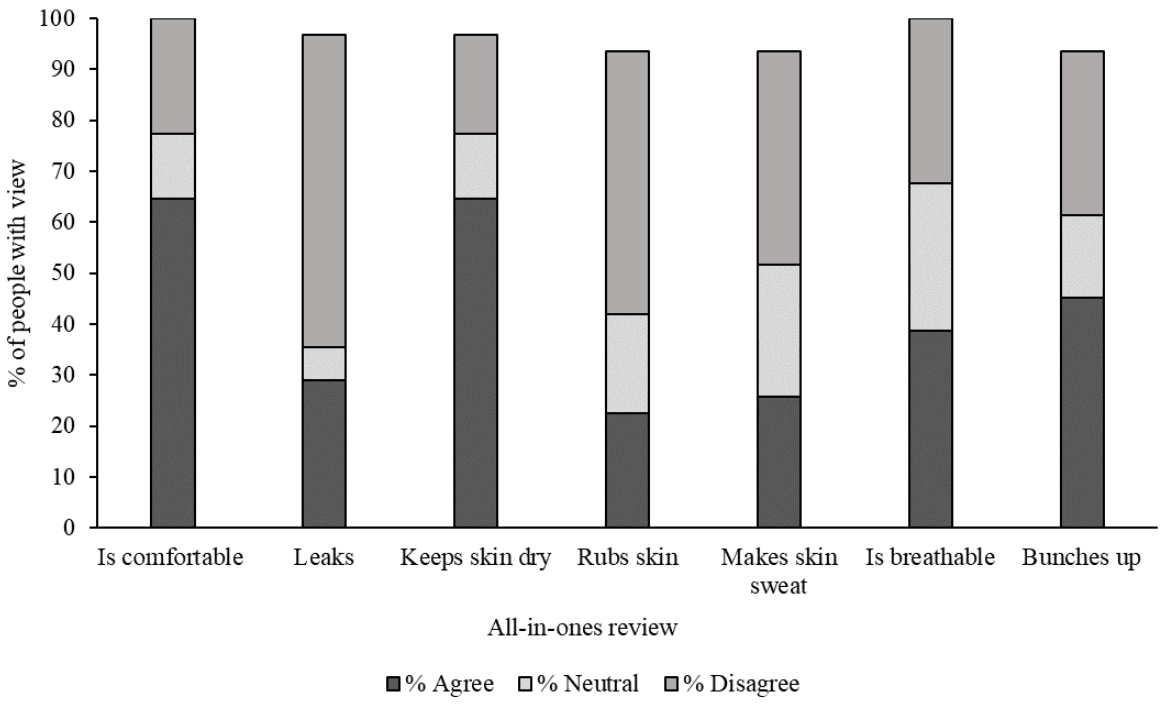


*Figure 6.24 –All-in-ones: Chart showing the percentage of pad users who responded 'Agree', Disagree' or remained 'Neutral' about a series of statements regarding pad performance, n=31.*

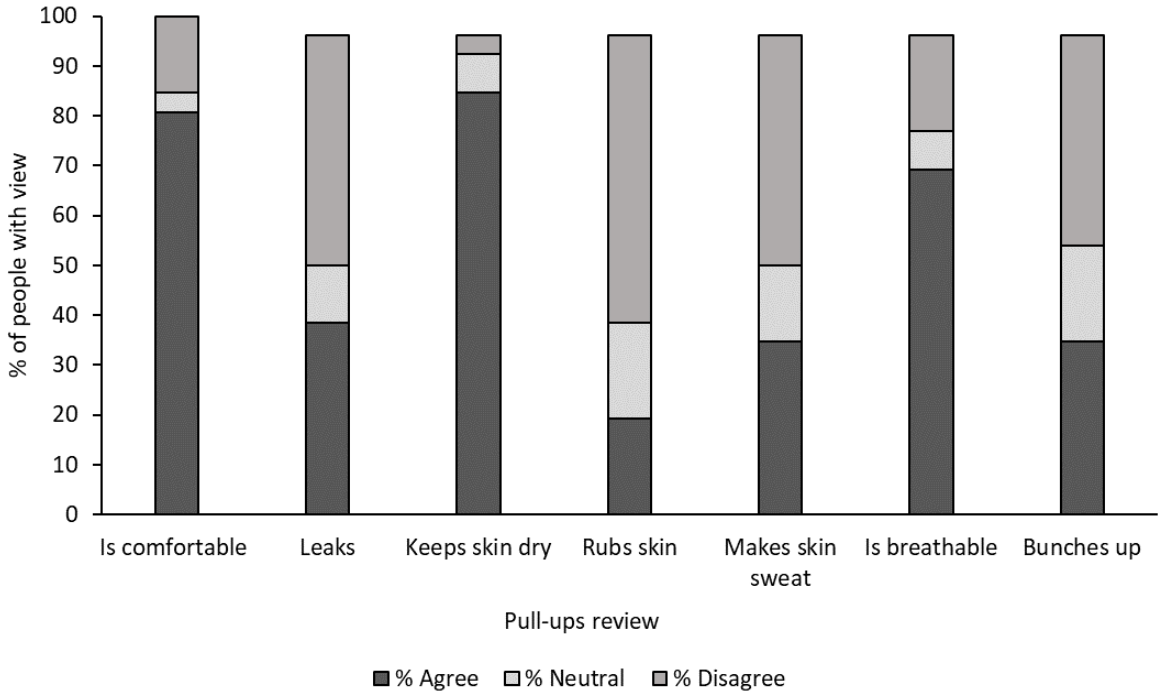


*Figure 6.25 – Pull-ups: Chart showing the percentage of pad users who responded 'Agree', Disagree' or remained 'Neutral' about a series of statements regarding pad performance, n=26.*

Pull-ups were rated as comfortable by users (with over 80% in agreement), whereas less than 60% of pads users and just over 60% of all-in-one users agreed they were comfortable. All-in-ones were best for low leakage with less than 30% saying their pad leaked. Pull-ups performed best for keeping skin dry. All-in-ones users were less likely to agree their product was breathable, compared to other absorbent product users. Pad users were more likely to report their product as bunching up compared to other product users.

## 6.14 Discussion and Recommendations

From the in-depth interviews conducted during the early design phases of the questionnaire the problems faced by people became apparent; e.g. there are restrictions on the supply and types of products available within the UK continence services. A typical supply of four pads per person per day is given by clinics and there is limited choice, plus only one type of absorbent product per person is provided. In the study results it was identified that 'being unable to change pads or garments as often as needed or soon after an episode' was the primary reason as to why people think they develop IAD. Therefore, the limited quantities of products being provided to patients by incontinence clinics could actively be contributing to the development of IAD. 'Combo' product users were found to have lower severity ratings of IAD, so a preliminary recommendation both for clinics and the community is to alternate between products to minimise extended periods of shear and friction on the same bodily locations. They could do this by providing products of different shapes and types so as to minimise extended periods of contact, rubbing, and pressure on the same skin sites, giving chance for the skin to recover.

It was noted that with the closure of public toilets and the inability to always access toilets in retail places, it is difficult for sufferers to change pads as frequently as needed. Implementation of the 'Just Can't Wait Card' has helped people as it allows access to toilets, in shops and stores which are generally closed off to the public. Unfortunately, not enough people know about the scheme.

Another problem highlighted was the lack of appropriate disposal facilities in most toilets. With hand-dryers being common place, they have replaced the use of paper towels and bins where people used to dispose of absorbent products. Women's toilets have sanitary bins, however these don't have large enough openings to accommodate large pads, bulky pull-ups and all-in-ones. Men often experience no bins available in the toilets for disposal of products. The resulting impact of this is that people carry around used products in their bags, and have sometimes plan trips in advance to ensure there is an accessible and appropriate toilet.

There is a lack of awareness of the prevalence of incontinence in the country, and as a result the urgency to make changes is not strong enough. The findings of the questionnaire were presented to the Sheffield

City Council Scrutiny Committee who were running a focused session debating the question 'Are the continence services meeting the needs of the people?'. A report was developed by the council based on the findings from the meeting. With the city council in Sheffield looking at ways to improve the continence service, there is hope that cities and health authorities can adapt to better accommodate patients and other community-living individuals, whether or not they choose to seek medical help. It is clear that the current medical system is not fully meeting the needs of the people and there are improvements to be made. With more research and education in this area, it is likely that incontinence and IAD sufferers would have better access to products, treatments and much needed advice.

## 6.15 Conclusions

The outcome was that 117 people responded to the questionnaire and relevant data was collected which proved extremely useful to gather new insights in the area of IAD in the community. The results of the questionnaire into incontinence and IAD in a community-living population have highlighted new relationships and potential causes of the development of this skin condition.

i. A very high percentage of IAD sufferers attribute the pad on skin interaction to be a big contributing factor to the development of their skin problems, along with not being able to change their absorbent product as often as needed or soon after an episode.
ii. A new severity scale for IAD was developed called the HIG Severity Index. This categorised people by looking at the frequency of which they experienced symptoms, their recovery time, and types of symptoms. New relationships were uncovered using the scale; they are discussed below in point iii.
iii. Several factors were found to impact the severity of IAD experienced by an individual, which were BMI, UI severity, type of incontinence, and the type of absorbent products used:
    - Higher BMI results in more severe cases of IAD.
    - With higher UI severity, IAD severity also increases.
    - Mixed incontinence (both urinary and faecal incontinence) results in more severe IAD.
    - The type of absorbent products used affects the IAD severity, with pull-up users more likely to suffer more severe IAD, and combo users less likely to have severe IAD.

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# Friction in the Skin-Pad Interface in the Presence of Topical Treatments

# 7

## 7.1 Introduction

Tribological studies of the skin-pad interface provide an improved physical understanding of the mechanisms which lead to the development of incontinence-associated dermatitis (IAD). In this chapter experimental methods are used to replicate an environment alike to the hostile skin-pad interface, and to identify the different ways that treatments interact with the skin and prevent damage. Such research has the potential to improve product compatibility, reduce the incidence of skin breakdown, provide faster healing times, and offer long-term cost savings for the NHS. Much of the previous work in this area in literature surrounds moisture-associated skin damage, tissue shear, and pressure, but friction is often overlooked; therefore, increasing tribological knowledge will be beneficial to sufferers and medical professionals.

Barrier treatments are frequently used alongside incontinence pads to provide the skin with a protective waterproof barrier and to guard skin against rubbing, chafing, and irritation. Researchers, clinicians, and patients all want to access the right combination of products to provide optimal conditions for skin protection. Looking at the tribological performance of topical treatments is important in order to better understand the sliding friction and to aid in the creation of products that allow skin to glide more easily, providing low friction contacts and reducing skin deformation. This chapter aims to bring further knowledge of frictional performance of common barrier products used in the treatment of IAD, and determine how the skin-pad interface changes when a treatment is applied to the skin.

## 7.2 Aims and Objectives

The aim of the study presented in this chapter was to evaluate the friction interactions between the volar forearm surface and an incontinence pad in dry and wet conditions, and test the effect of three topical treatments on the values of the dynamic coefficient of friction (DCoF) and static coefficient of friction (SCoF). The objectives were to:

- Customise the existing departmental friction rig by designing a new mount to be used to support an incontinence pad.
- Design an experimental protocol for *in vivo* friction tests between the pad and the volar forearm.

- Evaluate friction in the skin-pad interface in distinct loading conditions, and in wet and dry states.
- Determine the effects of the different topical treatments on the skin friction.

## 7.3 Equipment and Methodology

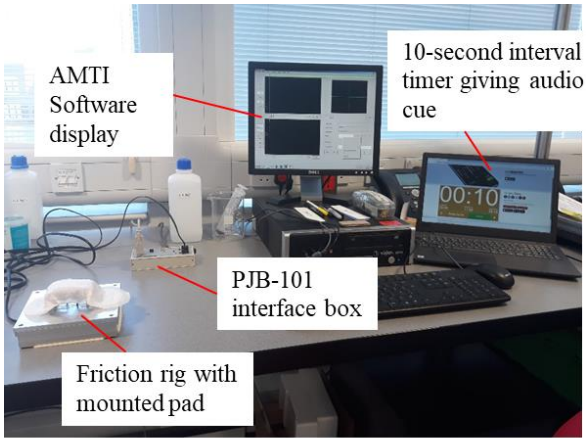
### 7.3.1 Summary

Eight participants were recruited for the study, with tests performed on the left volar forearm. *Tena Lady Discreet Normal* pads were mounted on a multi-axial force plate, and the experiments were conducted under dry conditions and wet conditions. To achieve wet conditions 80 ml of artificial urine (a saline solution, composed of deionised water of 0.9 NaCl) was syringed onto the pad and left to absorb for 5-minutes before friction tests were conducted.

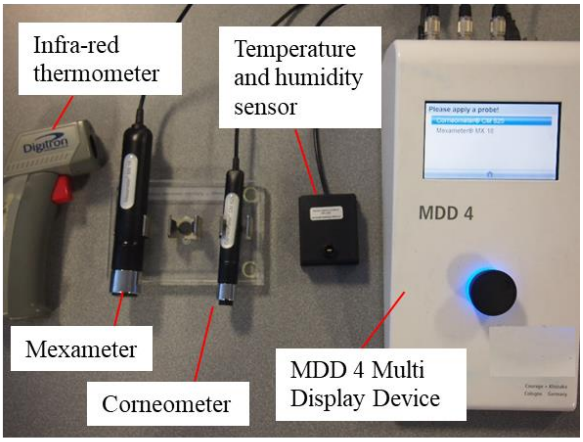
Three different loads of 1, 2, and 3N were investigated, alongside varying the skin treatments in the interface. Prior to each experiment, participants' skin was maintained in as close to a natural state as possible; they were instructed not to use any soap or other skin treatments on the forearm for at least 24-hrs prior to testing. Tests were conducted at least 48-hrs apart. An amount of 0.2ml (1.78 mg/cm$^2$) of barrier cream was applied to the treatment application area (defined in Figure 7.4), or one spray of *Sorbaderm Barrier Spray* was applied. Treatments rested on the skin for 5 minutes before the friction tests were started.

The equipment used in the experiment is shown in Figure 7.1, including a) the AMTI friction rig and b) the skin characterisation kit, previously seen in Chapters 3 & 4. Three skinfold caliper readings were taken from the test area of each participant in order to gain a quantitative indication of levels of sub-surface tissue. A 10-second interval bleep timer was used to inform participants when to change the sliding direction. The timer bleeped every 10-seconds for 120-seconds, to direct the pace of the 12 reciprocating strokes. The AMTI software was set to acquire 200 data points per second, and the average velocity of each forearm stroke was approximately 4mm/s. This average velocity was achieved using buffers set up on either side of the rig as a guide to direct participants how far to slide over the time periods of 10-seconds.

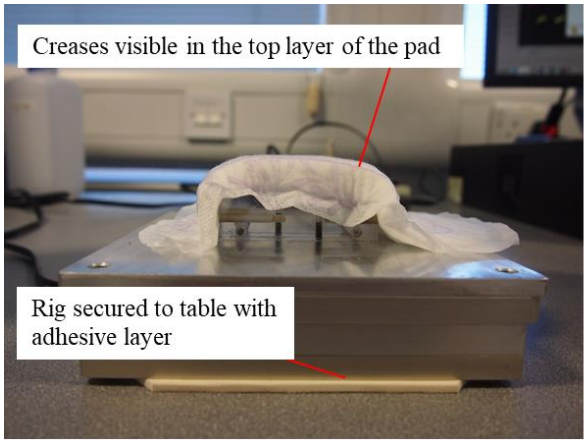
The first experimental study influenced the design of the friction methodology for this study, these learning points are summarised in the protocol review of the first study, see Section 4.5, 'Protocol Review and Learning Points'.



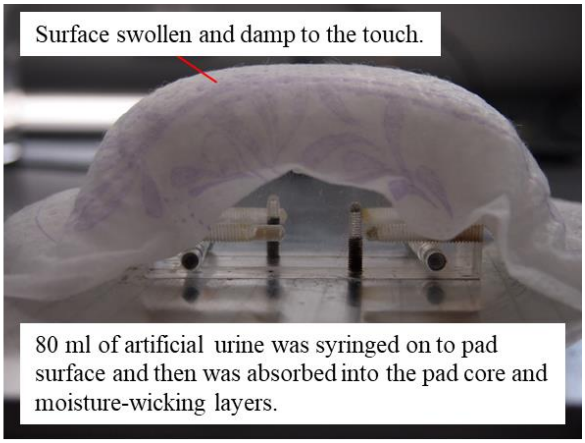

a) Equipment setup




b) Skin characterisation kit

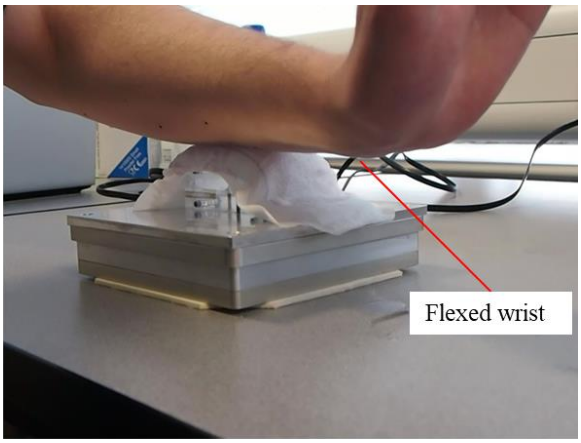



c) Dry-pad mounted on rig




d) Wet-pad mounted on rig


e) Skin treatments: Cavilon, Sorbaderm Cream and Spray




f) Arm alignment with rig

*Figure 7.1 - Equipment used in the skin-pad experiment. a) AMTI friction rig, AMTI software, and laptop setup with a countdown timer. b) skin characterisation testing devices, c) and d) are images of dry-pad and wet-pad mounted on the force plate, e) the three skin treatments used in the tests, and f) demonstrates the forearm contact position against the pad surface.*

The three treatments selected, shown in Figure 7.1 e), were *Cavilon Barrier Cream, Sorbaderm Barrier Cream,* and *Sorbaderm Barrier Spray*. The criteria for skin treatments to be included in the study were (i) commercial availability, (ii) clinical availability and/or being available on prescription, and (iii) being composed of different chemical constituent ingredients. More about these treatments can be found in Appendix B. Throughout this chapter the skin treatments that were used for the tests have also been referred to as the following:

- *Cavilon Barrier Cream* as *Cavilon*.
- *Sorbaderm Barrier Cream* as *Sorbarderm*.
- *Sorbaderm Barrier Spray* as spray or barrier spray.

The chosen absorbent pad was a *Tena Lady Mini Discreet Normal* pad, shown in Figure 7.1 c) under dry-pad conditions, and d) under wet-pad conditions. The surface material of the pad is composed of a blend of fibres: polypropene, polyethylene, polyester and viscose, which is designed to keep skin dry by quickly absorbing the liquid. Beneath this is an acquisition layer of polyester fibre which transports liquid from the surface to the core of the product for storage. The absorbent core of the product is composed of a combination of paper pulp and superabsorbent materials which can absorb many times their weight in water [1].

The capacity of absorbent incontinence products is measured using ISO 11948-1, and these guidelines use the Rothwell method to determine the total absorbency of the pad [2]. The total absorbency of a product is calculated through the total immersion of a pad into a reservoir of saline and letting it soak for 30-minutes. This is then followed by weighing the wet pad and subtracting the dry weight to see how much fluid the pad retained. A *Tena Lady Discreet Normal* pad has been experimentally recorded as having a total absorbency of 300 ml using the Rockwell method [3], but this number is far greater than the amount of urine that could be held in real life which is where "working capacity" becomes an important figure. Guidelines state that the working capacity of pads is approximately 30-50% of the total absorbency of the product, so taking the conservative estimate of 30%, the working capacity can be deemed to be 90 ml. In the experiments within this study a volume of 80 ml of artificial urine was chosen to reflect a volume close to the working capacity estimate.

The *Tena Lady Discreet Normal* pads were chosen for the skin-pad study because they are appropriate for medium bladder weakness, easily available to purchase in supermarkets, pharmacies, and with online retailers, and they were easy to secure to the friction rig, as well as not requiring any cutting of the pad in order to attach to the rig.

The normal loads of 1N, 2N, and 3N were chosen because they fairly are low loads which were easy for participants to maintain over each sliding stroke for the duration of 120 seconds, alongside causing minimal discomfort. Exerting higher loads could have caused arm fatigue for participants, as well as the potential for some people to experience either a willingness to withdraw from the experiments, or

an inconsistency in the results as any arm fatigue or pain impacting the ability to maintain the force, velocity, so affecting the reliability of the data. Many volar forearm studies in literature use low loading conditions, consistent with those used in this experimental study protocol [4-7]. Additionally, the skin-pad interface experiences low loading conditions during regular wear, however the forces exerted in a typical skin-pad interface were not measured. Examples where a person may experience a greater force could be if a pad or underwear was too tight, or in the case of seated pressure on the skin, there would be higher loads encountered on the body-surface contact points.

### 7.3.2 Friction Rig Modification

The friction rig, presented previously in Chapters 3 & 4, was modified to include a mount for the incontinence pad, see Figure 7.2, which replaced the previous mounted steel ball See Appendix E for a full CAD drawing of the mount design.

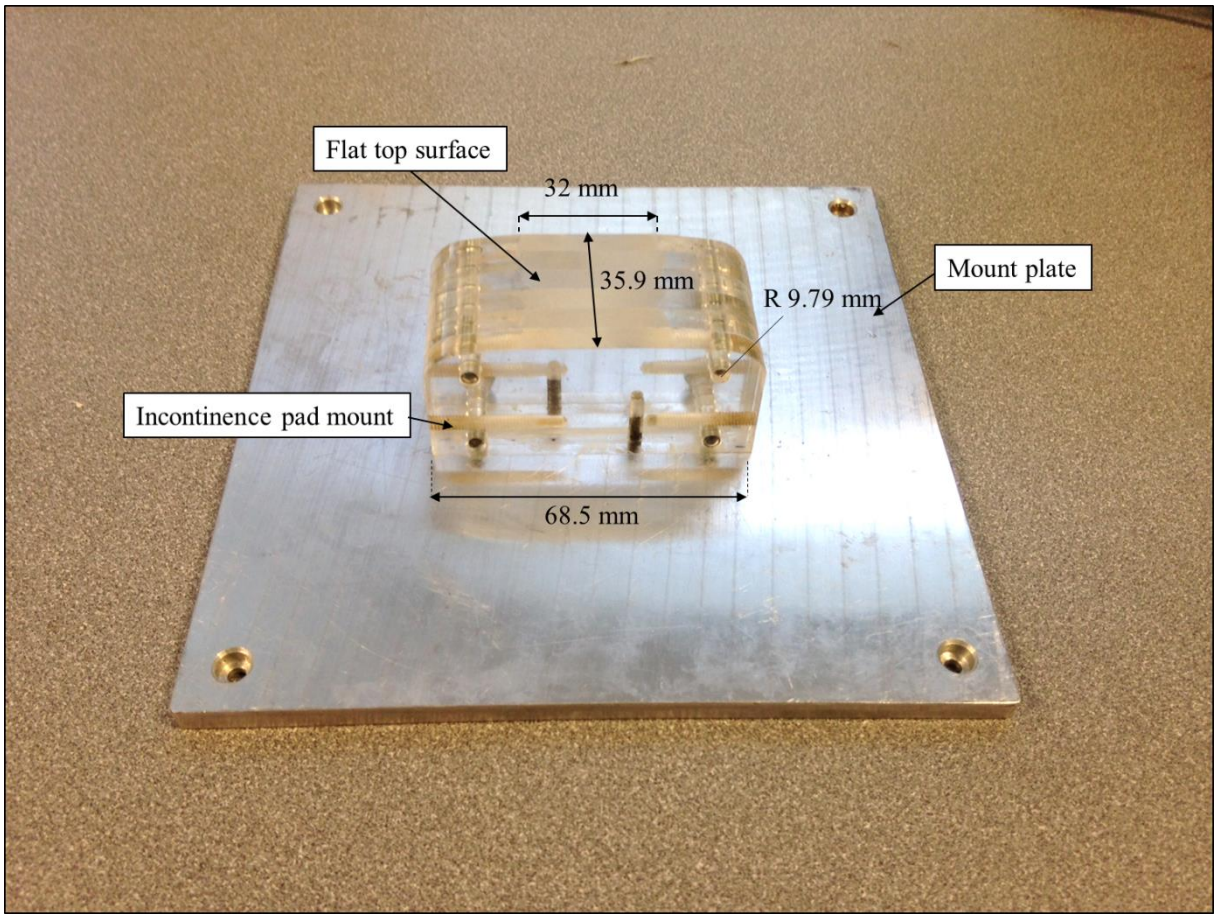



*Figure 7.2 - Image of the mount design for the multi-axial force plate, where R is the radius of curvature, a full CAD drawing can be found in Appendix E.*

The mount shape and size provided a rectangular elevated contact surface for the pad to attach securely to whilst maintaining contact with the forearm. Rounded edges were important in order to provide a suitable contact surface for the sticky underside of the pad to hold in place throughout testing; square

edges could risk tearing holes in the pad underside during repeated sliding. The width of the mount was suitable for the size of the *Tena Lady Normal Discreet* incontinence pad, allowing a slight overlapping over the edges. The pad contact surface was suitable to fit within all of the participant's volar forearms, i.e. it was not too large. For example, with a wider mount a narrow forearm could end up with a smaller skin-pad contact, than somebody with a larger forearm, because there would be an excess of pad surrounding the forearm. Additionally, the length of the mount top surface was sufficient to still give space for sliding up and down the forearm. For example, if the mount was designed to have the entire length of the pad in contact with the arm then the space for any reciprocating movement would be too small, and also in testing it was important not to have a test site on or near the wrist due to the difference in anatomy, and instead needed to be conducted on the volar forearm.

Figure 7.3 shows a schematic of the position of the incontinence pad on the rig, along with the reciprocating direction of movement of the forearm in the x-direction.

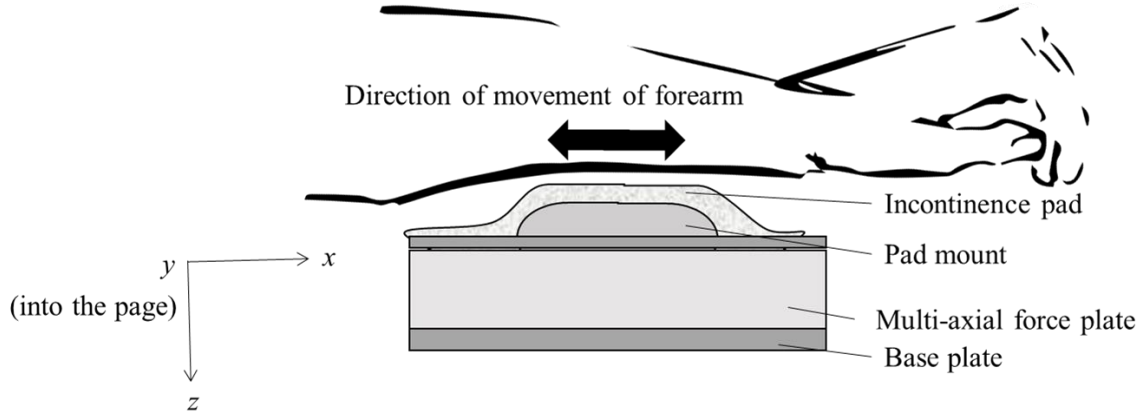



*Figure 7.3 - Schematic of the friction rig and the volar forearm. Directions of the axes indicate that the x-axis is the general direction of movement of the forearm, the y-axis is the lateral movement, and the z-axis is the direction of the applied normal force.*

### 7.3.3 Test Site Measurements and Markings

The test site was marked and measured to provide relevant test areas as defined in Figure 7.4 a) and b). Treatment was applied across the entire treatment application area and the control sites were used to measure skin temperature, redness and moisture levels before and after tests.

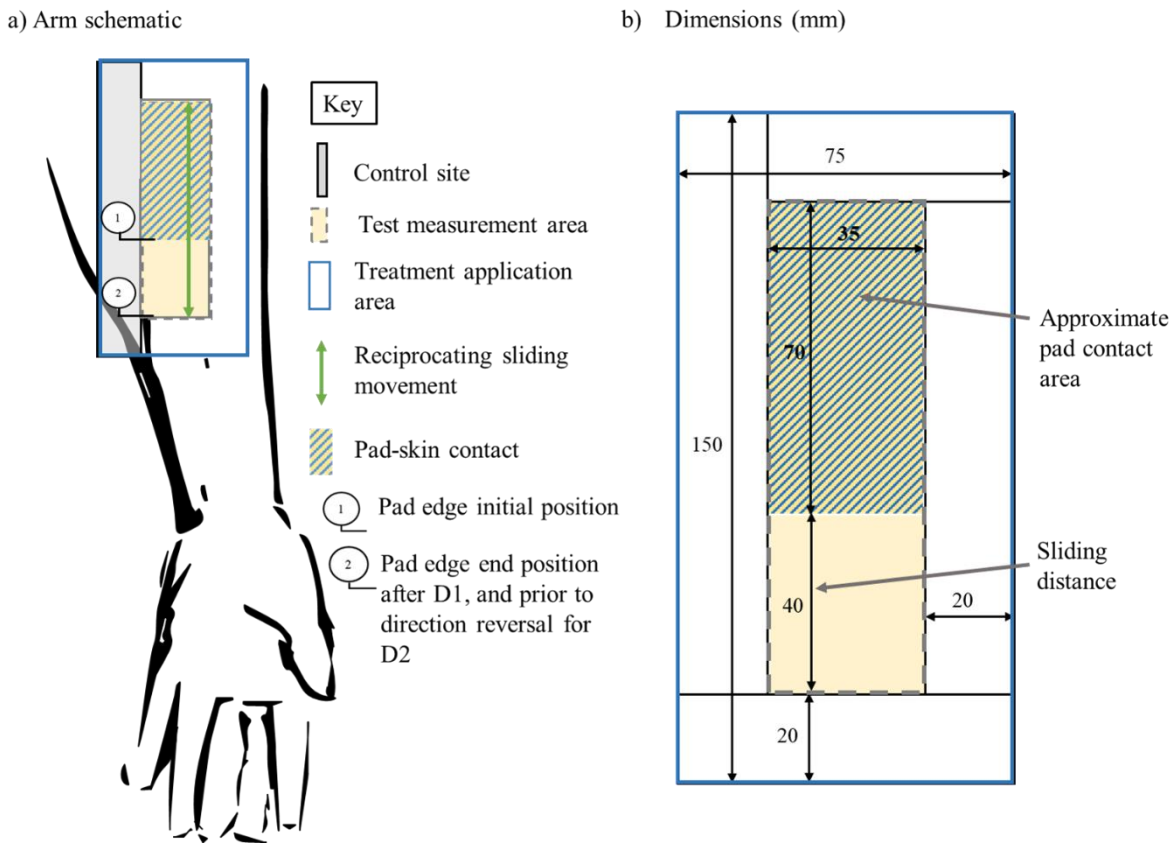



*Figure 7.4 - Forearm schematic and dimensions.*

### 7.3.4 Contact Area Pilot Test

A short pilot test was conducted to assess the contact area between the pad and the skin surface, see Figure 7.5. A thick layer of *Sudocrem* was spread over the forearm, and the participant was instructed to press the forearm downwards onto the pad surface at a force of 3N. Anywhere on the forearm that made contact with the pad surface resulted in a layer of the treatment being partially removed, therefore leaving a visible indication of the shape and area of contact between the two surfaces. This treatment was not used in any of the experiments, however it was chosen for the contact area tests due to its ability to remain in a thick opaque layer after application, meaning that the impression was clearly defined. An example of this can be seen in Figure 7.5.


*Figure 7.5 - Contact area between the pad and the forearm*

The area of the removed cream lay within the template marked test site, showing that the marked area was a slight overestimate of the true pad-skin contact area; the discrepancy arose due to the curvature of the surface of the forearm, which meant the edges of the forearm test site generally did not make full contact with the pad. The area of the removed cream is the 'apparent' contact area, however the 'real' contact area will always be smaller than the apparent contact area because the pad surface and the skin did not maintain full contact other than on asperities. Skin and pad surface irregularities also impact the real contact area of the skin-pad interface. In this example, the test site marked on the forearm had an area of 24.5cm$^2$, whereas the approximate apparent contact area for the skin and pad was 22.4 cm$^2$. The real contact area is unknown due to such measurements requiring study on a microscopic scale which was outside the scope of this research.

### 7.3.5 Methodology

All tests were carried out in the Human Interaction Group Lab situated in the George Porter building of The University of Sheffield, and ethical approval was obtained from the University of Sheffield Ethics Committee (Ethics Number 026173), see Appendix D. Measurements were carried out between 20-24°C, 30-40% humidity. Friction tests were carried out according to the protocol defined in Table 7.1, where in each test session just one treatment condition was investigated but at three different normal loads. For example, in one test session the investigation looked at the skin site containing no treatment against a wet pad, at normal loads of 1, 2, and 3N. In a separate test session (i.e. at least 48-hours apart from the prior session) the specification would then, for example, look at skin treated with *Cavilon Barrier Cream* in a dry pad state, at the normal loads of 1, 2, and 3N.

On the first test day for each participant three skinfold caliper tests were conducted across the test area indicated in Figure 7.6. According to Jackson *et al*. [8] and Wells and Fewtrell [9] 'taking raw skinfold

data can give a good indication of the regional fatness, unlike other measures like BMI or circumference measures alone'. Therefore, to give an idea of volar forearm fat levels, this method was deemed to be a more appropriate way to quantify interparticipant anatomical differences than other measures. Plastic calipers like those shown in Figure 7.6 are accurate to the nearest 0.5 mm.

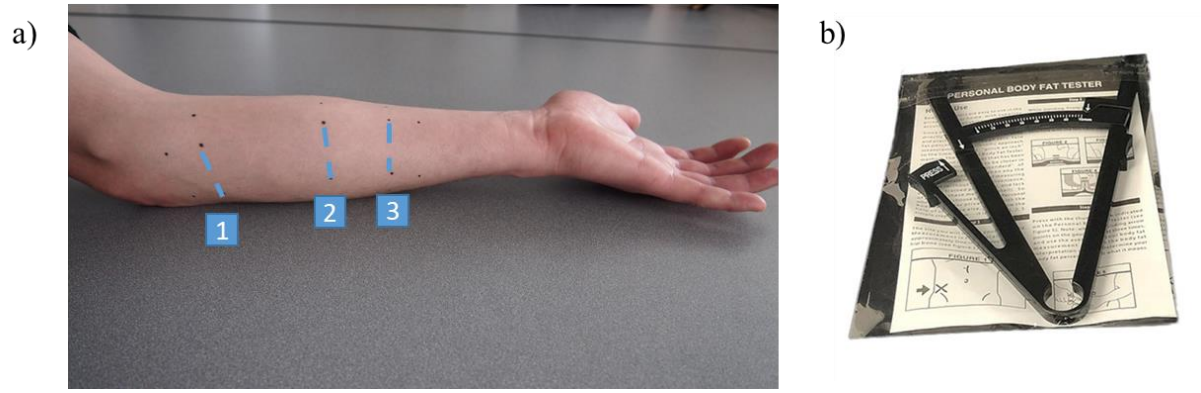



*Figure 7.6 - a) Shows the location of each of the three skin caliper tests conducted on a given participant. The test measurements spanned the whole portion of the sliding area of the friction tests where the pad made contact with the forearm. b) An image of the caliper device used to pinch the subsurface tissue and measure the thickness in mm of the tissue held between the pincers.*

In total there were eight different test sessions for each participant, and these were conducted on separate days, separated by at least 48-hours between each test session. All participants attended all eight test days, where the following test conditions were investigated:

- Untreated skin – dry pad
- Skin treated with *Cavilon Barrier Cream* – dry pad
- Skin treated with *Sorbaderm Barrier Cream* – dry pad
- Skin treated with *Sorbaderm Barrier Spray* – dry pad
- Untreated skin – wet pad
- Skin treated with *Cavilon Barrier Cream*– wet pad
- Skin treated with *Sorbaderm Barrier Cream* – wet pad
- Skin treated with *Sorbaderm Barrier Spray* – wet pad

During the friction tests participants were able to observe and adjust the normal load by viewing the software interface, see Figure 7.7 for a photograph of the interface and Figure 7.8 for the schematic. Prior to each test participants were told what normal load the test was to be run at, and shown a target grid line which was on the software interface so that they could reliably maintain the correct load throughout the test. The sliding speed was directed by an audio cue every 10-seconds. The triangular pointers indicate the line where forces are recorded as zero. Flexion of the wrist, as shown in Figure

7.1 f), allowed activation of muscles in the forearm which made the sliding motion more steady and controlled.

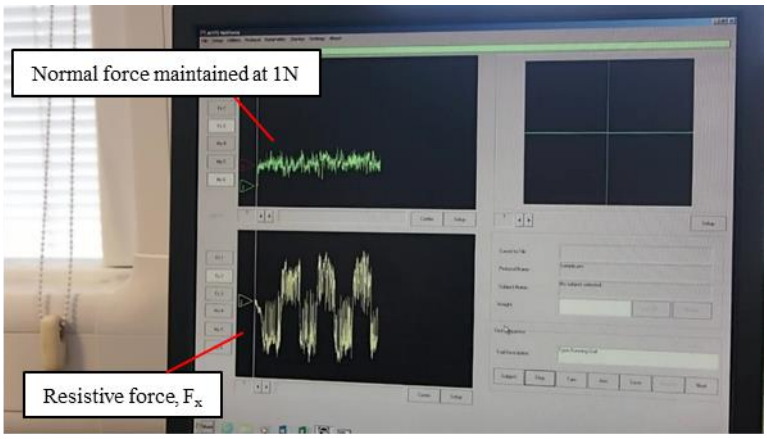



*Figure 7.7 - The participant screen view during the test of the AMTI software interface, the top left shows the normal force exerted so the participant could load the arm accordingly and adjust as needed during the test. The test being conducted in the figure is of Sorbaderm Barrier Spray in a wet-pad condition.*

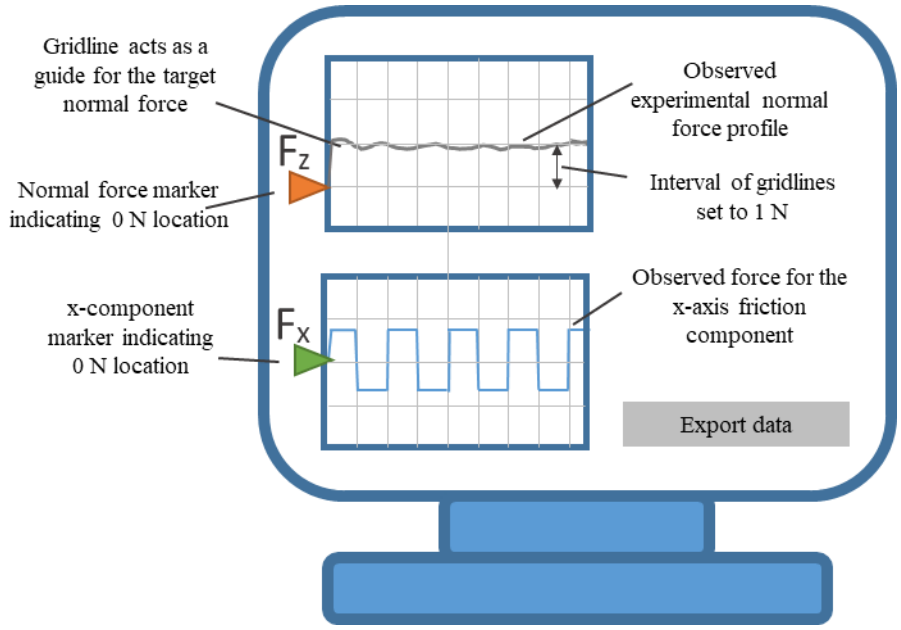



*Figure 7.8 - Schematic of the software interface.*

Table 7.1 highlights the protocol for one test session, whereby just one treatment condition was investigated. Then on following days the protocol was repeated again. The entire set of experiments lasted approximately 3 to 4 weeks, but it was also dependant on the participants' commitments during the time period.

*Table 7.1 - Experiment Protocol*

| | Step | Notes |
|---|---|---|
| 1 | Acclimatisation | • The participant acclimatised to the conditions of the room for 15-20 minutes. |
| 2 | Caliper test | • On one occasion only (Test Session 1), during the acclimatisation period, skin fold caliper measurements were taken on the marked sliding test area site on the forearm. |
| 3 | Locating and marking the test site | • The test area was identified by placing the forearm onto the friction rig where a piece of cardboard was resting on the test area of the pad. The cardboard was pre-cut to the size of the 35x75 mm chosen size of the test area. The arm was then lifted from the rig with the piece of cardboard held in place and then the template was used to mark the forearm using a marker pen on the corners of the cardboard template. This method provided a way of ensuring that a correct and comfortable arm position could be achieved for each participant.<br>• After the initial area was marked then other areas of the test site were measured with a ruler and marked according to the dimensions shown in Figure 7.4, such as the control area, the treatment application area, and the sliding contact area. |
| 4 | Skin measurements | • The forearm of the participant was placed in a supine position for initial skin measurements of temperature, moisture, and redness of the test area and the control site. |
| 5 | Treatment application and addition of artificial urine to pad | • A selected treatment was then applied to the treatment application area (or no treatment at all).<br>• If conducting a wet-pad test then 80 ml of artificial urine (room temperature 0.9 NaCl), was added to the exterior top surface of the incontinence pad, using a syringe. |
| 6 | Wait | • A timer was set giving a 5-minute waiting time before beginning the friction tests in Step 7. This was important because it allowed the pad absorb the artificial urine, and also let the treatment rest on skin. |
| 7 | Friction tests at a load of 1N | • The participant positioned arm onto test rig.<br>• The countdown timer was set<br>• A loading phase of 5-seconds was given to reach the required normal force of 1N.<br>• The timer bleep indicated when to begin moving arm backwards, and after another 10-seconds bleeped when to reverse the direction.<br>• The full duration of sliding during the friction test was for 120-seconds, and at the end the participant was directed to remove their arm from the rig.<br>• The data was exported and saved. |

| | | |
|---|---|---|
| 8 | Friction tests at a load of 2N | • Step 7 was repeated but at a load of 2N instead of 1N |
| 9 | Friction tests at a load of 3N | • Step 7 was repeated but at a load of 3N instead of 1N |
| 10 | Skin measurements | • Step 4 was repeated |
| 11 | End | • End of test session |

Figure 7.9 shows a plan view of the experimental set-up, with the directions of sliding movement of the forearm shown on the figure. The rationale for separating Direction 1 (D1) and Direction 2 (D2) in the data analysis protocol is discussed and explained further in Section 7.4.

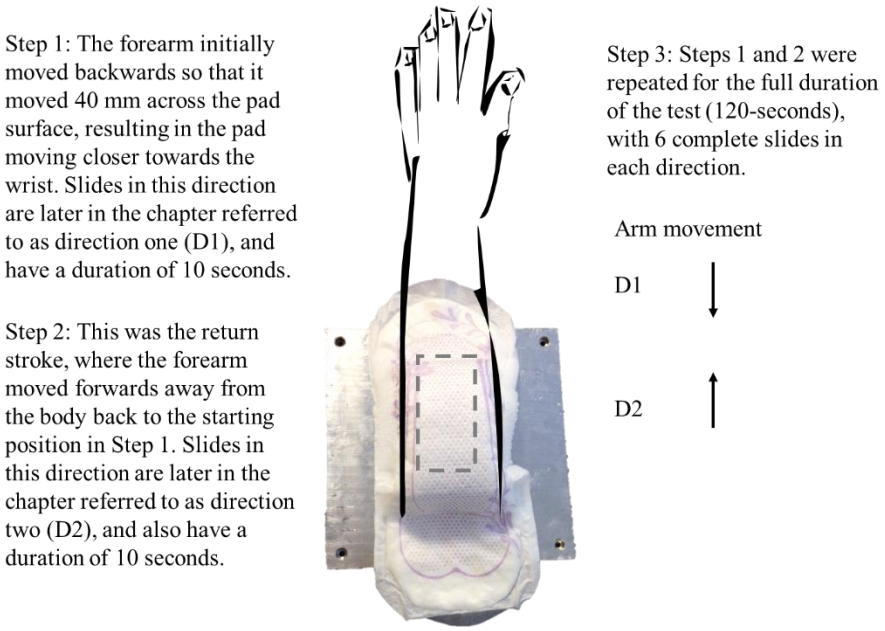



*Figure 7.9 Plan view showing the test area of the forearm aligned with the pad surface to make an approximate contact area dimensioned 3.5cm x 7.5cm. The dotted area signifies the test area markings on the underside of the forearm. The directions of movement (D1 and D2) are labelled and described.*

## 7.4 Data Analysis Protocol

Raw data collected during one test run is shown as an example in Figure 7.10, the data presented is from P2 in untreated dry conditions at a normal applied load of 3N. The normal force profile for the full 120-seconds is displayed in Figure 7.10 a). The friction force b) was calculated using the resultant

of the horizontal x and y friction components, where 'Friction Force' was the force acting in the plane normal to the applied load that resists the motion. The orientation of the axes in relation to the experiment schematic were shown previously in Figure 7.3. The CoF profile determined from the raw data can be seen in Figure 7.10 c), where the y-axis is reported as CoF, which is a common and well accepted practice in published work, although the SCoF and DCoF will only relate to certain portions of the data. Both extracted friction coefficient values require specific data extraction protocols which are described in Figure 7.11 and Figure 7.12.

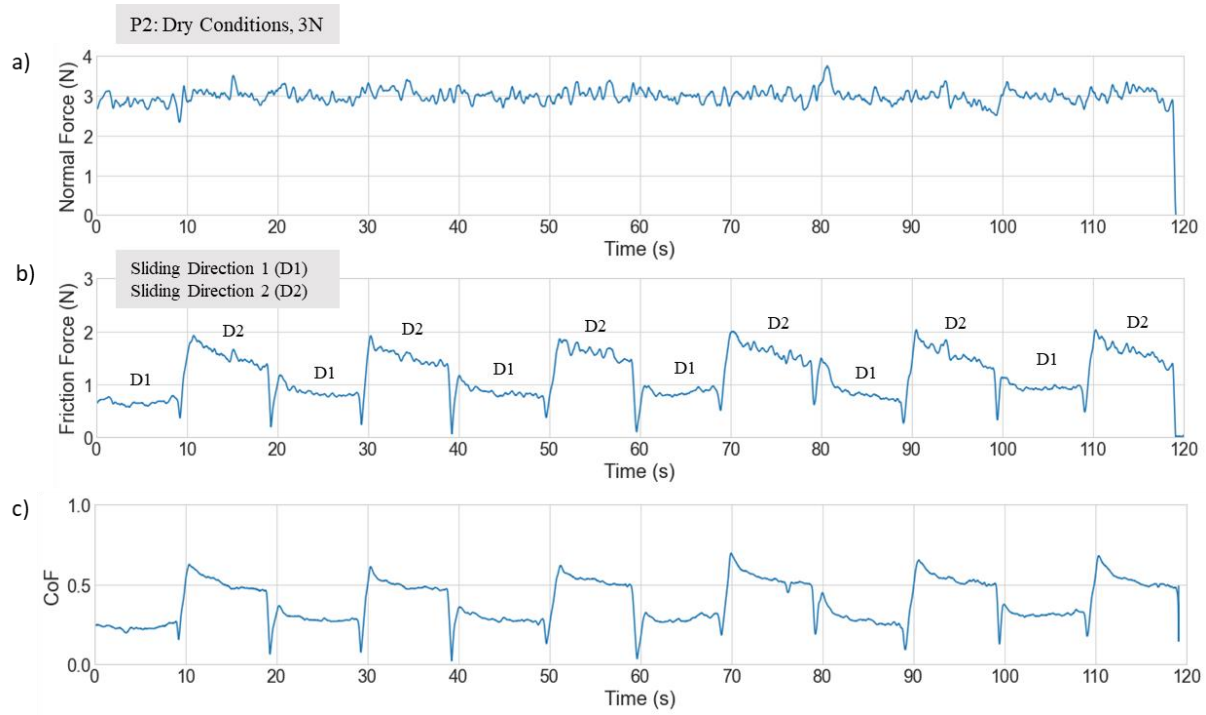



*Figure 7.10 - Profiles of the normal force, friction force and CoF during a dry-pad test. Part a) is what the participant sees as part of the software interface allowing them to have a real-time view of normal force, part b) shows the friction force of the full 12 slides as a resultant of the $F_x$ and $F_y$ components, and c) is the calculated friction coefficient profile where $\mu = F_R/F_N$.*

The direction of sliding directly impacted the magnitude of the CoF, see Figure 7.10 b) and c). Therefore, it was necessary to calculate the DCoF separately for D1 and D2, where D2 was always higher, almost by a factor of 2 in this case. The method of extracting the DCoF is shown in Figure 7.11, where for each slide the average DCoF was calculated using the middle 5-seconds of each 10-second slide, which equated to taken the average of 1000 data points over the 5-seconds interval. The total DCoF for each test was then reported as an average of the 6-slides per direction, giving two separate values, one for the DCoF in D1, and the other for the DCoF in D2, along with the corresponding standard deviations (SD).

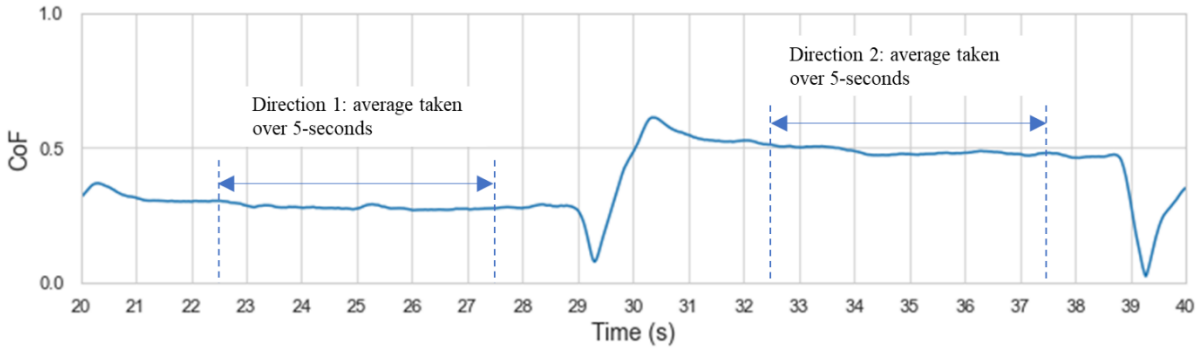



*Figure 7.11 - An extract of Figure 7.10 with one slide from D1 and one slide from D2. In each direction the average DCoF was calculated for a 5-second section within the mid portion each slide.*

The method used to identify the SCoF for each participant and treatment condition is shown in Figure 7.12. The range of the x-axis has been modified in this example to show the first 60-seconds rather than 120-seconds in order to provide the reader a more detailed view of the profile and the key points. For the SCoF analysis the average of each direction were taken across the full 120-seconds of the experiment, minus the first D1 slide which was neglected.

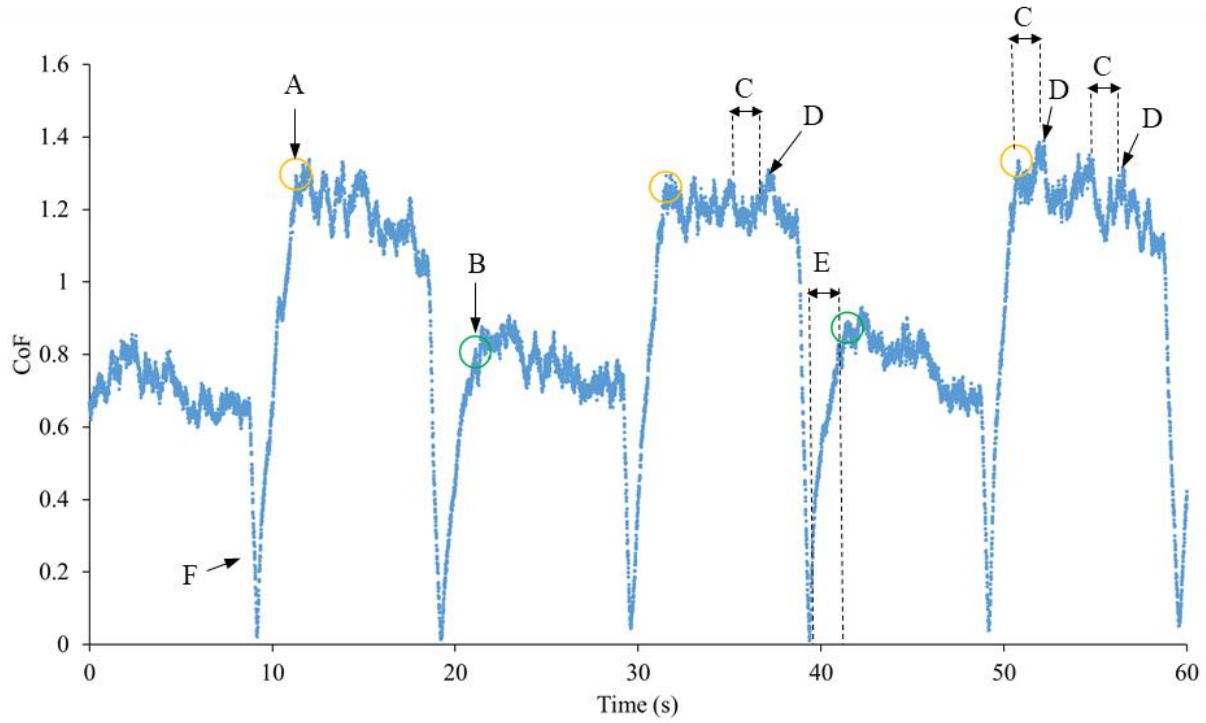



*Figure 7.12 - Key features of a friction coefficient profile; yellow and green markers show the points of data extraction used to calculate the SCoF. Green markers indicate portions of the profile to extract SCoF data for D1, and yellow circles indicate those for D1. The example data profile is from P2, in wet conditions, with Sorbaderm at a normal force of 3N.*

The initial slide in D1 was eliminated in the SCoF analysis due to this slide usually exhibiting a different initial profile shape to subsequent slides. For each sliding directions averages were taken from the 5-slides in D1, and 6-slides in D2. The point at which sliding was first initiated was chosen as the point to extract and average SCoF data points, allowing cross comparisons of treatments to be made. The highest point was identified and then averaged along with the ten surrounding data points. The points C and D on Figure 7.12 have been highlighted because these also are areas where the SCoF can be identified on profiles. These areas arise due to stick-slip between the pad and skin, leading to small undulations in the amplitude of the profile, but these mid-slide values were not incorporated into the SCoF analysis. Properties of each individual tribosystem (i.e. pad wetness, anatomical differences, and/or presence of treatment), resulted in a differing system responses with varying levels of stick-slip, therefore in order to ensure fair comparisons were made only the SCoF immediately after the direction

changes (at the initial part of the slide) were considered in the calculations, as this was present for all participants and tests.

## 7.5 Results

### 7.5.1 Overview

The participant information and skin characterisation are shown in Table 7.2, including age, gender and the baseline untreated skin moisture levels. Skinfold calliper measurements were taken to provide supplementary data of subsurface tissue amounts, which have been found to influence the skin mechanical properties, shear, and friction interaction with the pad. The device shown in Figure 7.6, although a crude measure, was easy to use and gave a better indication of the amount of fatty tissue in the forearm to therefore act as an indicator of the local compliance of the skin within the test area.

*Table 7.2 - Participant information and skin characterisation*

| Participant number | Age | Sex | Moisture (c.u.) ± SD | Skinfold caliper (mm) ± SD | Temperature (°C) | Redness |
|---|---|---|---|---|---|---|
| P1 | 21 | F | 24.9 ± 2.50 | 6.67 ± 2.31 | 28.2 ± 1.40 | 177.6 ± 24.68 |
| P2 | 29 | F | 30.2 ± 2.98 | 4.67 ± 0.58 | 29.2 ± 1.64 | 194.7 ± 11.98 |
| P3 | 30 | F | 34.2 ± 3.43 | 3.67 ± 0.58 | 29.9 ± 0.92 | 196.3 ± 22.12 |
| P4 | 27 | M | 37.4 ± 1.63 | 2.00 ± 0.00 | 29.6 ± 0.99 | 163.2 ± 19.12 |
| P5 | 26 | M | 48.0 ± 5.05 | 2.33 ± 0.58 | 30.8 ± 1.42 | 175.9 ± 19.12 |
| P6 | 28 | M | 32.0 ± 1.35 | 4.67 ± 1.15 | 30.4 ± 1.25 | 435.4 ± 13.13 |
| P7 | 27 | M | 52.9 ± 3.11 | 2.67 ± 0.58 | 29.5 ± 0.63 | 181.9 ± 18.98 |
| P8 | 35 | F | 36.7 ± 2.36 | 10.67 ± 2.31 | 29.0 ± 1.28 | 126.6 ± 10.87 |

Table 7.6 shows the average DCoF datasets at 3N for each of the test conditions for participants individually, with an overall average DCoF of all participants for each treatment summarised at the bottom row of each table, and Table 7.7 to Table 7.10 display the equivalent SCoF data.

*Table 7.3 - Dynamic friction coefficients for each treatment in dry conditions, Direction 1*

| Conditions - Dry, Force 3N, Direction 1 | Average DCoF ± SD | | | |
|---|---|---|---|---|
| Participant Number | Untreated | Cavilon | Sorbaderm | Spray |
| P1 | 0.515 ± 0.033 | 0.594 ± 0.041 | 0.840 ± 0.020 | 0.869 ± 0.070 |
| P2 | 0.275 ± 0.028 | 0.412 ± 0.011 | 0.725 ± 0.017 | 0.759 ± 0.007 |
| P3 | 0.237 ± 0.016 | 0.636 ± 0.011 | 0.713 ± 0.026 | 0.764 ± 0.045 |
| P4 | 0.196 ± 0.031 | 0.459 ± 0.028 | 0.623 ± 0.035 | 0.359 ± 0.030 |
| P5 | 0.387 ± 0.026 | 0.604 ± 0.043 | 1.015 ± 0.016 | 0.507 ± 0.019 |
| P6 | 0.443 ± 0.026 | 0.555 ± 0.023 | 0.886 ± 0.033 | 1.046 ± 0.062 |
| P7 | 0.326 ± 0.017 | 0.561 ± 0.076 | 0.903 ± 0.082 | 0.782 ± 0.062 |
| P8 | 0.303 ± 0.017 | 0.561 ± 0.024 | 0.699 ± 0.026 | 0.742 ± 0.037 |
| Average DCoF (All Participants) ± SD | 0.335 ± 0.107 | 0.548 ± 0.075 | 0.800 ± 0.131 | 0.728 ± 0.211 |

*Table 7.4 - Dynamic friction coefficients for each treatment in dry conditions, Direction 2*

| Conditions – Dry, Force 3N, Direction 2 | Average DCoF ± SD | | | |
|---|---|---|---|---|
| Participant Number | Untreated | Cavilon | Sorbaderm | Spray |
| P1 | 0.408 ± 0.060 | 0.509 ± 0.036 | 0.737 ± 0.020 | 0.779 ± 0.020 |
| P2 | 0.519 ± 0.017 | 0.634 ± 0.020 | 0.669 ± 0.057 | 1.120 ± 0.057 |
| P3 | 0.590 ± 0.008 | 0.490 ± 0.016 | 0.901 ± 0.047 | 0.824 ± 0.047 |
| P4 | 0.547 ± 0.030 | 0.579 ± 0.044 | 1.024 ± 0.033 | 0.783 ± 0.033 |
| P5 | 0.660 ± 0.018 | 0.533 ± 0.009 | 0.846 ± 0.075 | 0.416 ± 0.075 |
| P6 | 0.348 ± 0.011 | 0.639 ± 0.017 | 0.902 ± 0.073 | 1.184 ± 0.073 |
| P7 | 0.719 ± 0.026 | 0.702 ± 0.050 | 1.033 ± 0.052 | 1.061 ± 0.052 |
| P8 | 0.469 ± 0.033 | 0.719 ± 0.026 | 0.794 ± 0.021 | 0.966 ± 0.021 |
| Average DCoF (All Participants) ± SD | 0.532 ± 0.124 | 0.601 ± 0.087 | 0.863 ± 0.129 | 0.892 ± 0.247 |

*Table 7.5 - Dynamic friction coefficients for each treatment in wet conditions, Direction 1*

| Conditions - Wet, Force 3N, Direction 1 | Average DCoF ± SD | | | |
|---|---|---|---|---|
| Participant Number | Untreated | Cavilon | Sorbaderm | Spray |
| P1 | 0.940 ± 0.105 | 0.667 ± 0.067 | 1.004 ± 0.069 | 1.311 ± 0.100 |
| P2 | 0.805 ± 0.053 | 0.587 ± 0.018 | 0.958 ± 0.040 | 0.896 ± 0.032 |
| P3 | 0.511 ± 0.053 | 0.579 ± 0.042 | 0.941 ± 0.112 | 1.162 ± 0.224 |
| P4 | 0.795 ± 0.028 | 0.679 ± 0.036 | 0.790 ± 0.035 | 0.793 ± 0.104 |
| P5 | 0.886 ± 0.052 | 0.730 ± 0.018 | 1.308 ± 0.019 | 0.900 ± 0.072 |
| P6 | 0.900 ± 0.094 | 0.650 ± 0.036 | 0.947 ± 0.107 | 1.251 ± 0.109 |
| P7 | 0.684 ± 0.051 | 0.545 ± 0.031 | 0.765 ± 0.045 | 1.009 ± 0.097 |
| P8 | 0.768 ± 0.034 | 0.527 ± 0.111 | 0.900 ± 0.087 | 0.853 ± 0.040 |
| Average DCoF (All Participants) ± SD | 0.786 ± 0.138 | 0.621 ± 0.072 | 0.952 ± 0.166 | 1.022 ± 0.196 |

*Table 7.6 - Dynamic friction coefficients for each treatment in wet conditions, Direction 2*

| Conditions – Wet, Force 3N, Direction 2 | Average DCoF ± SD | | | |
|---|---|---|---|---|
| Participant Number | Untreated | Cavilon | Sorbaderm | Spray |
| P1 | 1.185 ± 0.074 | 0.651 ± 0.022 | 1.166 ± 0.060 | 1.130 ± 0.036 |
| P2 | 1.273 ± 0.061 | 0.652 ± 0.013 | 1.337 ± 0.068 | 1.286 ± 0.051 |
| P3 | 1.051 ± 0.100 | 0.735 ± 0.050 | 1.018 ± 0.022 | 1.174 ± 0.154 |
| P4 | 1.304 ± 0.042 | 0.561 ± 0.043 | 1.256 ± 0.019 | 1.596 ± 0.259 |
| P5 | 1.179 ± 0.865 | 0.605 ± 0.045 | 1.006 ± 0.086 | 1.362 ± 0.146 |
| P6 | 0.865 ± 0.061 | 0.628 ± 0.019 | 1.195 ± 0.073 | 1.381 ± 0.127 |
| P7 | 1.222 ± 0.105 | 0.864 ± 0.041 | 1.379 ± 0.041 | 1.258 ± 0.060 |
| P8 | 1.217 ± 0.127 | 0.137 ± 0.971 | 0.971 ± 0.050 | 0.879 ± 0.103 |
| Average DCoF (All Participants) ± SD | 1.162 ± 0.142 | 0.693 ± 0.112 | 1.166 ± 0.155 | 1.271 ± 0.213 |

*Table 7.7 - Static friction coefficients for each treatment in dry conditions – D1*

| Conditions – Dry, Force 3N, Direction 1 | Average DCoF ± SD | | | |
|---|---|---|---|---|
| Participant Number | Untreated | Cavilon | Sorbaderm | Spray |
| P1 | 0.598 ± 0.092 | 0.778 ± 0.080 | 1.000 ± 0.030 | 1.440 ± 0.092 |
| P2 | 0.402 ± 0.044 | 0.591 ± 0.080 | 0.920 ± 0.033 | 0.914 ± 0.068 |
| P3 | 0.336 ± 0.017 | 0.783 ± 0.023 | 1.015 ± 0.077 | 1.080 ± 0.101 |
| P4 | 0.336 ± 0.024 | 0.669 ± 0.044 | 0.895 ± 0.096 | 0.599 ± 0.028 |
| P5 | 0.503 ± 0.055 | 0.789 ± 0.035 | 1.270 ± 0.057 | 0.748 ± 0.034 |
| P6 | 0.611 ± 0.030 | 0.679 ± 0.034 | 1.094 ± 0.113 | 1.508 ± 0.195 |
| P7 | 0.492 ± 0.032 | 0.758 ± 0.105 | 1.189 ± 0.083 | 1.086 ±0.091 |
| P8 | 0.389 ± 0.012 | 0.660 ± 0.030 | 0.822 ± 0.034 | 1.075 ± 0.060 |
| Average DCoF (All Participants) ± SD | 0.458 ± 0.109 | 0.713 ± 0.073 | 1.026 ± 0.151 | 1.056 ± 0.311 |

*Table 7.8 - Static friction coefficients for each treatment in dry conditions – D2*

| Conditions – Dry, Force 3N, Direction 2 | Average DCoF ± SD | | | |
|---|---|---|---|---|
| Participant Number | Untreated | Cavilon | Sorbaderm | Spray |
| P1 | 0.625 ± 0.033 | 0.697 ± 0.034 | 0.912 ± 0.034 | 1.222 ± 0.102 |
| P2 | 0.545 ± 0.141 | 0.773 ± 0.022 | 0.862 ± 0.028 | 1.687 ± 0.107 |
| P3 | 0.700 ± 0.011 | 0.581 ± 0.027 | 1.176 ± 0.071 | 1.313 ± 0.067 |
| P4 | 0.763 ± 0.023 | 0.754 ± 0.034 | 1.311 ± 0.086 | 1.115 ± 0.080 |
| P5 | 0.794 ± 0.021 | 0.691 ± 0.031 | 0.955 ± 0.056 | 0.604 ± 0.101 |
| P6 | 0.472 ± 0.009 | 0.702 ± 0.014 | 1.075 ± 0.010 | 1.602 ± 0.219 |
| P7 | 0.873 ± 0.023 | 0.855 ± 0.039 | 1.240 ± 0.064 | 1.512 ± 0.148 |
| P8 | 0.593 ± 0.022 | 0.747 ± 0.029 | 0.854 ± 0.032 | 1.202 ± 0.053 |
| Average DCoF (All Participants) ± SD | 0.671 ± 0.136 | 0.725 ± 0.079 | 1.048 ± 0.178 | 1.282 ± 0.342 |

*Table 7.9 - Static friction coefficients for each treatment in wet conditions – D1*

| Conditions – Wet, Force 3N, Direction 1 | Average DCoF ± SD | | | |
|---|---|---|---|---|
| Participant Number | Untreated | Cavilon | Sorbaderm | Spray |
| P1 | 1.268 ± 0.015 | 0.835 ± 0.097 | 1.248 ± 0.097 | 2.265 ± 0.268 |
| P2 | 0.931 ± 0.058 | 0.729 ± 0.032 | 1.168 ± 0.083 | 1.357 ± 0.044 |
| P3 | 0.618 ± 0.035 | 0.732 ± 0.040 | 1.151 ± 0.140 | 1.897 ± 0.451 |
| P4 | 1.025 ± 0.032 | 0.908 ± 0.064 | 0.967 ± 0.045 | 1.002 ± 0.044 |
| P5 | 1.020 ± 0.080 | 0.729 ± 0.060 | 1.217 ± 0.114 | 2.086 ± 0.316 |
| P6 | 1.041 ± 0.082 | 0.775 ± 0.030 | 1.186 ± 0.054 | 2.162 ± 0.359 |
| P7 | 0.951 ± 0.066 | 0.702 ± 0.084 | 0.986 ± 0.066 | 1.579 ± 0.168 |
| P8 | 0.961 ± 0.058 | 0.583 ± 0.024 | 1.092 ± 0.136 | 1.642 ± 0.102 |
| Average DCoF (All Participants) ± SD | 0.977 ± 0.180 | 0.749 ± 0.100 | 1.127 ± 0.104 | 1.749 ± 0.435 |

*Table 7.10 - Static friction coefficients for each treatment in wet conditions – D2*

| Conditions – Wet, Force 3N, Direction 2 | Average DCoF ± SD | | | |
|---|---|---|---|---|
| Participant Number | Untreated | Cavilon | Sorbaderm | Spray |
| P1 | 1.309 ± 0.067 | 0.851 ± 0.037 | 1.336 ± 0.046 | 2.037 ± 0.221 |
| P2 | 1.320 ± 0.095 | 0.766 ± 0.028 | 1.553 ± 0.041 | 2.433 ± 1.889 |
| P3 | 1.210 ± 0.116 | 0.732 ± 0.041 | 1.163 ± 0.035 | 2.460 ± 0.161 |
| P4 | 1.494 ± 0.067 | 0.763 ± 0.035 | 1.452 ± 0.039 | 2.747 ± 0.122 |
| P5 | 1.275 ± 0.033 | 0.780 ± 0.038 | 1.469 ± 0.047 | 1.770 ± 0.138 |
| P6 | 0.988 ± 0.054 | 0.692 ± 0.036 | 1.343 ± 0.069 | 2.558 ± 0.197 |
| P7 | 1.292 ± 0.187 | 0.978 ± 0.043 | 1.613 ± 0.068 | 2.127 ± 0.180 |
| P8 | 1.547 ± 0.152 | 1.135 ± 0.057 | 1.114 ± 0.066 | 1.750 ± 0.055 |
| Average DCoF (All Participants) ± SD | 1.304 ± 0.171 | 0.837 ± 0.149 | 1.380 ± 0.177 | 2.235 ± 0.370 |

In all cases for each individual participant the standard deviations were very low, which can be demonstrated by the coefficient of variation (CV). For example, in the dry-pad untreated condition, see Table 7.3, Participant 1 (P1) had a DCoF value of 0.515 and an SD of 0.033, which gave a low CV of 0.06, calculated according to Equation 5. This low SD indicated that the extracted CoF for each slide was numerically consistent and in agreement with other slides of the same direction, therefore it was appropriate to take an average across the slides to produce a reliable directional DCoF.

$$CV = \frac{SD}{mean}$$ where a CV < 1 indicates a low variation Equation 5

Overall the small variations indicated that averaging the friction coefficients for each direction slide provided a reliable estimate for the treatment conditions. As expected the interparticipant standard deviations of the friction coefficients were higher than those taken on an individual participant basis (this example gives a CV of 0.3), however this is still classified as a low variation as it is less than 1.

The addition of water and/or treatments to the skin resulted in greater interparticipant variation in friction coefficients than in the dry untreated conditions, showing that applying products or altering the natural conditions of skin gives a different friction response in each participant, which is dependent on the unique characteristics and properties of the person whose skin is being tested. Gerhardt *et al*. [10] found that woven fabrics that were moistened resulted in greater than twice the CoF compared to the untreated skin rubbed against a dry fabric. The results in this study agree with these findings; in D1 it was found that the average DCoF in D1 wet-conditions was 2.3 times greater than dry D1 conditions, and in D2 the average DCoF in wet conditions was 2.2 times greater than dry conditions.

Understanding skin in its natural untreated state is of primary importance when conducting experiments to assess the effects of topical treatments. In the age group studied in this research (21 to 35-years old), it was found that untreated skin had a mean moisture level of 40.4 c.u., a mean tissue compliance of 4.67 mm, and at 3N a DCoF of D1 = 0.335 ± 0.107 (mean average ± SD), D2 = 0.532 ± 0.124 in a dry-pad state, and D1 = 0.786 ± 0.138, D2 = 1.162 ± 0.142 in a wet-pad state. The untreated skin mean average SCoF was calculated to be D1 = 0.458 ± 0.109, D2 = 0.671 ± 0.136 in a dry-pad state, and D1 = 0.977 ± 0.180, D2 = 1.304 ± 0.171 in a wet-pad state. The findings are discussed in greater detail throughout this chapter, including the effects of different treatments on the DCoF and SCoF, along with possible explanations for the different friction responses shown in D1 and D2.

### 7.5.2 Friction Profiles

This section presents a full set of CoF profiles for Participant 2 (P2). Before each profile is presented, a summary of some of the key friction characteristics that could be present within a CoF profile are introduced in Figure 7.13. These points of interest will come in useful for the upcoming friction profiles of P2, and will also be valuable to know for the later discussions.

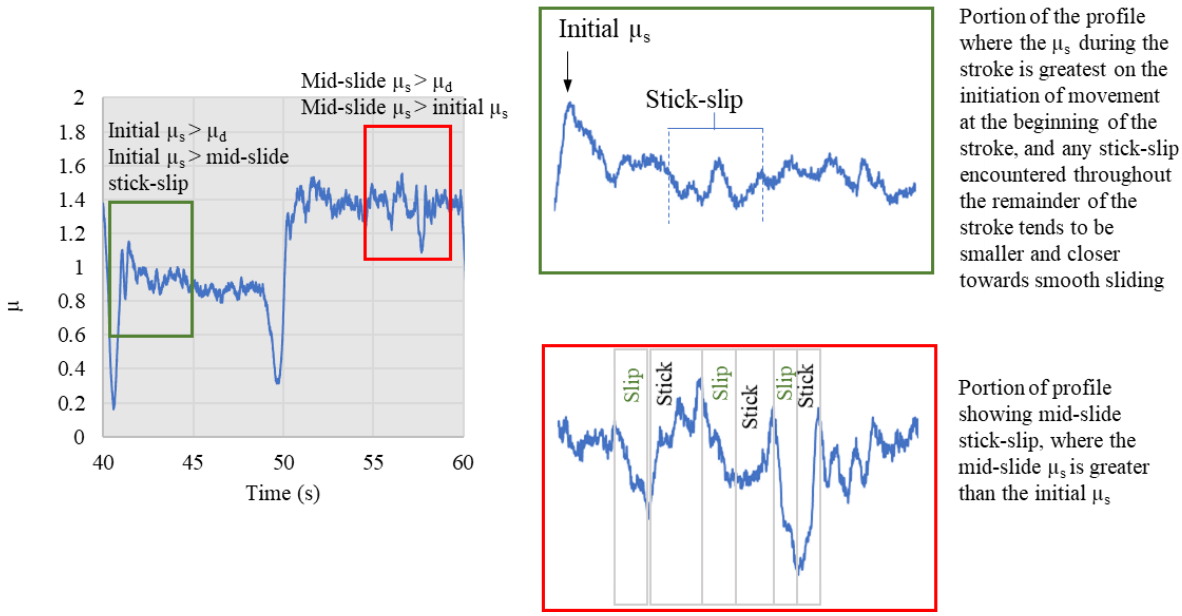



*Figure 7.13 - Stick-slip patterns in the friction profiles – Example curve is from P2 Sorbaderm Barrier Cream, wet-pad conditions, 3N normal force.*

The stick-slip action occurred when the pad was 'stuck' adhesively on certain areas of the skin causing the friction force to rise, until a slight separation happened between the two surfaces causing a rapid decline in the friction force.

The presented profiles in Figure 7.14 to Figure 7.17 illustrate key features of the friction response associated with each treatment. The results are separated into four figures; each in either untreated or treated state, and at a normal force of 3N. P2 was selected as an example because the CoF profile of this chosen participant fairly consistently lay within the middle range of the other participants, therefore giving a good average representation of the CoF profiles for all participants. See Appendix C for the full set of CoF profiles for all participants at 3N. For the three loading conditions, the shape of the profiles were largely consistent, therefore a 3N load was chosen for the examples, rather than including figures for all normal forces.

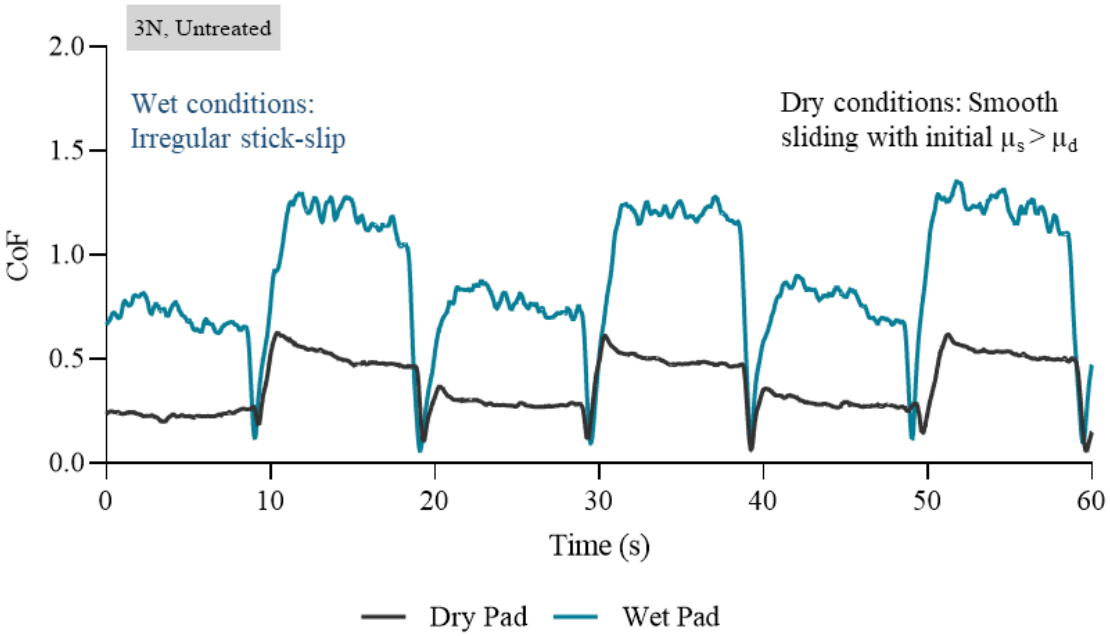



*Figure 7.14 - Friction coeffient profiles in wet and dry conditions for the first 60-seconds / 6 slides of the experiment. Condition: 3N and untreated.*

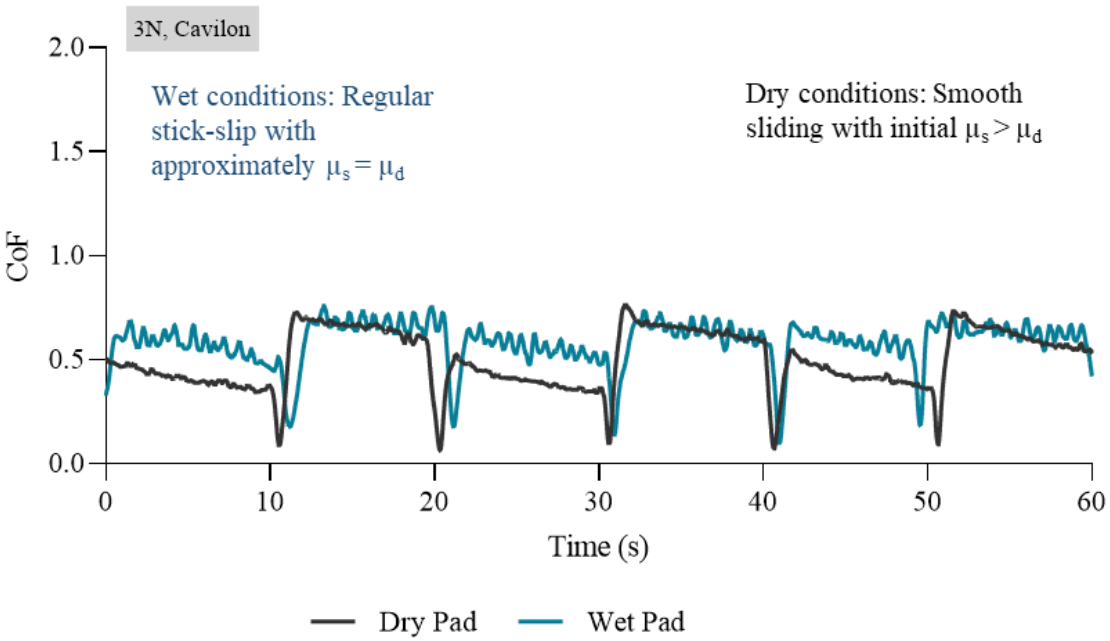



*Figure 7.15 - Friction coeffient profiles in wet and dry conditions for the first 60-seconds / 6 slides of the experiment. Condition: 3N and treated with Cavilon..*

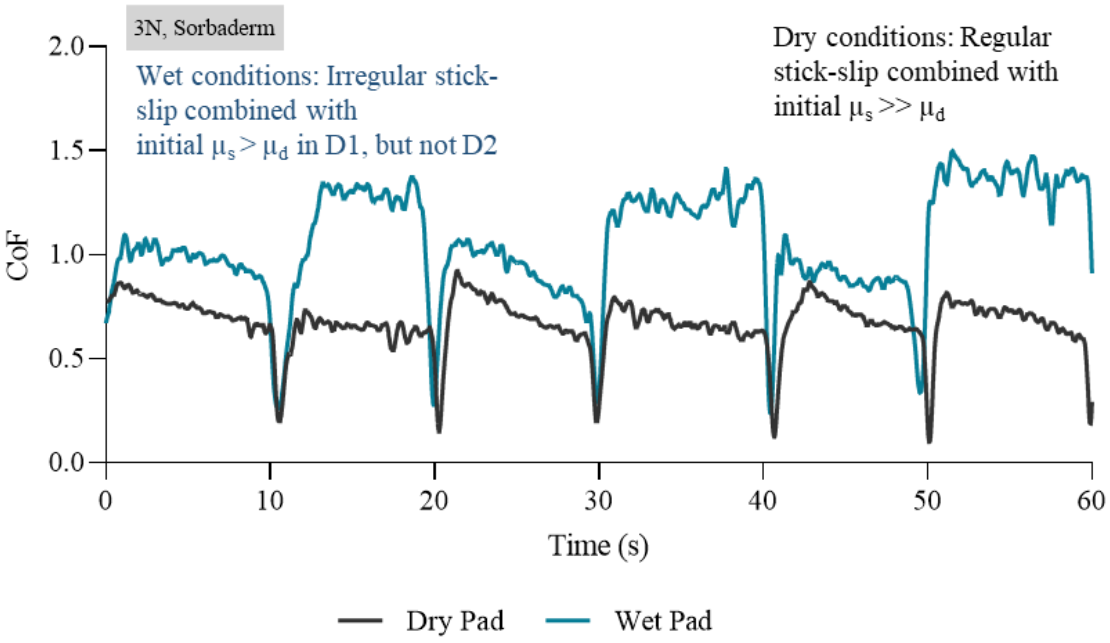



*Figure 7.16 - Friction coeffient profiles in wet and dry conditions for the first 60-seconds / 6 slides of the experiment. Condition: 3N and treated with Sorbaderm Barrier Cream.*

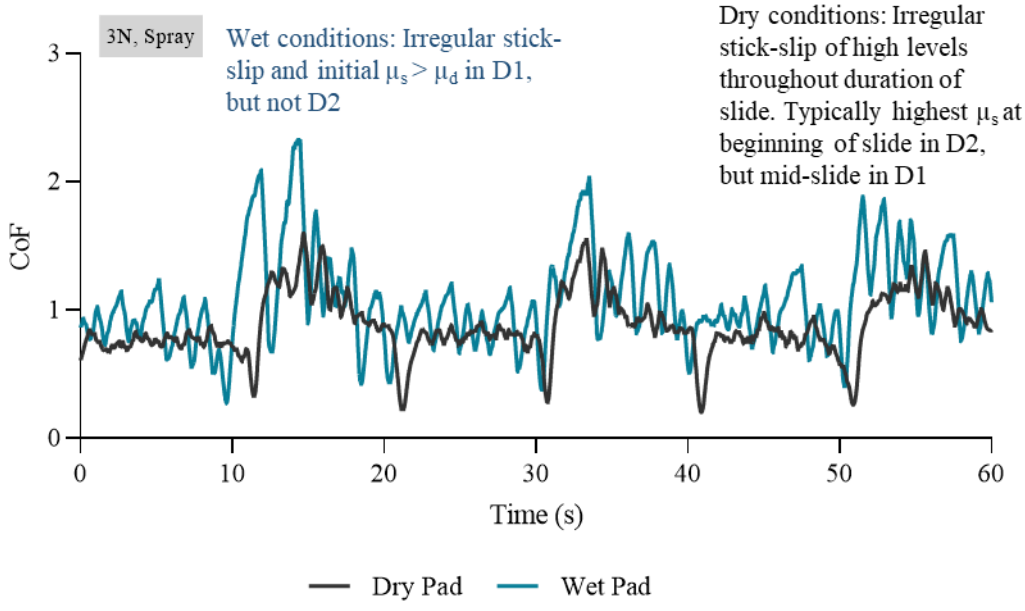



*Figure 7.17 - Friction coeffient profiles in wet and dry conditions for the first 60-seconds / 6 slides of the experiment. Condition: 3N and treated with Sorbaderm Barrier Spray.*

Figure 7.14 features the CoF profiles from the dry pad and wet pad in the first 60-seconds of the untreated skin friction test. The CoF in wet conditions was over a factor of two higher than in dry conditions. Notably the DCoF and SCoF of D1 were both lower than those of D2 in both dry and wet conditions. This directional difference could be due to cyclical loading and unloading of the skin as the direction changes. Tissue displacement during D1 could result in a preloading at the start of D2, which in turn resulted in more tissue to push back into. A realignment of collagen may also have occurred which could have resulted in a change in the mechanical properties of the skin. In Chapter 2 it was stated that 'collagen fibres have a tensile strength greater than that of an equal size cross section of steel wire, giving a capability to support over 10,000 times their weight' [11], and consequently any change in orientation or stretching of collagen fibres could have resulted in a greater force required to move the skin across the pad to return to the starting position. This response occurred throughout the full 120-seconds of each experiment, though it is unclear whether this effect would have dissipated had the reciprocation continued for a longer period of time. Anatomical features may also have had an influence on this observation, such as the effects of Langer's lines, though the researcher suspects that the initial loading conditions provided the greatest contribution.

Wet conditions amplified the directional variation in CoF. Over the first second or so of the direction change the CoF increased, which happened until the friction between the two surfaces reached a peak (SCoF), and then sliding (DCoF) occurred. The wet conditions, as expected, had a higher CoF than the dry conditions, and the dry conditions had much less variation in amplitude as shown by the smooth profile. The wet pad condition had a greater amplitude during the dynamic portion of the CoF curve, which could be indicative of stick-slip interactions occurring between the pad and the skin, where the adhesive junctions between the surfaces become more difficult to overcome leading to a small increase in the friction coefficient.

Both of the contacting surfaces physically changed with the addition of a saline solution to the pad; the pad swelled as it becomes saturated, causing the top pad layer to become taut with a smoother surface, and high moisture levels of skin also resulted in a swelling and smoothing of the stratum corneum (as discussed previously in Chapter 4). The presence of moisture may have also caused fibres on the pad surface to lie flatter providing a lower surface roughness. With both surfaces becoming smoother and tauter the CoF increased due to the increase in contact area causing higher levels of adhesion and greater intermolecular attractions between the surfaces. In the dry conditions in Figure 7.14 pronounced peaks can be seen due to the SCoF, after which the friction coefficient smoothly declined to a plateau once sliding began. The static friction is higher than the dynamic friction because once the surfaces are moving relative to one another they have less time to adhere to one another.

Figure 7.15 displays the CoF profiles from the dry pad alongside the wet pad for the first 60 seconds of the friction test where *Cavilon* was applied to the skin. A distinctive feature of the profile is that wet

conditions exhibited micro stick-slip, a profile feature which didn't occur on the Cavilon treated dry pad. However, the stick-slip is very ordered, known as 'regular' stick-slip, i.e. the profile has a more consistent frequency and amplitude of fluctuation, compared to the other treated and untreated wet conditions. The stick-slip of *Cavilon* is characterised by uniform amplitude and frequency; this suggests that the skin was not undergoing excessive loads where the asperities met, because the skin was regularly 'slipping' and releasing before the SCoF built up to high levels. *Cavilon* application may result in the surfaces being less likely to adhere for long periods which could be for a number of reasons, for example high hydrophobicity thereby repelling water off the skin and in doing so preventing changes to the structure of the stratum corneum. Alternatively, it could provide a hydrodynamic film to promote steady sliding compared to what the other treatments can achieve. The way water chemically interacts with the treatments in the interface will be key to their frictional performance and the shape of their friction coefficient profiles. A treatment may stay in place, form an emulsion, transfer to the pad, or cause the skin surface to change either causing a higher or lower real contact area. Overall, the application of Cavilon resulted in adhesive junctions being broken more quickly and uniformly. In contrast, an irregular stick-slip is suggestive of greater adhesion and deformation leading to temporary sticking and subsequent CoF growth.

For *Cavilon* in wet conditions, D1 and D2 had similar friction coefficient values, a big contrast to the directional behaviour seen in untreated wet conditions. The shape of the profile suggests that the mechanism of effectiveness for *Cavilon* may be its ability to allow skin to slide over the pad with minimal to no tissue deformation. Another notable feature from Figure 7.15 is the overlapping profiles for wet and dry conditions, something which the *Sorbaderm Barrier Cream* and untreated skin did not exhibit, which suggests that *Cavilon* works well to maintain lower levels of friction in the interface even when a dry pad becomes wet. In a real-life scenario people may apply the cream once before undergoing several dry-wet cycles. If friction levels could be maintained at a constant level throughout these cycles then this would likely offer the most protection from the development of IAD, in that case *Cavilon* appears to offer a greater level of protective mechanism which the other treatments do not possess.

Figure 7.16 displays the CoF profiles from the dry pad and wet pad for the first 60-seconds of the friction test where *Sorbaderm Barrier Cream* was applied to the skin. The key features present are 1) stick-slip in both dry and wet conditions, and 2) the duration of sticking is greater in wet conditions, indicating that skin would be subjected to increased loading and associated shear strains and stresses. In dry conditions the SCoF in D1 is higher than D2, and the D1 DCoF starts off at a higher peak but reduced throughout the stroke to give a DCoF of similar value to D2. In wet conditions, the effects of the direction change on SCoF and DCoF are strong, giving rise to D2 with higher friction coefficients than D1. The type of stick-slip can be characterised as 'irregular' stick-slip. This results shows that when artificial urine interacts and combines with the *Sorbaderm Barrier Cream* the friction increased

to greater levels than skin containing no treatment. The wet conditions in the interface introduced increased tissue deformation and adhesion.

The barrier spray CoF profile, shown in Figure 7.17, exhibited a very different shaped profile in the dry and wet conditions compared to the other treatments. Some directional effects can be seen and a greater SCoF is reached in D2, and both sliding directions exhibit higher stick-slip amplitude and longer sticking time compared to the other treatments. Physically this manifested for the participants as a slight intermittent pulling sensation on the skin during sliding arm movement, which was often described as unpleasant. Sticking occurred more in wet conditions than dry conditions, where the large gaps between peaks represent the friction force building and then releasing. The amplitude of each peak reduced throughout any given D2 slide suggesting that when sliding is underway it becomes easier to break the adhesive junctions. As the tissue deforms during the slide it may also have an effect on reducing the strength of the adhesion, meaning that the CoF falls throughout the stroke. During the change in direction, the barrier spray has sufficient time to form a strong bond between the skin and the pad so that the initial SCoF is high, followed by further stick-slips of decreasing 'stickiness' as the bonds become weaker during a slide. This scenario seemed to occur most when changing from D1 to D2, which is likely due to the loading set up by D1 pulling the skin in that direction first, causing a bias in that direction throughout the test. Subsequently, if skin experiences these loading conditions regularly, overtime it could become damaged.

### 7.5.3 Friction Coefficients in Three Loading Conditions

Comparisons of how the treatments at different normal forces altered the DCoF in the skin-pad interface are shown in Figure 7.18 (dry conditions) and Figure 7.19 (wet conditions).

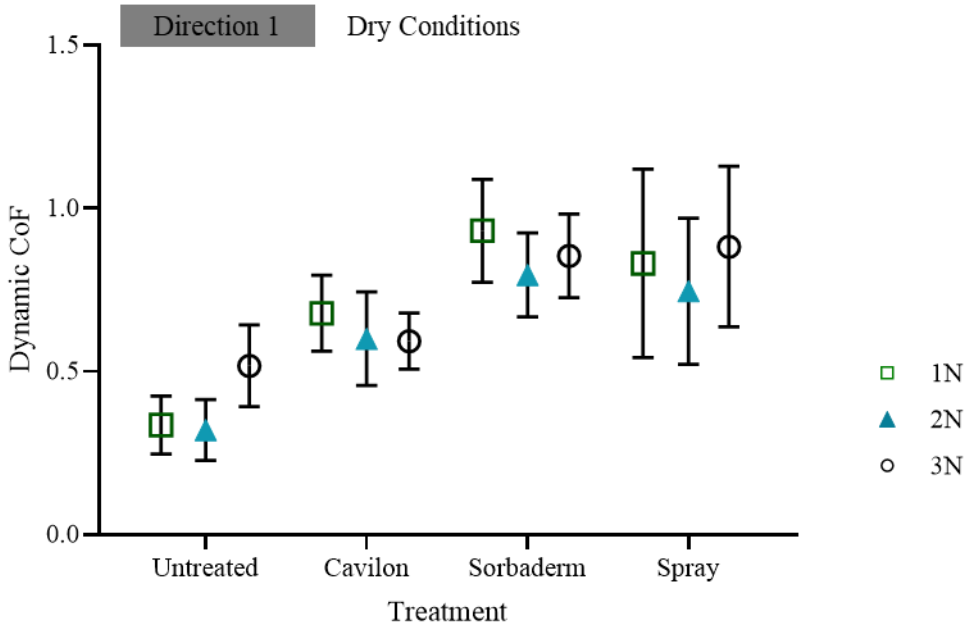



*Figure 7.18 - Average DCoF in dry conditions for P1-P8 with the different treatments and tests carried out at three different normal forces of 1N, 2N, and 3N.*

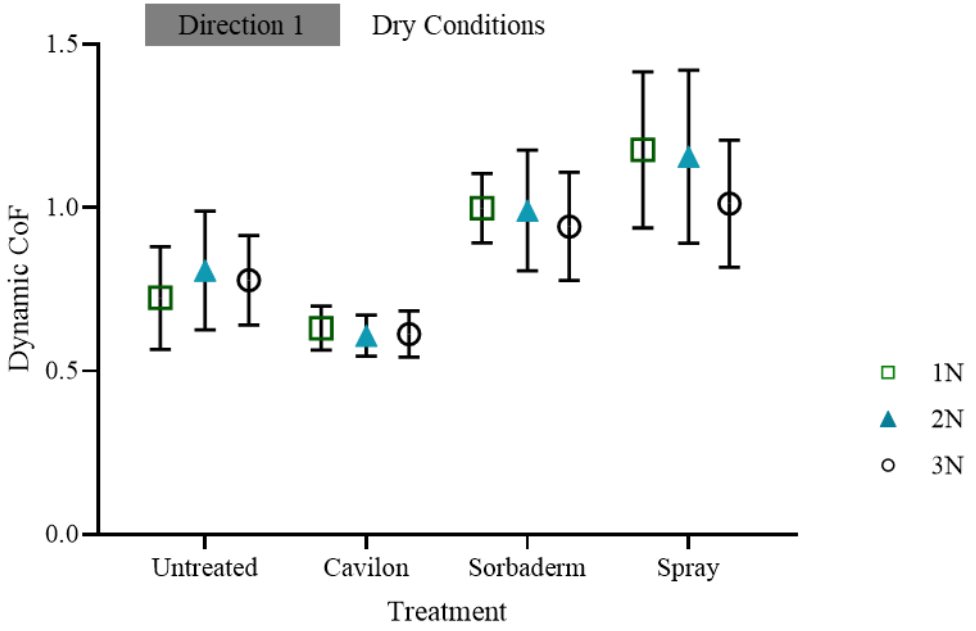



*Figure 7.19 - Average DCoF in wet conditions for P1-P8 with the different treatments and tests carried out at three different normal forces of 1N, 2N, and 3N.*

The average DCoF of untreated skin in dry conditions, see Figure 7.18, was lower than any treatment site in all three loading conditions, showing that dry untreated skin largely promotes the lowest friction environment. In wet conditions the size of the normal load had no measurable effect on the DCoF with *Cavilon* applied, as shown by the data points clustered around ~0.6 in Figure 7.19. The spread of the friction coefficients in both Figure 7.18 and Figure 7.19 show that the DCoF might have been dependent on the normal load, however there was no consistency across the treatments in whether a low load gives a high or low CoF.

A large number of friction influencers exist in the interface, such as the contact surface geometry, material properties of both contacting surfaces, and the loading direction. The normal force might only play a small part, for more detail on factors and parameters that could impact the friction within the skin-pad interface see Chapter 2, Section 2.6. Other variables to consider are evaporation rates of treatments, treatment viscosity, absorption into the SC, transfer of treatment to the pad, and interparticipant differences. The barrier spray in dry and wet conditions resulted in a wide range of friction coefficients across the participants, indicated by the long error bars. Tomlinson *et al*. [12] found the finger reached a maximum contact area at a low load of 1N, so forces above resulted in a linear relationship between normal force and friction force. This may have also been the case for skin treated with *Cavilon*, as the 2N and 3N DCoFs overlap, however more tests are required to verify this statement.

### 7.5.4 Skin Characterisation Kit Results

Alongside friction measurements the skin characterisation kit was used to measure the test sites and control sites prior to the friction tests being carried out, and then directly after the friction tests, however no measureable or statistically significant effects of treatments were found before and after any of the treatment tests in both wet and dry conditions ($p > 0.05$). *Mexameter* readings did not show any changes in the redness of the skin; it is possible that the duration of friction exposure was not long enough to induce redness, and the tests were likely not aggressive enough to cause measurable irritation. Researchers in the future could gain ethical approval to incorporate sufficiently vigorous protocols to emulate the skin-pad environment; perhaps with a combination of longer test duration, chemical irritants or tape stripping of skin. Overall, there was no indication that any one treatment was associated with preventing increased redness.

The volar forearm temperature recordings showed no significant changes in temperature from before and after tests in the dry conditions ($p > 0.05$). In the wet conditions all sites on average underwent cooling due to the room-temperature water that was applied to the pad, (Untreated -0.02% ± 3.24 ($p > 0.05$), *Cavilon* -4.12% ± 2.55 ($p > 0.05$), *Sorbaderm* -5.54% ± 3.12 ($p = 0.0156$), *Spray* -3.9% ± 2.01 ($p = 0.156$)). In the skin pad environment typically the skin is closer to 35°C with higher humidity, plus

the urine is released at internal body temperature of ~37°C, therefore the artificial urine and rig were not an ideal mimic. A reason for the *Sorbaderm Barrier Cream* and *Sorbaderm Barrier Spray* statistically significantly cooling the skin the skin is that by having the treatment on the skin the evaporation rate reduced which meant that during the 'after' tests, more water resided on the surface for longer therefore lowering the epidermal temperature. Whereas with the untreated skin site the water had direct contact with the warm skin which may have resulted in a greater evaporation rate post-test therefore allowing the skin to dry more quickly, and subsequently warm-up once the water had evaporated.

Caliper tests were carried out to give an indication of the amount of underlying subcutaneous fat, but either there were not enough data points to establish whether there was a relationship with the CoF, or the device and device protocol may not have been to a high enough degree of precision. To investigate this relationship further, a greater number of tests subjects could be recruited with varying differences in the thickness of their volar forearm hypodermis.

### 7.5.5 Percentage Change in the DCoF from Untreated to Treated Sites

The average percentage changes that occurred from untreated dry states to treated dry states at three different normal forces are presented in Figure 7.20, alongside the corresponding data and *p* values in Table 7.11. In this chapter the statistical analyses were conducted using a two-tailed parametric t-tests at significance level of $p < 0.05$. Before conducting the t-tests the Shapiro-Wilk test was used to confirm that data sets were normally distributed.

In all three dry-pad loading conditions the application of treatments on average increased the DCoF. For a 3N normal force test condition the average DCoF across the eight participants increased from untreated conditions by 20.7% with *Cavilon*, 71.9% with *Sorbaderm* Barrier Cream, and 83.2% with *Sorbaderm* Barrier Spray. Despite the average increase the 3N *Cavilon* sites showed no significant change from untreated conditions, $p = 0.197$, whereas all other treatments and loading conditions showed significant percentage increase from the baseline untreated levels, see Table 7.11.

At low loads of 1N and 2N percentage increases were higher than recorded at 3N, which may have arisen due to the maximum real contact area already being achieved in an untreated 3N test, so the effects of the addition of treatment could only increase the friction to a certain extent beyond what was reached in untreated conditions.

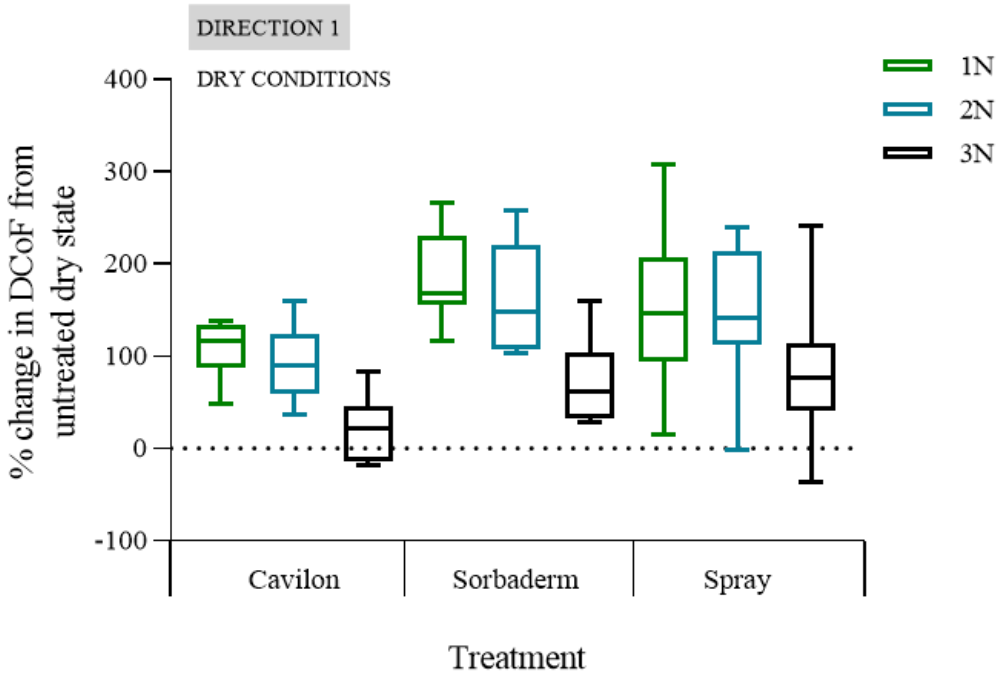



*Figure 7.20 - Percentage change from untreated dry to dry pad with treatments at three different normal forces 1N, 2N, and 3N. Direction 1*

*Table 7.11- Corresponding data table for Figure 7.20 showing the % change for treated conditions compared to the equivalent untreated state in dry conditions. Significant p values are marked with an asterisk.*

| Dry conditions | Percentage change in DCoF from untreated skin to treatment added (%) | | | | | |
|---|---|---|---|---|---|---|
| Normal force (N) | *Cavilon* | *p* value | *Sorbaderm* | *p* value | Spray | *p* value |
| 1 N | 107.9 | * < 0.0001 | 186.3 | * <0.0001 | 154.9 | * 0.0012 |
| 2 N | 93.9 | * 0.0001 | 160.4 | * <0.0001 | 143.8 | * 0.0009 |
| 3 N | 20.7 | 0.1969 | 71.9 | * 0.0003 | 83.2 | * 0.0129 |

In a dry-pad state all treatments statistically significantly increased the DCoF ($p < 0.05$), with one exception which was the *Cavilon* at a load of 3N ($p = 0.197$). Skin treated with *Cavilon* on average had an increase in the DCoF of 20.7%, whereas in skin treated with *Sorbaderm Barrier Cream* and *Sorbaderm Barrier Spray* the dynamic coefficient increased by 71.9% and 83.2% respectively. Similarly, in the 1N and 2N loading conditions *Cavilon* treated skin did not incur such high increases in friction as the other treatments. Possibly the formulation of *Cavilon* dried more quickly than the other treatments, or dried to a smoother finish which could mean the pad fibres were less likely to form adhesive junctions within the interface. The frictional differences between these treatments in a dry interface is interesting because it could be indicative of the product wear rate; if a treatment is exposed to higher friction coefficients initially after application then potentially the protective layer could wear away faster than intended.

Adding any given treatment into the lower normal force conditions of a 1N or 2N tribosystem resulted in a higher percentage increase in DCoF compared to the 3N loading conditions. A possible explanation is that at low loads the contact area is also lower, so when a treatment is added to the interface the real contact area can increase by a greater percentage because there is far more potential to grow than in higher loading conditions which may already be at close to a maximum contact area. Therefore, at low loads the number and strength of adhesive junctions also have the ability to increase in number, more so than that of the 3N tribosystem, where the real contact area has almost already reached its maximum.

Figure 7.21 and Table 7.12 show the percentage changes in the DCoF from the untreated wet states to treated wet states at three different normal forces.

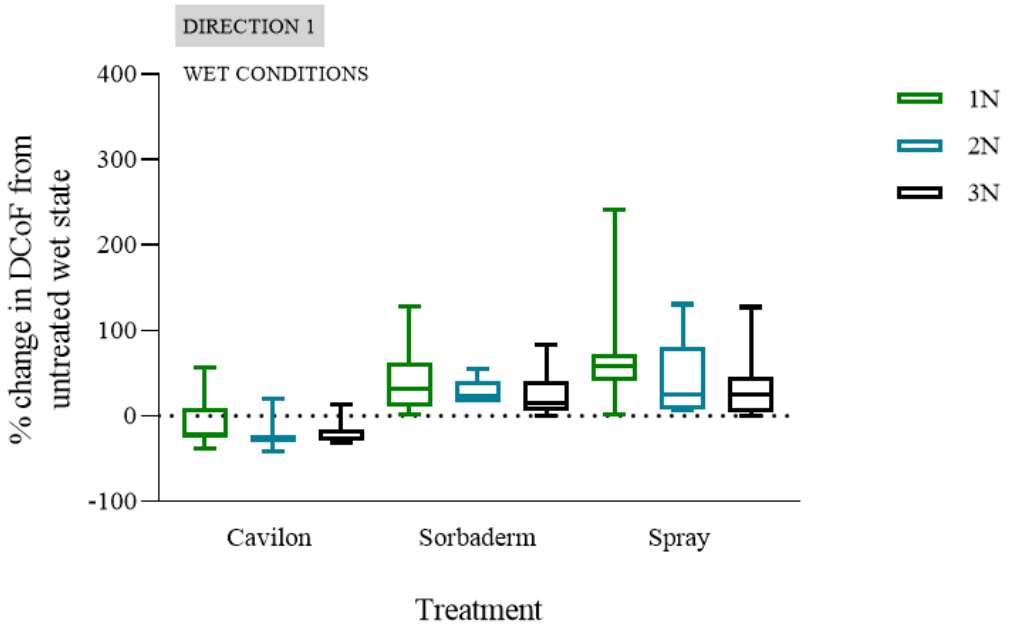



*Figure 7.21 Percentage change from untreated wet to wet pad with treatments at three different normal forces 1N, 2N, and 3N, Direction 1.*

*Table 7.12 - Corresponding data table for Figure 7.21 – percentage changes when tests were conducted with treatments compared to the equivalent untreated state in wet conditions.*

| Wet conditions | Percentage change in DCoF from untreated skin to treatment added (%) | | | | | |
|---|---|---|---|---|---|---|
| Normal force (N) | *Cavilon* | *p* value | *Sorbaderm* | *p* value | Spray | *p* value |
| 1 N | - 9.07 | 0.1910 | 41.0 | * 0.0064 | 73.0 | * 0.0041 |
| 2 N | - 22.1 | * 0.0194 | 28.1 | * 0.0226 | 43.6 | * 0.0187 |
| 3 N | - 20.5 | * 0.0031 | 23.9 | * 0.0270 | 34.6 | * 0.0219 |

Of the three treatments studied, only *Cavilon* reduced the friction between the pad and skin compared to untreated skin in wet conditions, see Figure 7.21, these reductions in friction coefficients were

statistically significant at loads of 2N (-22.1%, $p = 0.019$) and 3N (-20.5%, $p = 0.003$). In wet conditions, the *Cavilon* may have formed a lubricating layer by transforming the film into an emulsion thereby activating a hydrodynamic lubrication regime. *Sorbaderm* cream and spray treated sites displayed a statistically significant percentage increase in the DCoF compared to an untreated wet-pad state, therefore their application as friction reducing modifiers was found not to be present. The barrier spray treated sites had the highest percentage increase in DCoF, and the spray also had the most varied effect on participants' skin, evidenced by a large range and interquartile range.

The barrier spray results showed that in both dry and wet conditions it increased the friction coefficients. The stick-slip behaviour displayed with this treatment may have led to greater friction on average partly due to a greater deformation of the skin and/or the pad. Bernatchez *et al*. [13] found that a competitor barrier film of similar chemical constituency to the *Sorbaderm* spray reduced the CoF of hydrated skin against a 100% cotton bed linen. This converse finding could be due to differences between the two protocols, where in the experiments of Bernatchez *et al*. [13] the skin was hydrated through water submersion, rather than the external surface (sheets) being wet, whereas, in this study the external surface (the pad) was hydrated.

### 7.5.6 Static and Dynamic Friction Coefficients and Directional Effects

The results for the dynamic and static friction coefficient values in dry and wet conditions at 3N are shown in Figure 7.22 (D1) and Figure 7.23 (D2).

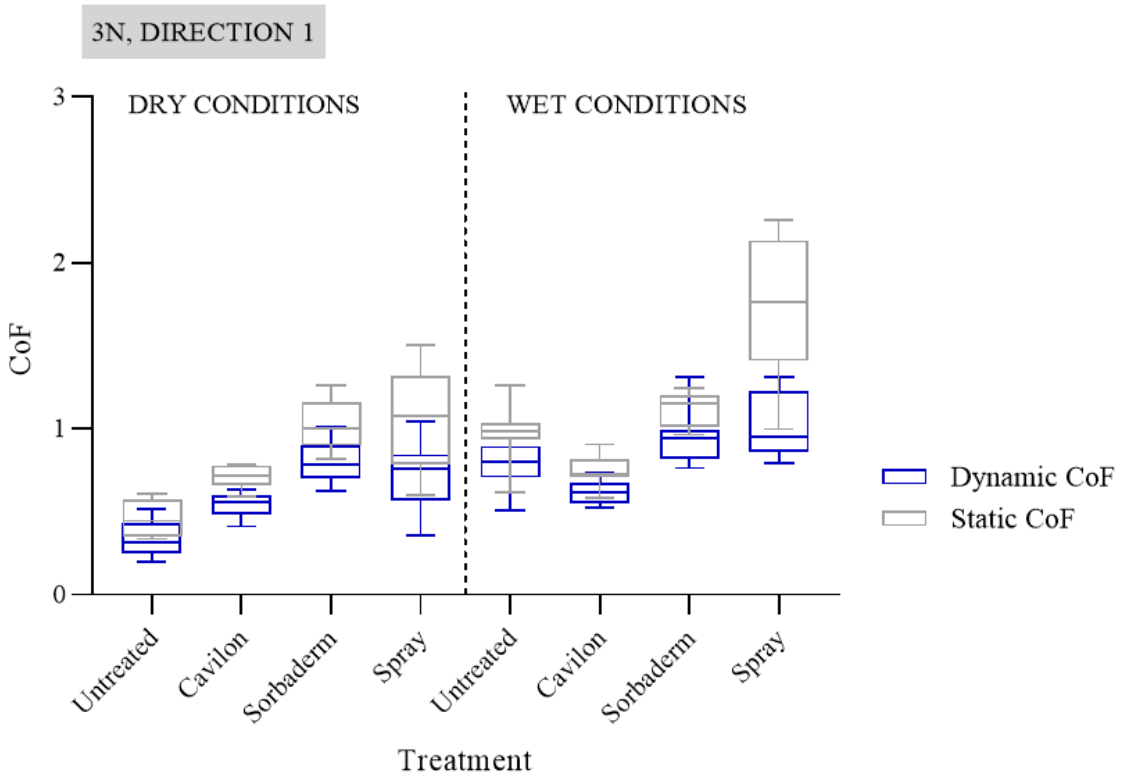



*Figure 7.22 - Box plots of SCoF and DCoF according to different treatments applied in wet and dry conditions. The results are for 3N in Direction 1.*

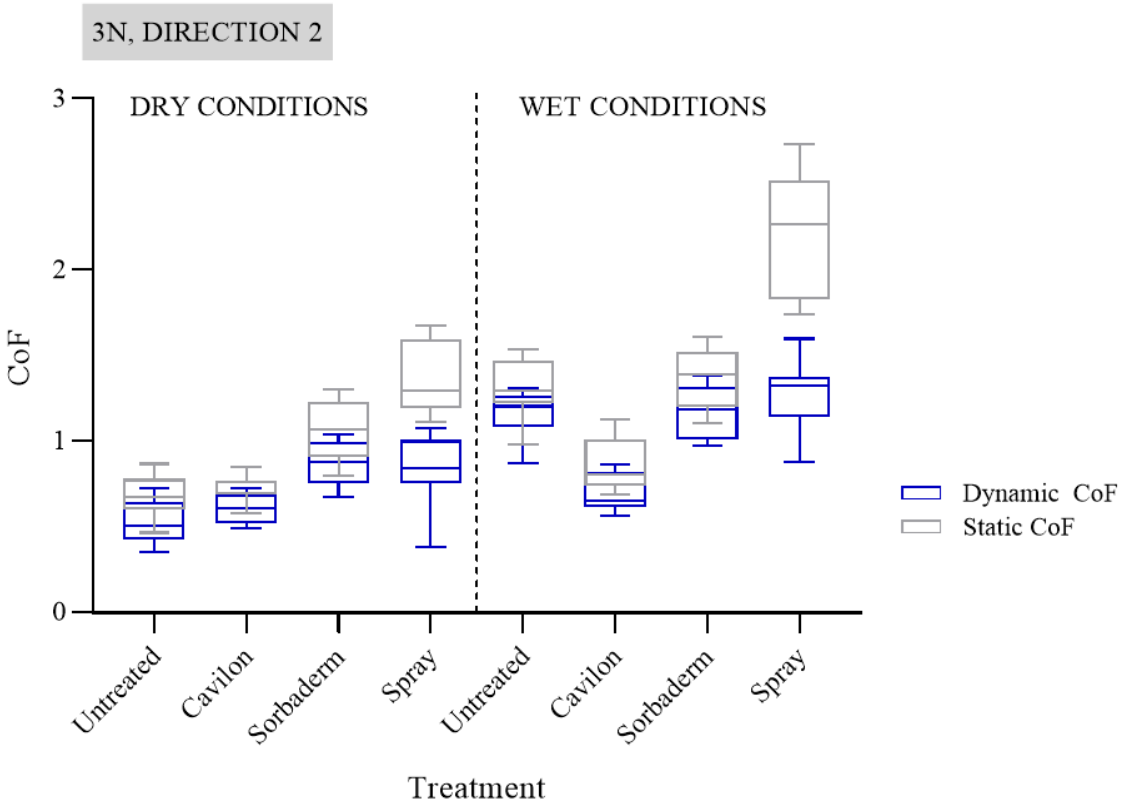



*Figure 7.23 - Box plots of SCoF and DCoF according to different treatments applied in wet and dry conditions. The results are for 3N in Direction 2.*

The box-plot overlay in Figure 7.22 for D1 shows that each treatment in both wet and dry conditions had different sized intervals between DCoF and SCoF, so the way the tribosystem interacts in each system differs at the start of the stroke and mid-stroke depending on the treatment applied. As expected, in all states the SCoF was statistically significantly higher than that of the DCoF ($p < 0.05$), though *Sorbaderm* cream and spray both showed a greater difference between the two values, highlighting that before sliding occurs the skin undergoes a greater friction force, which is indicative of greater shear occurring.

The DCoF of untreated wet skin was over twice as high as the value for dry skin, demonstrating that wet conditions significantly increased friction in the skin-pad interface. In other experiments in literature it was found that CoF increased after application of water to the skin, and slowly over a period of 20-30 minutes of drying time the skin hydration returned to the original levels [14-16].

In any two surfaces sliding over one another the real contact area is much smaller than the apparent contact area which leads to contact friction and 'non-contact' friction. Capillary adhesion or viscous adhesion can significantly contribute to the overall friction in surface interaction, and Lee *et al*. [17] stated that when there is water or treatment on the skin then nanobridges form on asperities. A wet pad has a larger contact area than a dry pad due to the absorption of the artificial urine which causes swelling of the core in turn stretching the surface layer of the pad. Subsequently with the combination of contact friction and non-contact friction increasing in a wet pad scenario, this explains why such a large change in the CoF values was seen from the dry to wet conditions in both Figure 7.22 and Figure 7.23. The tribosystem demonstrably changed when a pad became wet, highlighting the necessity of moisture wicking pads and changing absorbent products as soon as possible after becoming wet or reaching capacity.

Amongst all treatments, *Cavilon* had the lowest median DCoF, SCoF, and interquartile range compared to other treatments, indicating that it would be more suitable to minimise friction when compared to the other treatments tested in this work. It was also able to provide the most consistent skin friction conditions independent of the participant it was applied to. Potentially the presence of *Cavilon* in a tribological interface can enable adhesive connections to be broken more uniformly, and/or it may have reduced the strength of the smaller and weaker molecular attractions between the surfaces e.g. Van der Waals forces. Notably, *Cavilon* also was the only treatment in this work to decrease the DCoF or SCoF in wet conditions, meaning it was the best all round treatment for maintaining low levels of friction in a skin-pad interface. The SCoF was on average highest for skin treated with a spray in wet conditions, to varying degrees depending on the participant, as shown by the large interquartile range in Figure 7.22. The high SCoF of the spray is potentially a cause for concern in maintaining skin integrity; the repeated high friction and shear on the skin could weaken the SC and reduce healthy blood flow to the underlying tissue in the case of excessive prolonged shear and cyclic deformations.

*Differences Between D1 and D2*

Figure 7.23, shown previously, presents the CoF findings from D2 of each treatment condition, at a normal load of 3N. The results for D1 and D2 show similar effects for each treatment irrespective of direction, however arm movement in D2 for all scenarios has higher CoF on average than D1. The reason why D2 displays higher DCoF and SCoF on average than D1 could be due to the tissue displacement that occurs throughout D1.

To give an indication of the amount of shear occurring during the tests the percentage differences between the SCoF in D1 and D2 were calculated using the data previously presented in Section 7.5.1 (Table 7.7, Table 7.8, Table 7.9, and Table 7.10). The results of these calculations for the dry and wet conditions can be seen in Figure 7.24. The assumption is the greater the percentage difference is between D1 and D2, then the more shear the skin encounters over the course of the reciprocations.

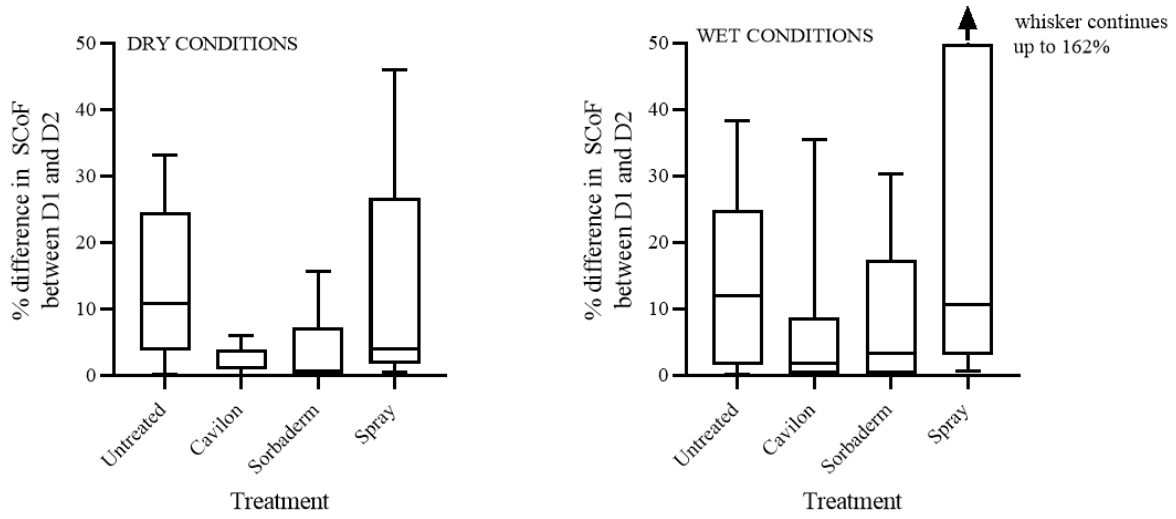



*Figure 7.24 – Box plots showing the percentage difference between the SCoF experienced in D1 and D2.*

The D1 to D2 percentage differences (mean ± SD) for the SCoF were lowest for *Cavilon* dry (2.05 ± 2.14), *Sorbaderm* dry (2.05 % ± 2.14), and *Cavilon* wet (6.99 % ± 12.02). These values area much smaller than the D1-D2 percentage differences for untreated dry (13.70 % ± 11.84) and untreated skin wet (14.13 % ± 13.35), which show much smaller variations in comparison that possibly these conditions experienced less shear and therefore may have been protected from surface and sub-surface shear stresses throughout strokes and direction changes. All of the boxes, with the exception of the untreated wet conditions are positively skewed (i.e. mean > median), showing that most data points are clustered within the lower quartiles. However, a couple of individuals experienced a much larger

percentage difference in the directional SCoF change than others, in particular those with skin sites in wet conditions treated with spray. The percentage increase of 162% between D1 and D2 was recorded for P4 in wet-pad spray treated conditions, this participant also was measured to have the lowest levels of sub-surface fat in the skinfold caliper tests. In both wet and dry conditions, the corresponding boxes to skin sites treated with *Cavilon* were short, indicating the data points consistently fell around the median. The other two treatments and untreated conditions all comparably had more variable data.

In dry conditions the median lines of *Cavilon*, *Sorbaderm*, and the spray can all can be seen to lie entirely below and outside of the untreated interquartile range box, which means there is likely to be a difference between treated and untreated skin even though the boxes overlap. This shows that treatments do have the benefit of altering the SCoF within the interface, even though they might not keep the DCoF as low as an untreated dry condition. Therefore, adding a treatment offers a more uniform SCoF across the full profile in both directions. In wet conditions the median line of the Cavilon also is observed to lie below and outside the untreated wet box, providing further evidence of its suitability to sustain less volatile SCoF changes in wet-pad conditions where skin is at its most vulnerable. The percentage difference for the SCoF between D1 and D2 was greatest on average for the untreated wet condition, which indicates that this condition poses the greatest risk of shear loading which could lead to skin irritation. In dry conditions the directional percentage was also higher than those of the other treatments in a dry-pad state.

A skin system with lower SCoF, such as those of untreated dry skin and skin treated with *Cavilon*, generally appeared to experience lower friction throughout the cycle, i.e. a lower DCoF than the *Sorbaderm* or the spray, resulting in less surface abrasion and minimised sloughing of cells. However, the untreated dry and wet skin had on average greater directional differences in SCoF, indicative of higher surface and subsurface shear.

Therefore, in both a wet and dry state all of the treatments had the effect on average of reducing the directional effects on the SCoF, thereby giving a more uniform D1 and D2 static friction coefficient. This suggests that all treatments work to reduce tissue shear which most likely provides a large contribution to the protective mechanisms by which they maintain skin integrity.

### 7.5.7 Dynamic Friction Coefficients on an Individual Participant Basis

The effects of each treatment on the DCoF on an individual participant basis has been detailed in Figure 7.25 to form a summary of the skin friction across the group of eight participants.

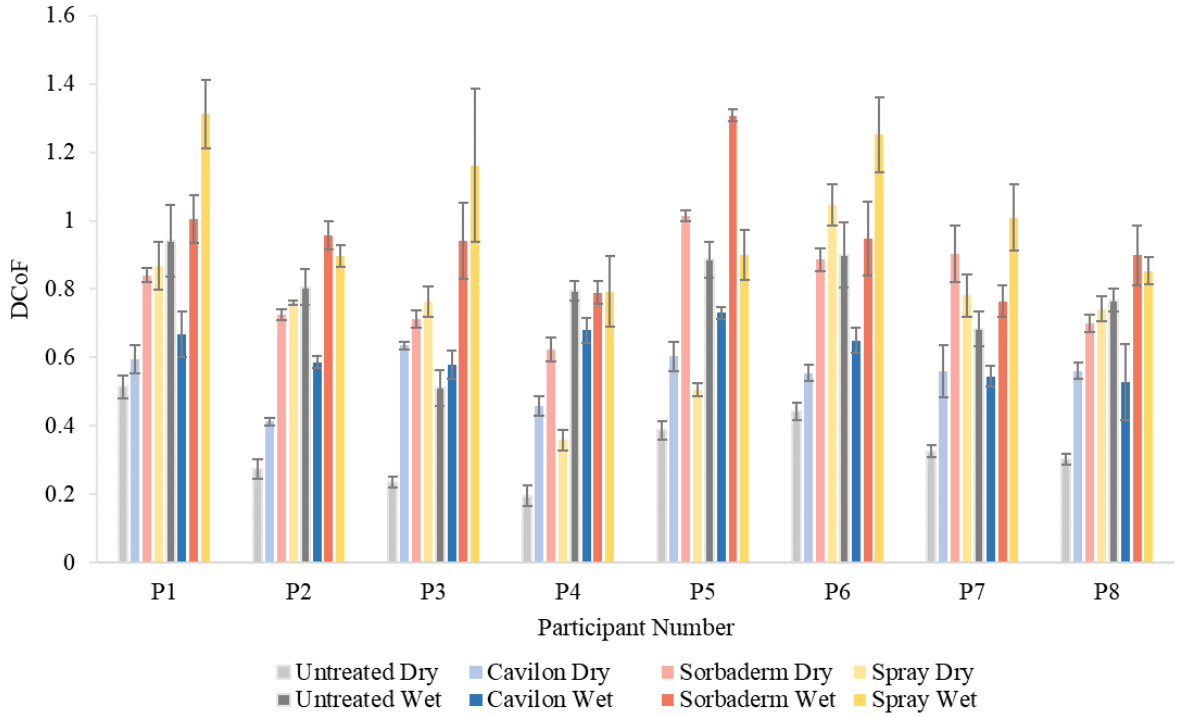



*Figure 7.25 - The DCoF between the skin and pad in all treatment conditions for all participants (D1, normal load 3N).*

In wet-pad conditions 50% of participants incurred the highest DCoF when barrier spray was applied to skin, 37.5% of participants had highest DCoF with *Sorbaderm Barrier Cream*, and in 87.5% of participants *Cavilon* reduced the DCoF to below that of an untreated wet state.

In all participants the addition of any treatment in a dry-pad interface increased the friction coefficient, which could be expected due to the addition of moisture (from the treatment composition), as well as the introduction of a thin film layer of varying tackiness. It was not possible to deduce from the data whether an increase in CoF with a treatment in a dry condition could pose a greater risk to skin integrity as opposed to skin remaining untreated in a dry environment. The importance of *Cavilon* in a wet-pad interface is its distinguishing feature; being the only treatment shown to reduce the CoF values. In a dry environment *Cavilon* also maintained a lower DCoF relative to other treatments.

The expectation would be that specially formulated barrier treatments would all reduce friction in wet-conditions, especially as friction modification for barrier treatments is commonly listed in publications and product descriptions as a beneficial side-effect [18, 19]. Therefore, the findings were surprising that for seven of the eight participants the *Sorbaderm Barrier Cream* and the spray were both found to increase the DCoF in wet conditions, whereas the *Cavilon* formulation had the effect of reducing the DCoF for all participants. Salehi *et al*. [20] discussed that the composition of different treatments results

in different interfacial viscosities, and in higher viscosity creams greater forces are required to shear the interfaces, giving improved dissipation of shear stress. This is a desirable factor to consider in the design of skin treatments because as the evidenced research shows that shear is a great risk factor to skin integrity (Beeckman, 2017). However, as barrier protection products treatments are recommended to be applied sparingly their mechanism of protection is not likely to be dependent on the interfacial viscosity of treatments. This is because the thin films are often dry that there may not be a significant contribution of viscous flow to the tribological interface. In wet-conditions then there is potential for the barrier treatment to form a lubricating emulsion, but further testing would be needed to validate the rheological properties of the treatments in the dry and wet interface. In all conditions, the application of normal force and movement of the skin across the pad likely resulted in some level of bunching, compression, and other deformations of the pad structure. These pad changes may have also contributed to the inter-participant differences.

## 7.6 Key Findings and Limitations

### 7.6.1 Key Findings

*Cavilon Barrier Cream*, *Sorbaderm Barrier Cream* and *Sorbaderm Barrier Spray* are medically reported to share many of the same benefits, such as being wash-off resistant, not blocking absorbency of incontinence pads, and they provide a waterproof barrier to protect against bodily fluids and friction. However, in this work it has been found that tribologically they perform very differently. With *Cavilon* being the only treatment to reduce friction in the wet-pad interface its application as a friction modifier to lower friction within the skin-pad interface is supported by the findings of this study. The low CoF is most likely a result of a reduction in both the adhesion and deformation components of the friction. *Cavilon* many primarily function as an interfacial lubricant by reducing micro stick-slip. The variability of the friction behaviour of different treatments has also been discussed in literature; according to Holroyd and Graham [21] ‘the evidence does suggest there is variability in the efficacy and the ability of commercial products to protect the skin, prevent maceration, and maintain adequate skin health’. They also point out that it is ‘essential to carry out an individualised assessment on each patient to ensure the optimum management plan is in place’. This work takes a step in the right direction to identify friction characteristics of barrier products, thereby providing better understanding of the frictional performance of individual treatments to fill a gap in the knowledge.

Another factor to consider with the application of the barrier creams is they are designed to remain on the skin for long periods of time, so interaction with a pad surface should theoretically not result in treatment being removed from the skin. However, a situation with high friction forces encountered in the interface it could be indicative of more likelihood of sloughing treatment from the skin and

transferring to the pad. A destruction of the integrity of the treatment layer would remove the protective shield that the treatment provides to the skin. All treatments incorporated polymer ingredients into their formula which contributes to the long lasting nature of the product on the skin, upwards of 24-hours. The friction altering behaviours of the treatments may have been achieved through altering the contact area, changing the height of asperities, formation of hydrodynamic films and by altering molecular attractions between the surfaces.

It was found that the applied normal force had no consistent effect on the CoF across the group of participants. Though different friction coefficients were recorded at each load, they varied in order of magnitude depending on the treatment applied and pad state. Notable features exhibited in the barrier spray tests were difficulty of movement, high SCoF, recorded and visible stick-slip which became more extreme in wet conditions, and there was more sticking as the normal force increased. The change in direction (D1 and D2) had an influence on the value of the DCoF and SCoF recorded. In general, D2 values were higher than those reported in D1.

Determining a good friction relationship versus a bad one is difficult due to the different loading situations that occur in day-to-day life. However, in the context of this work, a desirable tribosystem for the skin-pad interface in wet and dry conditions can be summarised as one with:

- low friction, as the combined effects of chemical irritation and friction result in weakened skin which can lead to skin breakdown [22].
- minimal shear, experimentally proven by the percentage differences between the SCoF in D1 and D2
- a profile containing smooth sliding, or low and regular stick-slip, as evidenced by assessment of the friction coefficient profiles
- a low initial SCoF because before the surfaces slide relative to one another is where the resistive forces are greatest and more force is needed to overcome the adhesive junctions
- a low DCoF because a low DCoF signifies minimal resistive forces in the interface, so there is less likelihood of skin damage caused by friction.
- equal levels of DCoF and SCoF, which can be seen in the smoother profiles. This ensures that stick-slip is minimised and therefore the associated discomfort is reduced.

The treatment identified in this study with the most versatility in meeting the above criteria is *Cavilon* because it reduced DCoF and SCoF in wet conditions compared to the untreated wet skin, whereas none of the other treatments had this effect. Additionally, in dry conditions the application of *Cavilon* did not significantly increase the DCoF or SCoF compared to the untreated skin in dry conditions. Again, both other skin treatments did not share this protective friction response. However, skin treated with any of the three barrier treatments was found to reduce the percentage difference between D1 and D2 SCoF

showing that by applying a skin treatment then deformation or ploughing of the skin during sliding was minimised.

These findings combined point towards *Cavilon* being the best treatment to prevent higher friction coefficients, as well as minimising surface and subsurface shear. All of these forces are proven to pose a risk to skin health due to reducing blood flow to the area, eventually resulting in cell weakness, cell death, and tissue fragility, [23]. Additionally, a predictable skin response like the one *Cavilon* produces is ideal in terms treating medical conditions, because a prescriber or advisor can be confident about the skin response for the majority of people.

Cyclical loading of the skin treated with a spray resulted a volatile friction response with high amplitude and rapid fluctuations. Values of SCoF for the spray in wet conditions were also significantly greater than in untreated skin or those containing other treatments. Pinching and pulling of the skin (stick-slip) was described as uncomfortable, and on this basis, a spray applied to a body area which undergoes a high amount of cyclical loading in wet conditions could be deemed substandard based on the friction response alone. However, the protective waterproof barrier properties of the spray would provide an alternative mechanism to help maintain skin integrity, so perhaps on people less mobile the high friction cyclical loading situations (such as walking, sitting up and sitting down), may not factor in as much. The spray was also found to reduce the effects of directional changes on the SCoF, indicating that it protects against tissue shear.

Friction was not reduced with the addition of treatments in a dry interface, though it is not known whether this poses a great risk to the skin as it is in wet conditions where the skin becomes more vulnerable. Overall, adverse loading on superficial and sub-surface tissue layers could result in localised tissue damaged, contributing to the development of IAD.

### 7.6.2 Limitations and Future Work

Overall, any human experiment protocol design involves compromises partly due to time restraints, and there is the unavoidable aspect of inter-participant variation: in areas such as anatomy, physiology, and motor control.

A limitation of the work was that participants were directed to apply the required load by reviewing the software on the computer screen, and the sliding speed was directed by an audio cue. This method of loading and movement may have resulted in some amount of human error, both due to the nature of the protocol as well as the skill of the participant. The speed of reversal was something that could have affected the initial strength of the resistive friction force (and therefore impacted the size of the SCoF). However, fluctuations of the loading and friction were not dissimilar to force profiles seen in experiments with Bruker Tribometers, or nanotribometers [20]. The low variability of the CoF between

slides for each participant gave confidence in the experimental protocol to produce repeatable data, and this was supported by the low coefficients of variation. Interparticipant variation was also fairly low, again indicated by the coefficients of variation (< 1). The confidence in the overall friction findings for different treatments, and wetness conditions was high due to the low variability of the data, and the similarity of the patterns that emerged in the shapes of the CoF profiles for the participants. Based on the confidence in the results it can be concluded that this method of participant directed loading contributes to a robust protocol, which is suitable to take forward in future experimental work to discover more about the skin-pad interface.

Altering the tribological interface through investigating the friction response of different types and brands of absorbent products would also be beneficial knowledge for the field. In the future experiments using pads, pull-ups, and all-in-ones of different capacities could be used. Specifically, the absorbent products could be classified into different groups based on their material composition, and surface roughness. It would also be beneficial to understand what happens to different pads and treatments on the skin with different quantities of artificial urine added to the pad. In future the investigation of more skin treatments varying sliding speeds would contribute further to the understanding of the tribological relationships. For example, a new protocol could be emulate the work of Derler *et al*. [24] where friction experiments were conducted at wide variety of sliding speeds (between 5 and 15 mm/s).

Testing human skin, although more complex and variable than artificial models, has greater clinical significance. The volar forearm was used as a surrogate for the regions typically affected by IAD: the buttocks, thighs, perineum and genital regions. The test site had limiting factors as it was inherently different from the body regions listed due to differences in the topography, anatomy, lipid levels, hair, bony prominences, and levels of perspiration. Additionally, the volar forearm has less volume of subsurface tissue than other bodily areas such as the buttocks and thighs which are common sites to experience IAD. Despite this limitation, the volar forearm region provides an easily accessible surface by which to reliably compare treatments in the skin-pad interface. Therefore, within the context of this work, and future work involving the skin-pad interface, the recommendation would be to keep utilising this surface.

## 7.7 Conclusions

This study reports on friction and shear in the skin-pad interface with the addition of different topical skin treatments. Three commercially available topical treatments were applied to participant skin and the resulting friction system property changes were analysed.

Recommendations from the findings of this work are to:

- Apply a treatment to the skin in both wet and dry pad states because all of the treatments had the effect on average of reducing the directional effects on the SCoF, meaning that all treatments worked to reduce tissue shear even if they did not reduce the friction coefficients.
- Choose a suitable capacity of pad with good moisture wicking ability in order to keep friction as low as possible because wet-conditions have been shown to exacerbate friction in the interface.

Some further notable observations:

- Addition of any of the three treatments in dry conditions increased the friction in the interface, but this increases was smallest for *Cavilon*.
- Protecting the skin with *Cavilon* could provide optimum defence from increased friction in wet conditions. It was the only treatment which reduced the CoF compared to untreated wet-pad conditions, in all loading conditions.
- The forearm displayed directional dependant dynamic and static friction coefficients, with D1 being lower than D2.
- The difference between D1 and D2 was greatest for the untreated wet condition, which indicates that this condition poses the greatest risk of skin irritation due to shear loading.

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# 8 Discussion and Conclusions

## 8.1 Discussion

This research project was undertaken to gather new insights into tribological relationships that occur in the skin-pad interface under different wetness conditions, and also to highlight the ways in which friction can be reduced, and friction mechanisms modified through the use of skin treatments. Each of the original six objectives outlined in Chapter 1 have been met to a significant degree, as outlined below.

A comprehensive literature review (Objective 1, Chapter 2) provided the basis for the study and indicted that greater research was needed to understand how barrier treatments behave in a tribological context, as well as the need for well-developed and defined protocols for *in vivo* skin testing, due to the vast differences in the findings by different researchers. The review also highlighted there are a lack of studies that integrate the patients and community into their work.

In order to develop reliable protocols (Objective 2, Chapter 3), initial experiments were conducted to gain understanding of some skin fundamentals. Application of the protocol (Objective 3, Chapter 4) identified possible correlations between friction, skin roughness, skin deformation, and skin moisture.

To gather insights into incontinence and incontinence-associated dermatitis (IAD) from a patient perspective, data was gathered through the use of an online questionnaire (Objective 4, Chapters 5 and 6). The questionnaire was unique because it was more inclusive for a wide population of people living with incontinence. The developed questionnaire helped to gain an understanding of personal experiences, IAD symptoms, as well as the types of absorbent products and treatments used. It was identified in literature that numerous IAD diagnostic tools have been developed, however these were found to be generally lengthy, time consuming, and not particularly user-friendly. This study went beyond the original objectives and developed a question based diagnostic severity index for IAD called the HIG Severity Index. It is a tool that in future has potential to be used for diagnostics to better connect the community with the resources and services they need.

The skin-pad friction study (Objective 5, Chapter 7), assessed the relative efficacy of skin treatments in reducing friction and with it, the likelihood of a person developing IAD. It was identified that *Cavilon* displayed unique frictional behaviour compared to the other treatments (*Sorbarderm Barrier Cream*,

and *Sorbaderm Barrier Spray*). In particular, in wet-pad conditions *Cavilon* reduced the coefficient of friction and provided a state of reduced shear loading.

The combined results from the experimental studies and the questionnaire proved successful in providing deeper insights into the friction mechanisms and also the risk factors associated with developing IAD. The aim to better understand the friction between the skin and incontinence pads to identify ways in which skin damage can be both managed and prevented, was addressed by putting together a series of recommendations (Objective 6). These recommendations could be used in the future to better inform health practitioners, and those living with IAD, of how to optimise the conditions in the skin-pad interface for the prevention of skin damage. It can be concluded there are a number of ways to improve tribological conditions in the skin-pad interface, and it is hoped that if the recommendations developed within this thesis are taken up then it could improve the lives of those with incontinence.

The structure of the thesis workflow is shown in Figure 8.1; it displays how different stages of the research linked with one another through the use of illustrative building blocks. Each hexagon depicts an area of research than was undertaken to reach the aim of building an understanding of friction in the skin-pad interface to prevent and manage skin damage. The initial experimental study design was the primary building block from which experimental studies 1 and 2 arose. By developing these protocols, the effects of treatments on skin were discovered, and the friction rig protocol was assessed. The 'evolution' arrow represents that the first study was critiqued and improved for the skin-pad study. Two main modifications involved redesigning the friction rig be suitable to mount an incontinence pad, and also the sliding protocol was modified to be reciprocating rather than unidirectional to provide more control over the sliding speed and control of the normal force.

The central hexagon contains the questionnaire element of the thesis, and this essentially tied a lot of the research together since it provided context, direction, and highlighted the importance of involving those affected by IAD into the research process. The questionnaire fed into better interpretation of the results of the skin-pad study, and also enabled new discovery of factors and friction influencers in the skin-pad interface, which can give rise to the development of IAD. The questionnaire also led to the design and development of the HIG Severity Index which helped identify risk factors for IAD. Finally, all of the building blocks of the project came together to form a series of recommendations relevant for the various stakeholders of the research. The recommendations are discussed in Section 8.2.

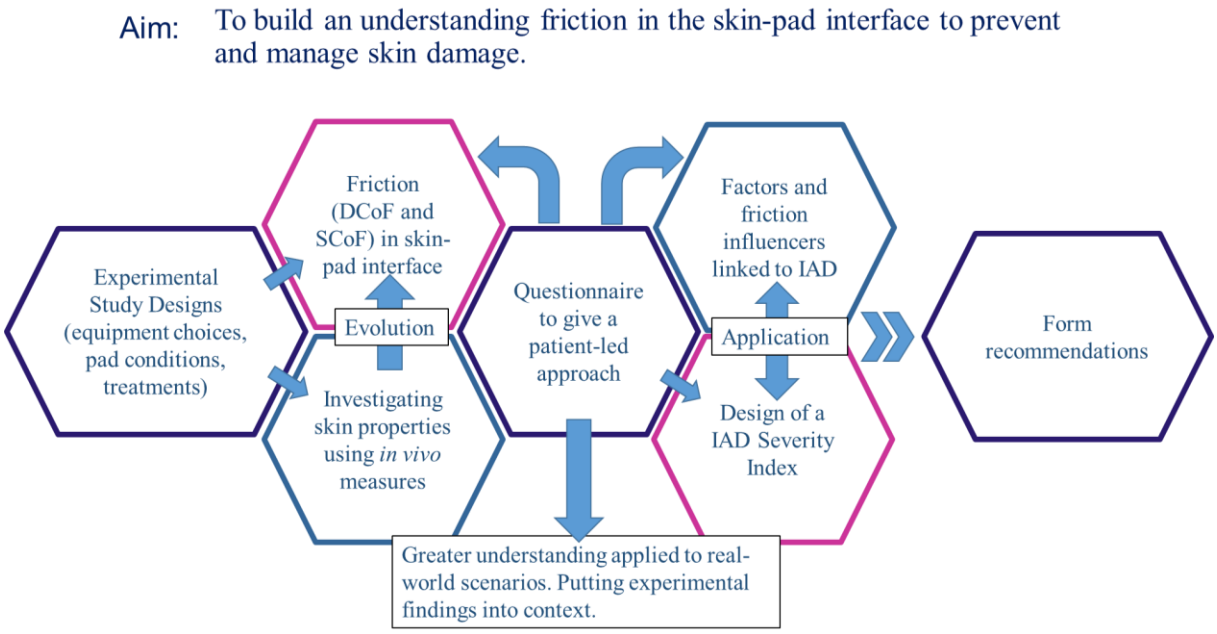


*Figure 8.1 – A figure illustrating the structural building blocks of the thesis and how they align and feedback into one another to achieve the aim.*

Each study contributed towards understanding the factors and friction influencers that can increase the risk of developing IAD. Figure 8.2 summarises these into five key factors (higher BMI, higher urinary incontinence (UI) severity, pad choice, interface conditions, and lack of knowledge). The arrows point to explanations for these conclusions, for example, having a higher UI severity, most likely results in the skin being exposed to more moisture, and therefore experiences more adverse interface conditions and a higher CoF. When a person experiences a higher UI severity then it is a greater risk factor for IAD because they will experience more episodes of voiding of larger amounts of urine, therefore skin is likely in contact with moisture for longer periods of time than somebody who has a milder form of UI.

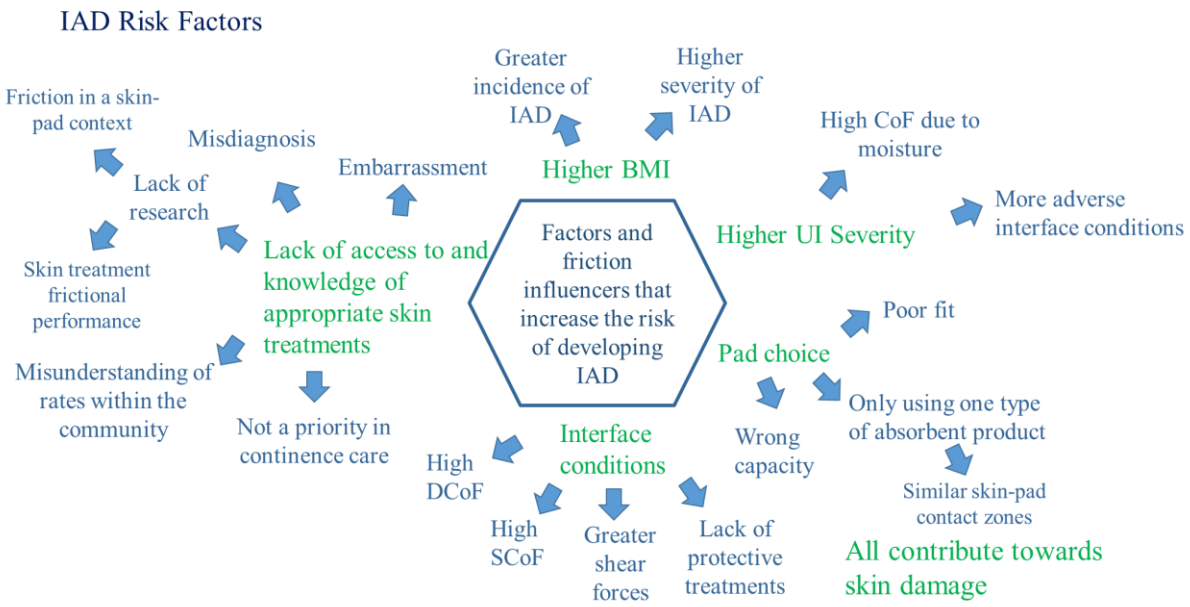


*Figure 8.2 - IAD risk factors*

If each of the IAD risk factors in Figure 8.2 were positively actioned it would reduce the number of people living with IAD, and would also reduce the severity of IAD. For example, further investigations could enhance product development for new treatments for IAD. Also, by making treatment advice more accessible to the community and patients, then people would be better able to manage their symptoms, reducing the risk of a person developing IAD.

The tribological interface conditions were investigated in both experimental studies. The first experimental study measured friction between the volar forearm skin and a steel probe, and it was found that there was a positive correlation between the deformability of the skin and the CoF. This finding highlighted that deformation behaviour of skin contributes towards the friction force. A more deformable tissue enables greater ploughing of the contact material into the skin, therefore increasing the friction between the surfaces. A limitation of this study was the unidirectional friction protocol which required improvement along with the use of a steel ball as the contacting material. However, some interesting relationships were identified, particularly between CoF and deformation, and moisture and roughness of skin.

The second experimental study investigated tribology in the skin-pad interface. It was found that the application of skin treatments modified friction in the interface. The unique characteristics of barrier treatments were explored through examining the dynamic and static CoFs, and also the individual friction profiles. *Cavilon* was found to reduce the dynamic and static CoF in wet conditions, due to the treatment reducing micro stick-slip, and likely reducing both the adhesive and ploughing mechanisms. The eight participants all experienced similar friction response, indicated by the low interparticipant coefficients of variation which provided confidence in the data.

## 8.2 Recommendations for Stakeholders

A list of recommendations based on the findings presented in this thesis is provided below, and they have been deemed applicable to stakeholders of this research: i) people living with IAD, ii) continence clinics, iii) the local council, industry, and iv) the scientific community. Some of these recommendations would benefit from further investigation and perhaps clinical validation, and when implemented they have the potential to improve the integrity of the skin barrier.

### 8.2.1 Recommendations for People Living with IAD

Recommendation 1: Make use of specially developed barrier products to reduce tissue shear.

The barrier treatments investigated in the skin-pad study in Chapter 7 found that they were likely effective in reducing shear loading, thereby preventing a build-up of subsurface stresses which are a risk factor for both IAD and pressure ulcers. Therefore, it is likely that other commercially available treatments would also have this effect, though this would need experimental validation before stating that all barrier treatments display these characteristics. *Vaseline*, marketed as a product to treat IAD, did not perform in a similar manner to *Cavilon* in the first study despite one of its intended marketed uses being to protect from diaper dermatitis and IAD.

Recommendation 2: Apply a good-all-rounder like Cavilon.

*Cavilon* has been shown to reduce the dynamic and static friction coefficients in wet-conditions, whilst also providing consistent friction, and minimal shear. It was also found to not be moisturising in the results from Chapter 4, which can be seen as a positive characteristic, as moisture increases friction. Not all of the treatments tribologically behaved in the same way, and in wet conditions only the *Cavilon* was found to reduce the dynamic coefficient of friction compared to the untreated wet pad conditions. Additionally, it was found to be a treatment which had a similar effect on all participants. This points to *Cavilon* producing a more reliable and predictable friction response, making it more likely to work on a larger proportion of the population. *Cavilon* could be identified as a good product to use when a person or medical practitioner is uncertain of what product to use. This recommendation does not mean that *Cavilon* would be the best product for a given person, however it does point toward *Cavilon* being more likely to reduce friction in wet conditions for a greater number of people compared to the other treatments investigated.

Recommendation 3: Minimise the amount of time spent in a wet-pad.

This statement may sound obvious, but it was found in Chapter 7 that the friction between the skin and pad goes up approximately two fold when a pad contains artificial urine. In literature it has also been highlighted that prolonged contact with urine weakens the skin barrier through means other than friction, such as hyperhydration, pH changes, and microbial changes. Keeping the skin surface dry can be recommended as one of the best practices for minimising the risk and severity of IAD. This further strengthens the current advice that it is important for users of absorbent products to minimise the amount of time spent in a wet pad and to ensure that the correct capacity of pad is being worn.

Recommendation 4: Where possible alternate the type of absorbent products used, e.g. use a pad and pull-ups, or pull-ups and all-in-ones.

In the questionnaire results the people who used a combination of absorbent products were found to have less severe IAD than those who used just one product type. Therefore, the recommendation is for those who suffer with IAD to try integrating at least one different absorbent product into their management of incontinence to see if the severity of symptoms reduces. For example, if a person uses incontinence pads, then they could look at also using pull-ups. Or another suggestion could be to alternate between wearing different pad brands because brands often have slightly different shapes, although interchanging brands was not investigated as part of the study. This recommendation is something that continence clinics could look into to assess if they are providing appropriate product types and whether the guidelines and resources are suitable for all patients.

Recommendation 5: Make use of the HIG Severity Index to help with diagnosis and signposting to the appropriate skin management techniques.

If the HIG Severity Index were to be implemented online then people with incontinence are recommended to make use the tool because it will help provide knowledge, advice, and resources. Monitoring could be done remotely by a patient filling the questions in online, or could be used pre-appointment to inform the consultation.

### 8.2.2 Recommendations for Continence Clinics

Recommendation 6: Make use of the HIG Severity Index to initially categorise the IAD severity of the patient and form a plan for their treatment.

Using the HIG Severity Index would provide an initial benchmark for a clinician to begin reviewing somebody. With it being a quick and simple question based tool then very little training would be required on how to use it, and the implementation within a medical setting would be straightforward, simple, and cost effective.

Recommendation 7: Use the HIG Severity Index to monitor progress of the patient and see whether the chosen management regime is improving their skin health.

Monitoring of skin health is important in the long term management of IAD. Using the index would enable clinicians to get a quantifiable overview of improvement or worsening of the IAD. Based on the results it could help determine which treatments are most suited to each person's skin.

Recommendation 8: Give people a sufficient quantity of absorbent products for incontinence, otherwise this can lead to patients rationing their supplies.

It was highlighted in the research that some NHS trusts limit people to four pads per day and only were allowed to give one type (e.g. only pads provided, rather than a combination of pads and pull-ups) to each person out of a very limited range.

Recommendation 9: Give skin advice and discuss recommended skin treatments in incontinence appointments and care plans.

It was highlighted in the research that some continence clinics never discuss incontinence-associated dermatitis, so people do not get treatment advice for their conditions. Instead the clinics solely focus on incontinence advice and distributing absorbent products.

### 8.2.3 Recommendations for the Local Council

Recommendation 10: Work towards improving disposal facilities in public toilets.

It was highlighted through talking to patients that due to hand dryers becoming more popular in toilets often there are no bins provided. In male toilets often there is no bin provided at all, and in female toilets the sanitary bins are much too small fit bulky absorbent products in. This leads to people having to carry around bags containing used products.

Recommendation 11: Continue reviews into local services, such as the one conducted by the Sheffield City Council Scrutiny Committee in 2020.

Reviews into services are important in order to discover where improvements are needed and also areas where the service is functioning well. A problem was identified through talking to patients is that each health district has their own unique management and budget, therefore patients experience very different service experiences based on the area they live in.

### 8.2.4 Recommendations for Industry and the Scientific Community

Recommendation 12: Use the findings from this research to explore reasons why *Cavilon* displayed unique friction characteristics.

Perhaps industry and the scientific community could inspect the constituent ingredients and formulations of treatments further, and use this knowledge in product development.

Recommendation 13: Conduct more of a detailed analysis into the shape of friction profiles rather than just relying on the coefficient of friction values to investigate skin tribology.

There is a great amount of information that can be gained from looking at individual friction coefficient profiles, such as the slope shape of the slides, the amplitude, and any areas of stick-slip and micro stick-slip.

Recommendation 14: Report the static coefficient of friction and not just the dynamic coefficient in friction experimental studies.

Static friction coefficients are often not reported in skin friction experiments, but this is an important value because it is where the skin experiences the highest friction (and likely greater

damage). If the static coefficients were analysed and reported by researchers, then it would provide more detailed information about each tribosystem.

## 8.3 Future Work

The future work that has been identified for each of the areas of work covered in this thesis has been outlined below.

*Experimental Study 1:*

1. As an extension of this work it would be beneficial to develop a protocol to investigate the deformability of tissue and its effects of volar forearm friction by recruiting participants and categorising them based on hypodermis thickness. This would enable the adhesion and deformation components of friction experiments to undergo greater scrutiny, and to estimate how much of a role deformation plays in the resulting friction force.
2. The one participant who was found to be categorised as having 'dry' skin responded differently to the application treatments, therefore in future it would be useful to recruit more participants with naturally dry skin to further investigate the effects of treatments on xerotic skin.
3. This work could be built upon by using a handheld friction device rather than a stationary probe. This would be desirable for ease of use and accessibility, removing the need for participants to control movement of a body part against the friction rig.

*Experimental Study 2:*

1. The second experimental study in this research focused solely on the frictional interactions within the skin-pad interface, only looking at one pad design. Another important research consideration for protecting the skin is in the advanced design and manufacturing of moisture wicking fabrics, and breathable materials to allow evaporation of water from the environment. Further work could be done in future to build on knowledge of the frictional effects of pads of differing shapes, capacities and material composition.
2. Based on these findings it may be that certain treatments perform well only in a specified set of environmental conditions, therefore it would be work better understanding treatment abilities alongside screening patient lifestyle and anatomy to calculate an appropriate treatment regime.
3. Along with testing the treatments it would be useful to better understand the constituent ingredients of skin treatments to give greater insight into what exact formulations have the best potential to reduce shear and friction. This knowledge would enable more effective treatments

to be developed. Additionally, the way water chemically interacts with the treatments in the interface will be key to frictional performance. A treatment may stay in place on the skin, form an emulsion, transfer to the pad, and make changes to the skin surface. Further research could investigate if any treatments do any harm through actively contributing to undesirable friction interactions to exacerbate IAD.

*Questionnaire:*

1. The results of the questionnaire led to the development of an IAD severity index which was named the 'HIG Severity Index'. This provided a way of categorising respondents into different IAD severity categories based on the frequency, duration, and symptoms of their episodes of IAD. To enable this tool to be used by patients and consumers further work is needed to validate whether the severity categories align with a clinical diagnosis. A suitable plan would most likely be to collaborate with wound care specialists or a dermatology research centre.
2. In the questionnaire participants were asked about skin treatments that they had used, and a large proportion of respondents chose to rate the product *Sudocrem*. As the treatment was clearly identified as a popular consumer product it would be beneficial for more treatments to be tested in future work, such as a variety different, films, and other products which have been identified as being widely used by the public.

Overall, linking a community perspective with better understanding of the parameters that affect the friction interactions between the skin and incontinence pads could improve selection of the most appropriate skin treatments, to target the prevention of skin damage and improve patient and community outcomes.

# Appendix A

A copy of the questionnaire that was released online in the format of a Google Form.

## Section 1: Participant Information Sheet

### Questionnaire Information

This questionnaire is part of a research project being conducted at the University of Sheffield. Incontinence affects hundreds of millions of people worldwide and results from this study will be used to better understand the experiences of people who have incontinence.

There is a consent form on the next page. The project has been approved by the Ethics Committee of the University of Sheffield.

1. Eligibility
- Anyone with incontinence between the ages of 20-80 years old can fill in this questionnaire.
- No formal diagnosis of incontinence is required.

2. Type of questions

The questions are mainly in the format of check boxes, but there is space at the end of the questionnaire for additional comments. No personal data such as data of birth, name or email address will be required. If you find any of the questions uncomfortable or difficult to answer then please skip over these questions.

3. Prize draw

Optional: If you wish to be entered into a prize draw to win £150 in amazon vouchers, please enter your email address at the end of the questionnaire. Your email address will not be linked with any data collected.

4. Is my data confidential?

All data is anonymous and is collected and stored according to university policy.

5. Data protection

According to data protection legislation, we are required to inform you that the legal basis we are applying in order to process your data is, 'processing is necessary for the performance of a task carried out in the public interest', (Article 6(1)(e)). More information on this can be found on the University of Sheffield website under the page GDPR Governance and Management, https://www.sheffield.ac.uk/govern/data-protection/privacy/general

6. Disclaimer

This research is not funded by any product manufacturers and will not be used for any marketing or commercial purposes.

7. Contact information

Project Supervisor: Dr Matt Carré m.j.carre@sheffield.ac.uk
Principal Researcher: Rachel Morecroft r.morecroft@sheffield.ac.uk

Read the information above and then tick below to continue. *

◯ Continue to next section

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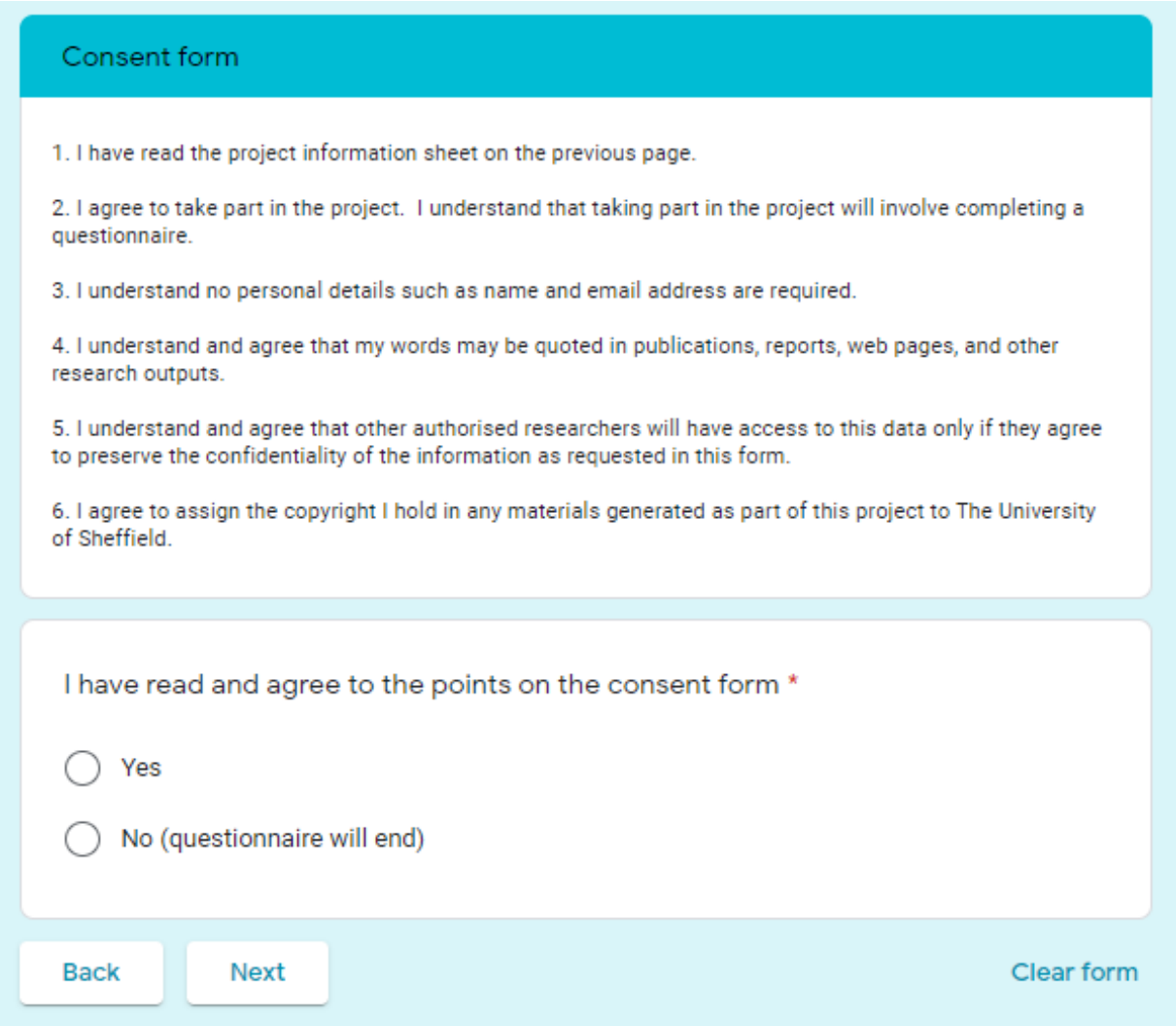
Section 2: Consent Form



Consent form

1. I have read the project information sheet on the previous page.

2. I agree to take part in the project. I understand that taking part in the project will involve completing a questionnaire.

3. I understand no personal details such as name and email address are required.

4. I understand and agree that my words may be quoted in publications, reports, web pages, and other research outputs.

5. I understand and agree that other authorised researchers will have access to this data only if they agree to preserve the confidentiality of the information as requested in this form.

6. I agree to assign the copyright I hold in any materials generated as part of this project to The University of Sheffield.

I have read and agree to the points on the consent form *

Yes

No (questionnaire will end)

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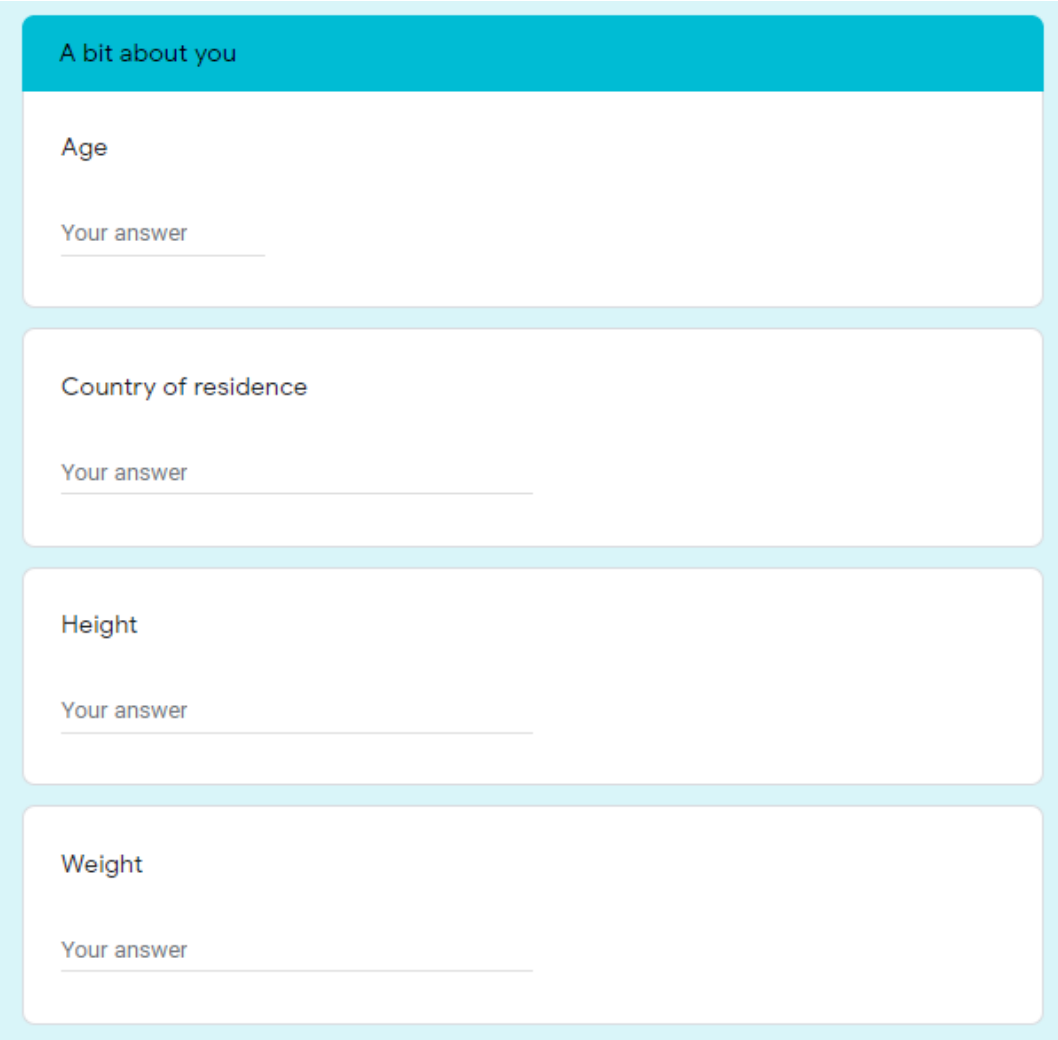
Section 3: Supplementary Data



How would you describe your body type?

- ◯ Underweight
- ◯ Normal weight
- ◯ Overweight
- ◯ Obese
- ◯ Other: _____

Please list any allergies or skin conditions.

Your answer

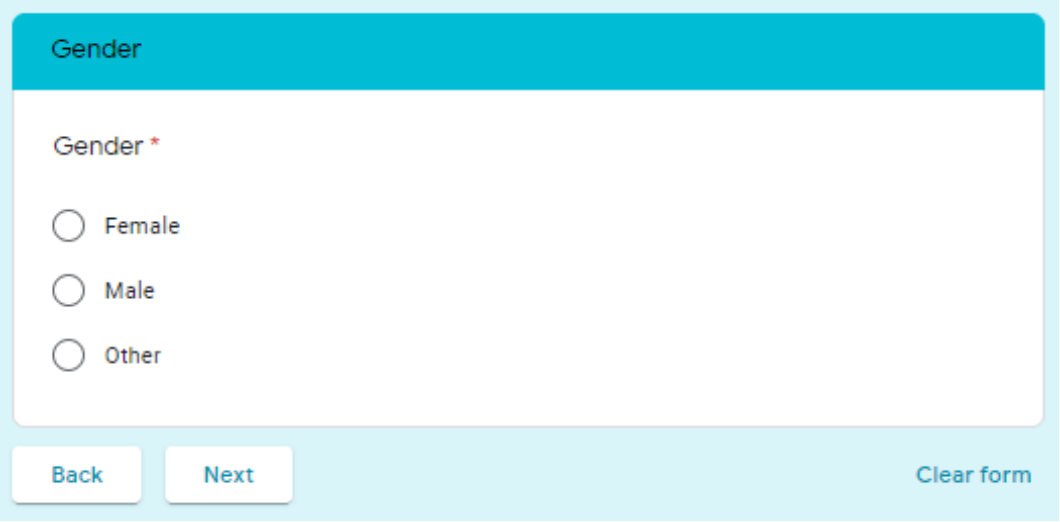
Please list any other medical conditions.

Your answer

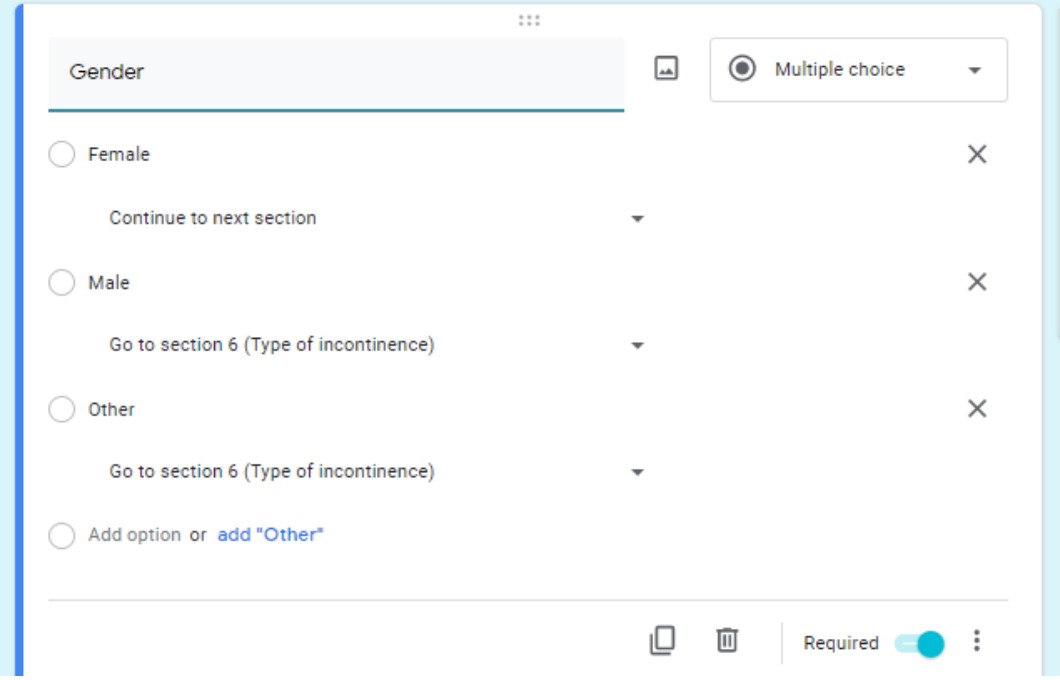
Back Next Clear form

Section 4: Gender

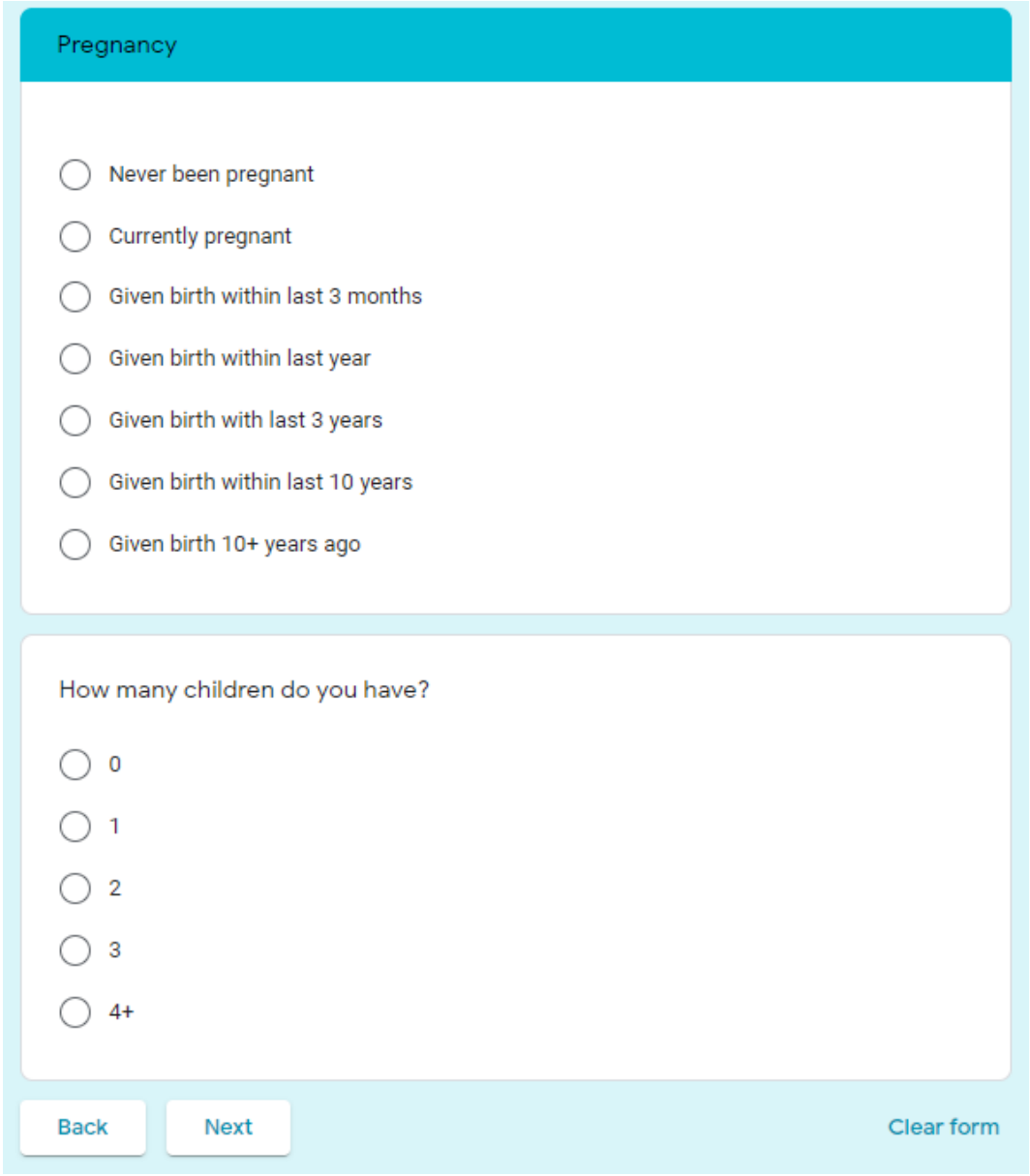
In Section 4 respondents were asked to select their gender, and the answer they provided rerouted the pathway of the questionnaire, so certain sections could be avoided if they were not relevant to the participant. For example, if a respondent selected ‘Female’ from the multiple choice, then they would continue to Section 5 about parity. If the respondent selected ‘Male’ or ‘Other’, then Section 5 would be skipped, and instead the respondent would be redirected to Section 6 to about incontinence.



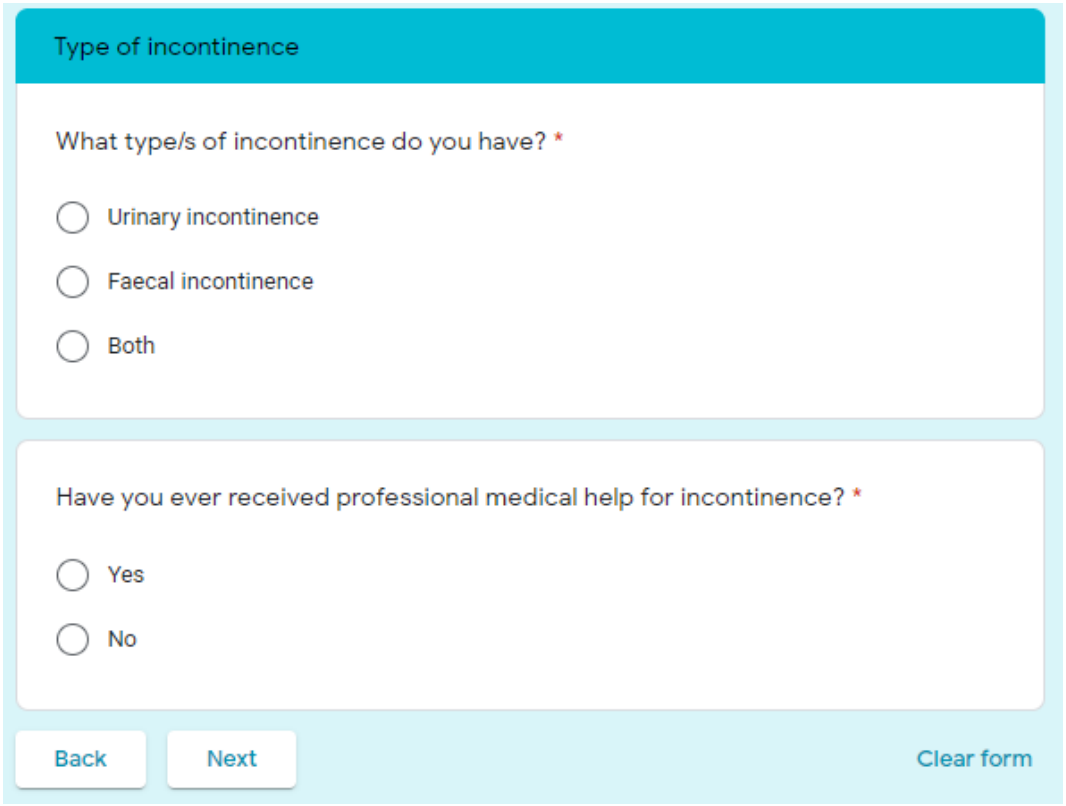

*Questionnaire Builder View:* The questionnaire builder within Google Forms shown below, easily allowed multiple pathways to be integrated. This type of question was used a number of times within the questionnaire, for other examples see Sections 8, 16, and 18.



Section 5: Parity



Section 6: Incontinence



Section 7: Incontinence Severity

## Incontinence

If you do not have urinary incontinence then skip the first two questions on this page.

How often do you experience urinary leakage?

- ◯ Less than once a month
- ◯ A few times a month
- ◯ A few times a week
- ◯ Every day and/or night

How much urine do you leak each time?

- ◯ Drops
- ◯ Small splashes
- ◯ More

How severe would you say your incontinence is?

- ◯ Mild
- ◯ Moderate
- ◯ Severe
- ◯ Very Severe

Does having incontinence have a negative impact on some of the following areas of your life?

| | Yes | Somewhat | No |
|---|---|---|---|
| Visiting friends and family | ○ | ○ | ○ |
| Travelling | ○ | ○ | ○ |
| Participating in sport activities | ○ | ○ | ○ |
| Financial burden | ○ | ○ | ○ |
| Emotionally | ○ | ○ | ○ |
| Work | ○ | ○ | ○ |
| Day-to-day tasks | ○ | ○ | ○ |
| Sleep quality | ○ | ○ | ○ |

Where do you access incontinence help and information? (Tick all that apply)

- [ ] Charities
- [ ] Continence nurse practitioners
- [ ] Friends/family
- [ ] GP
- [ ] Other medical professionals
- [ ] Online forums
- [ ] Online searches
- [ ] Support group (in person)
- [ ] Support group (online)
- [ ] Other: _____

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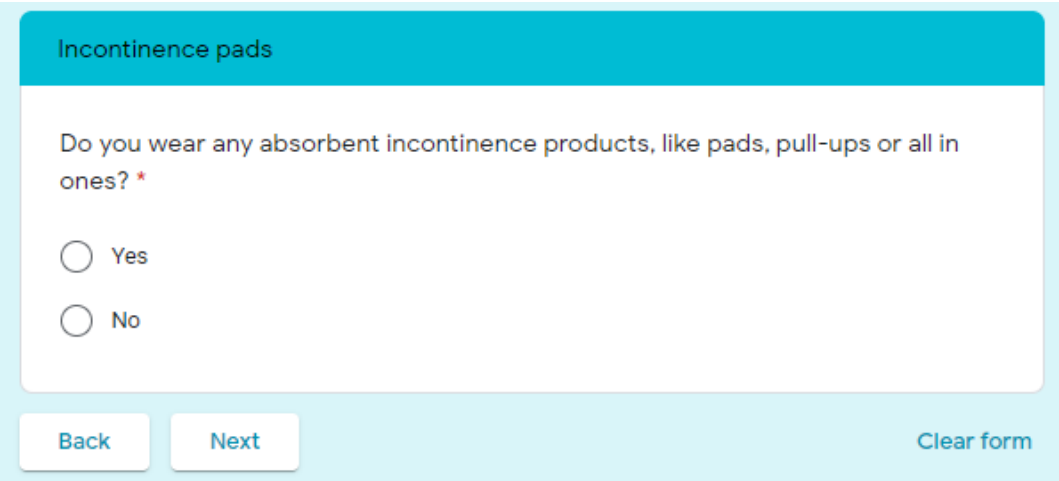
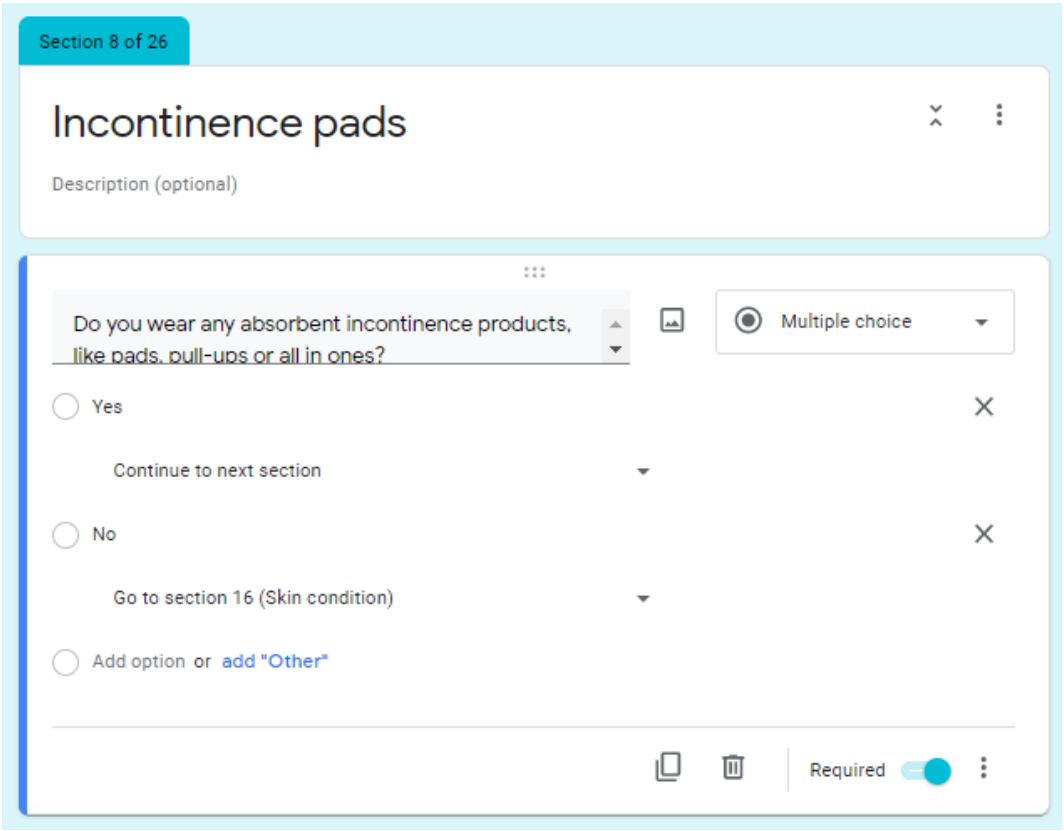
Section 8: Absorbent Product Use




*Questionnaire Builder View: Showing Multiple Pathways Based on the Answer Selected.*



Section 9: Absorbent Product Use

Incontinence pads

How often do you wear incontinence pads/pull-ups/all in ones?

- ◯ Less than once per month
- ◯ A few times a month
- ◯ A few times a week
- ◯ Every day and/or night

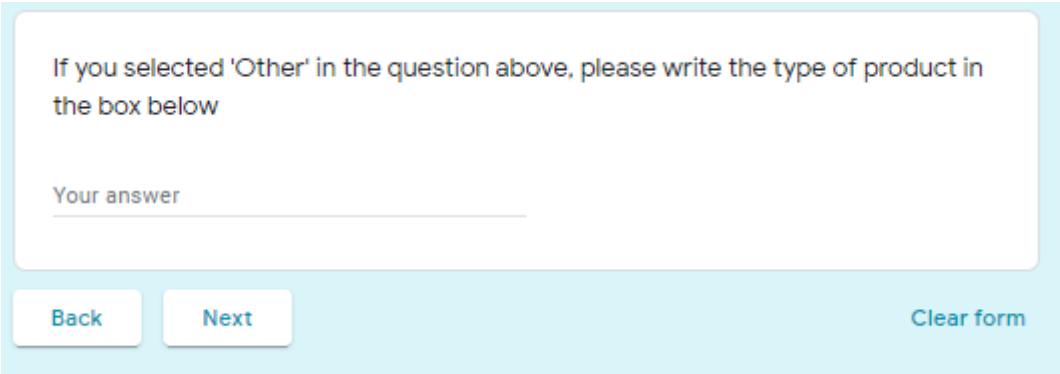
What type of products do you use?

☐ All in ones

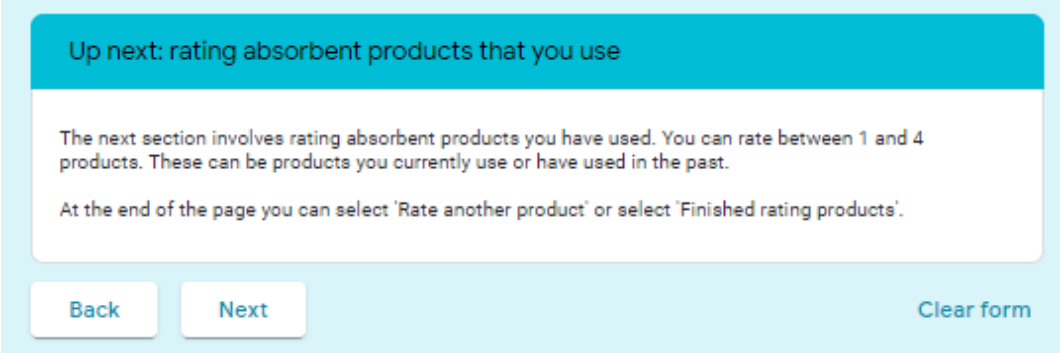
☐ Pads

☐ Pull-ups

☐ Other




Section 10: Information about upcoming section



Section 11: Absorbent Product Rating

## Product 1 Questions

Disclaimer: This research is not funded by any product manufacturers and will not be used for any marketing or commercial purposes.

Product name and brand

Your answer

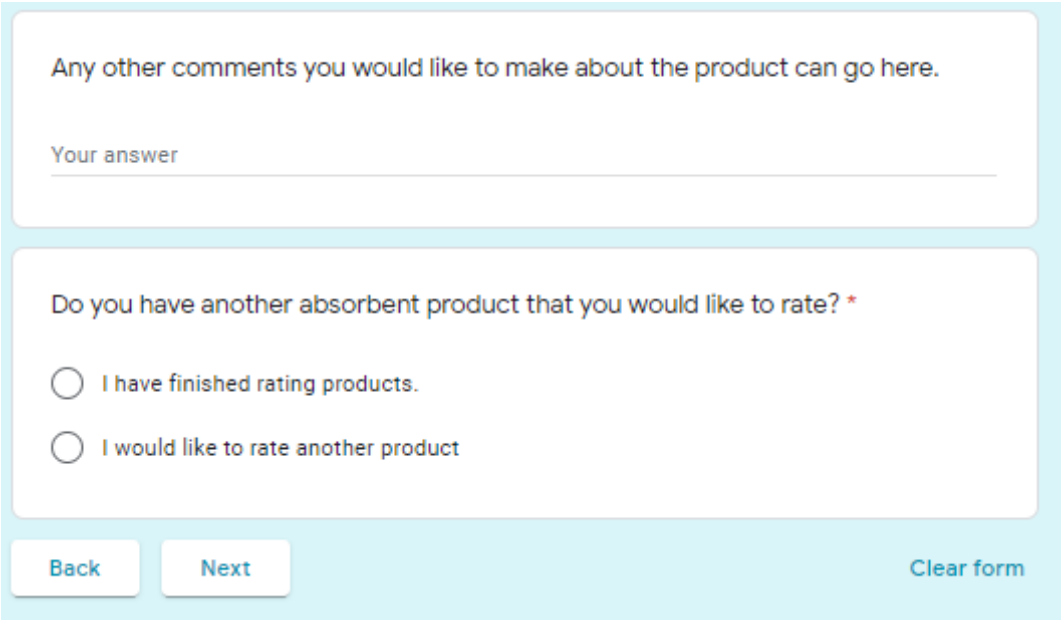
Questions about the pad/product

| | Disagree | Slightly disagree | Neither agree nor disagree | Slightly agree | Agree |
|---|---|---|---|---|---|
| It is comfortable | ○ | ○ | ○ | ○ | ○ |
| It keeps my skin dry | ○ | ○ | ○ | ○ | ○ |
| It is breathable | ○ | ○ | ○ | ○ | ○ |
| It bunches up | ○ | ○ | ○ | ○ | ○ |
| It leaks | ○ | ○ | ○ | ○ | ○ |
| It rubs my skin | ○ | ○ | ○ | ○ | ○ |
| It makes my skin sweaty | ○ | ○ | ○ | ○ | ○ |

If you selected 'Other' in the question above, please write the type of product in the box below

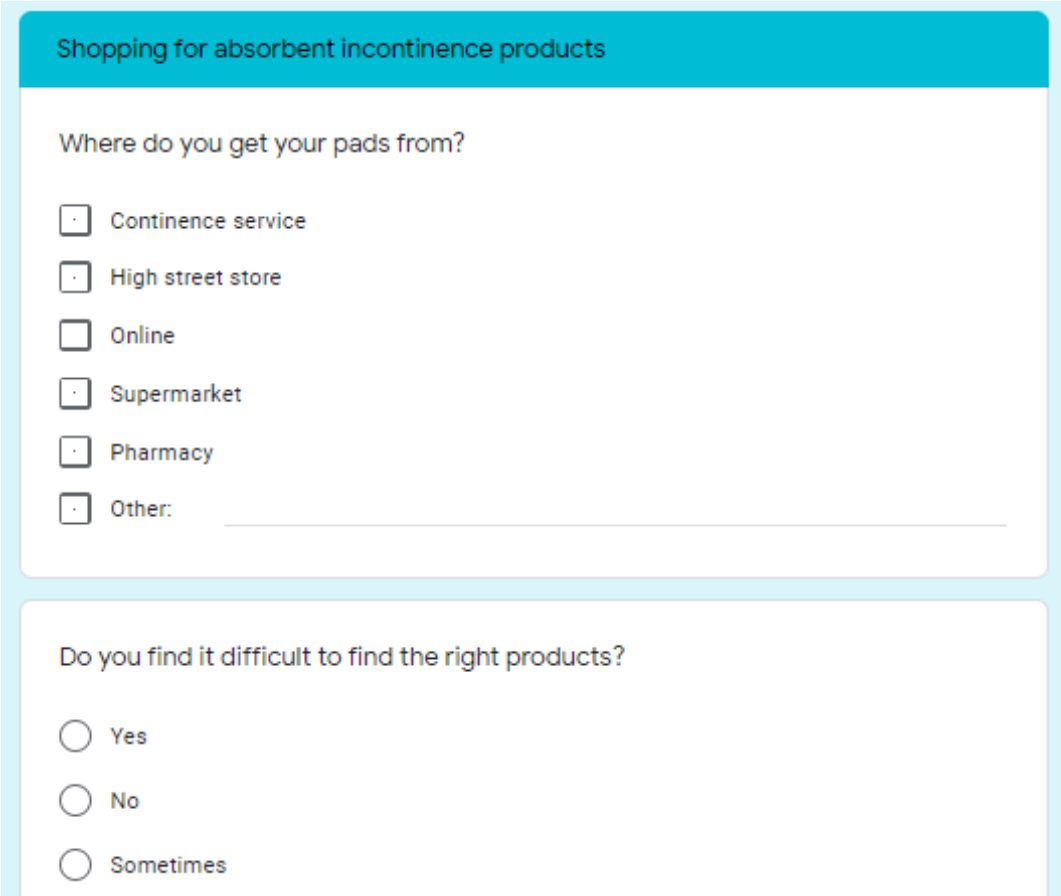
Your answer

Back Next Clear form




If a respondent chose to rate another product, then the questionnaire would take them onwards to Section 12. People could rate up to a maximum of four absorbent products between Sections 11-14. Therefore, following rating their products respondents were directed to Section 15 – 'Consumer Absorbent Product Sourcing'.

Section 15: Consumer Absorbent Product Sourcing

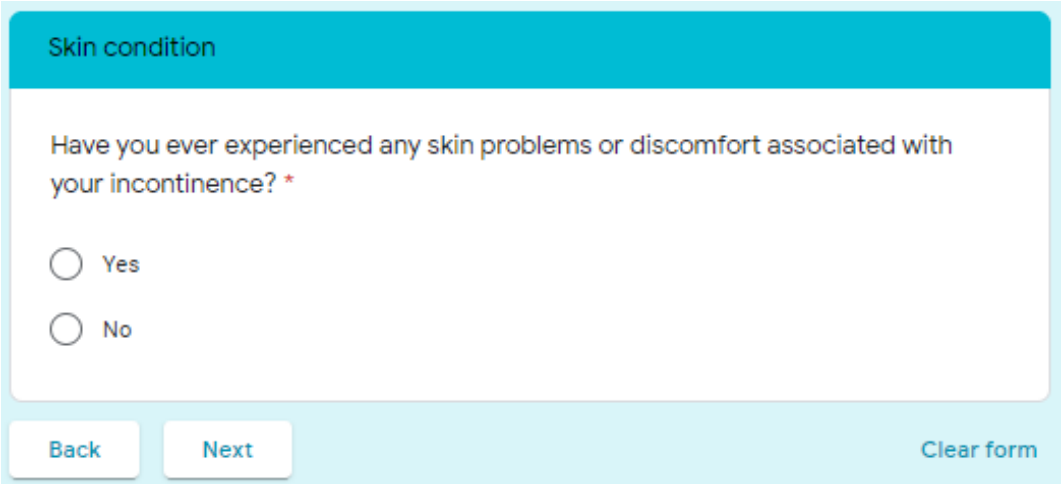


If you answered 'Yes' in the question above, in your experience why have you found it difficult to get absorbent products?

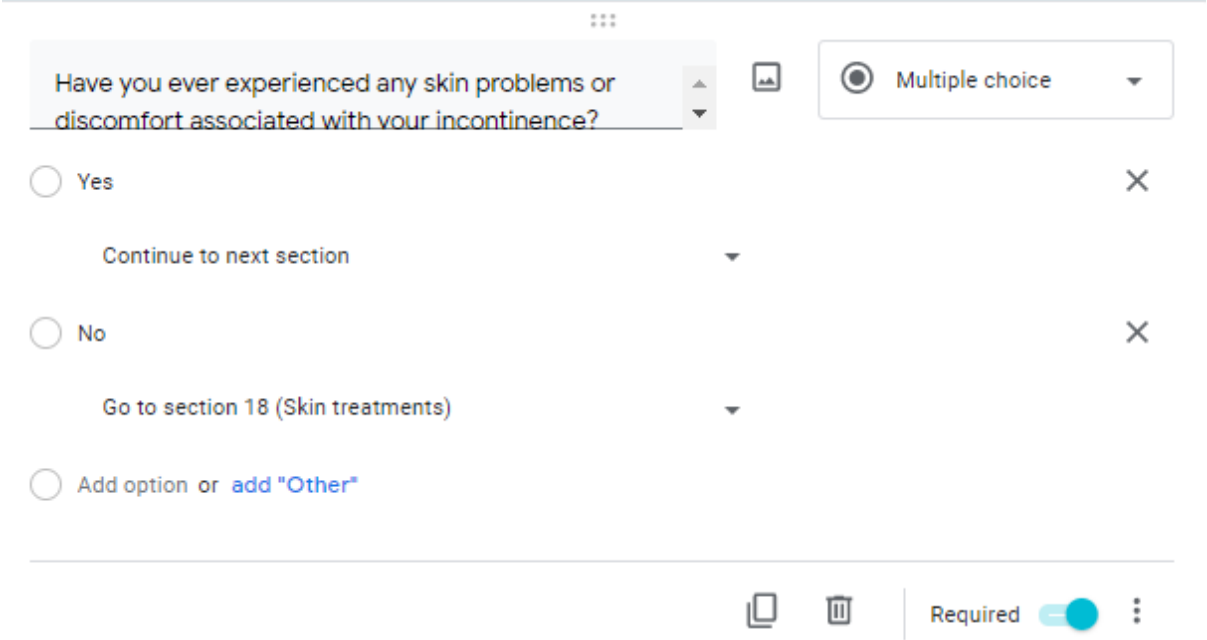
- [ ] Contradicting information and advice
- [ ] Cost of products
- [ ] Finding right products is a guessing game
- [ ] Lack of ability to get medical help
- [ ] Lack of information when seeking medical help
- [ ] Lack of guidelines
- [ ] Lack of marketing
- [ ] Lack of online reviews
- [ ] Lack of samples
- [ ] Products are medically restricted e.g. only one type of pad allocated
- [ ] Other: _____

Back Next Clear form

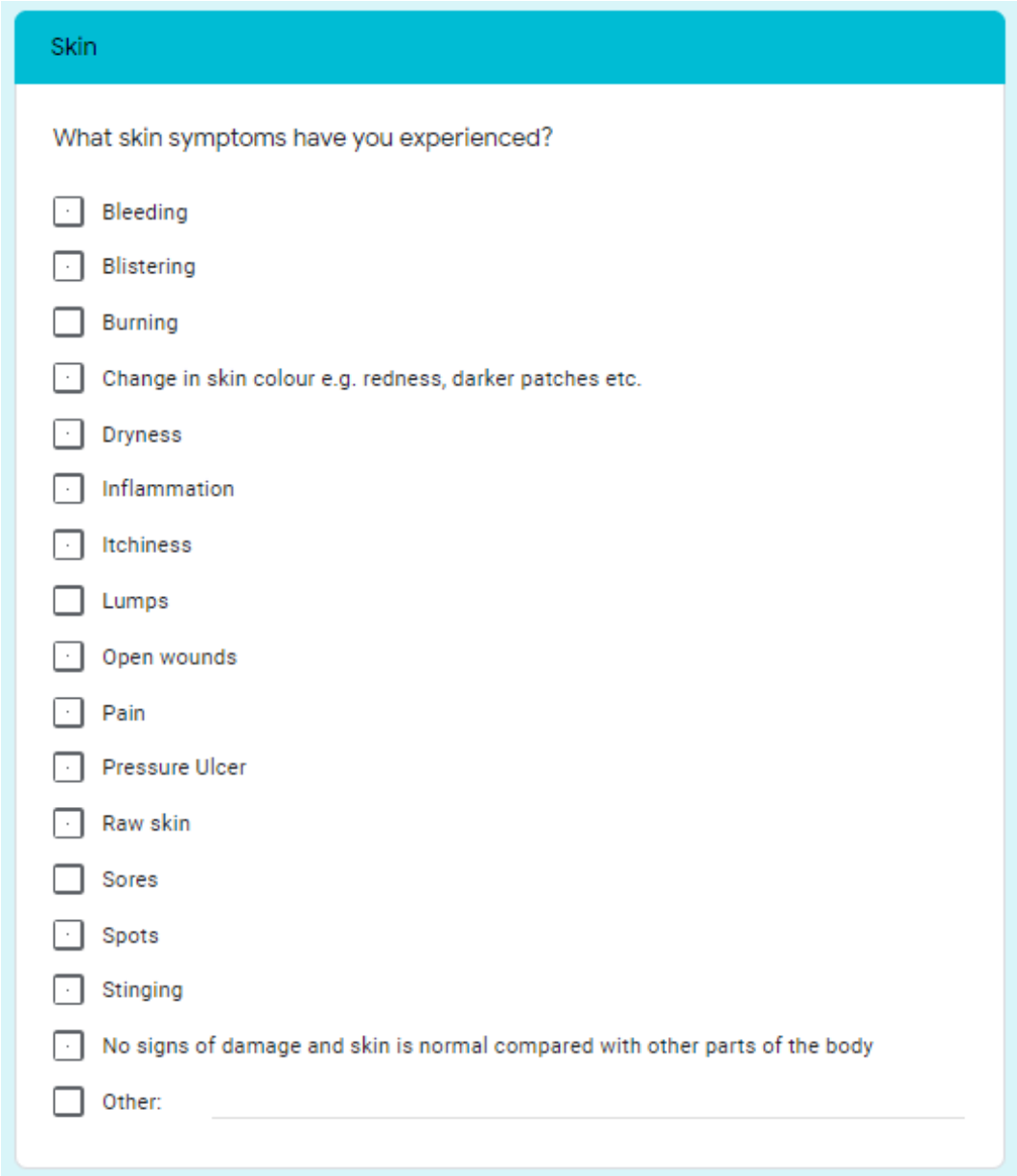
Section 16: Incontinence Associated Dermatitis




*Questionnaire Builder View: Showing Multiple Pathways Based on the Answer Selected.*



Section 17: Incontinence Associated Dermatitis Symptoms and Severity



Skin

What skin symptoms have you experienced?

- [ ] Bleeding
- [ ] Blistering
- [ ] Burning
- [ ] Change in skin colour e.g. redness, darker patches etc.
- [ ] Dryness
- [ ] Inflammation
- [ ] Itchiness
- [ ] Lumps
- [ ] Open wounds
- [ ] Pain
- [ ] Pressure Ulcer
- [ ] Raw skin
- [ ] Sores
- [ ] Spots
- [ ] Stinging
- [ ] No signs of damage and skin is normal compared with other parts of the body
- [ ] Other: _____

What one region of the body is most often affected?

Select from the drop down list

Choose

Choose

Buttocks

Groin

Groove between buttocks

Inner thighs

Labia

Lower abdomen

Lower back

Penis

Perineum

Scrotum

How often do you experience skin problems or discomfort associated with incontinence?

- ◯ Once or twice a year
- ◯ A few times a year
- ◯ Approximately once a month
- ◯ A couple of times a month
- ◯ Every week
- ◯ Other: _____

When you get sore skin, how long does it take to recover and heal?

- ◯ Within 3 days
- ◯ Within 1 week
- ◯ 1-2 weeks
- ◯ More than 2 weeks
- ◯ It never properly heals
- ◯ Other: _____

Have you ever sought medical help for your incontinence-associated skin damage?

- ◯ Yes
- ◯ No

Have you ever used medically prescribed products for these skin issues?

- ◯ Yes
- ◯ No

Have you ever had a pressure ulcer related to incontinence?

- ◯ Yes
- ◯ No

If known, choose the contact surface which causes skin problems to occur. Tick all that apply

- ☐ Skin on skin
- ☐ Pad on skin (or other absorbent product)
- ☐ Standard catheter on skin
- ☐ Sheath catheter on skin
- ☐ Underwear on skin
- ☐ Other clothing on skin
- ☐ Don't know
- ☐ Other: _____

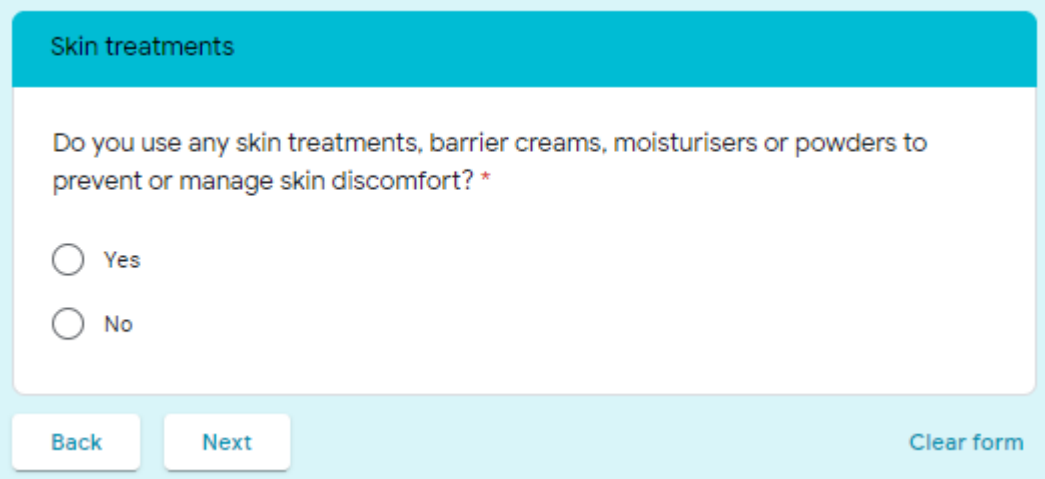
Do you think any of the following contribute to your skin problems?

Please tick all that apply

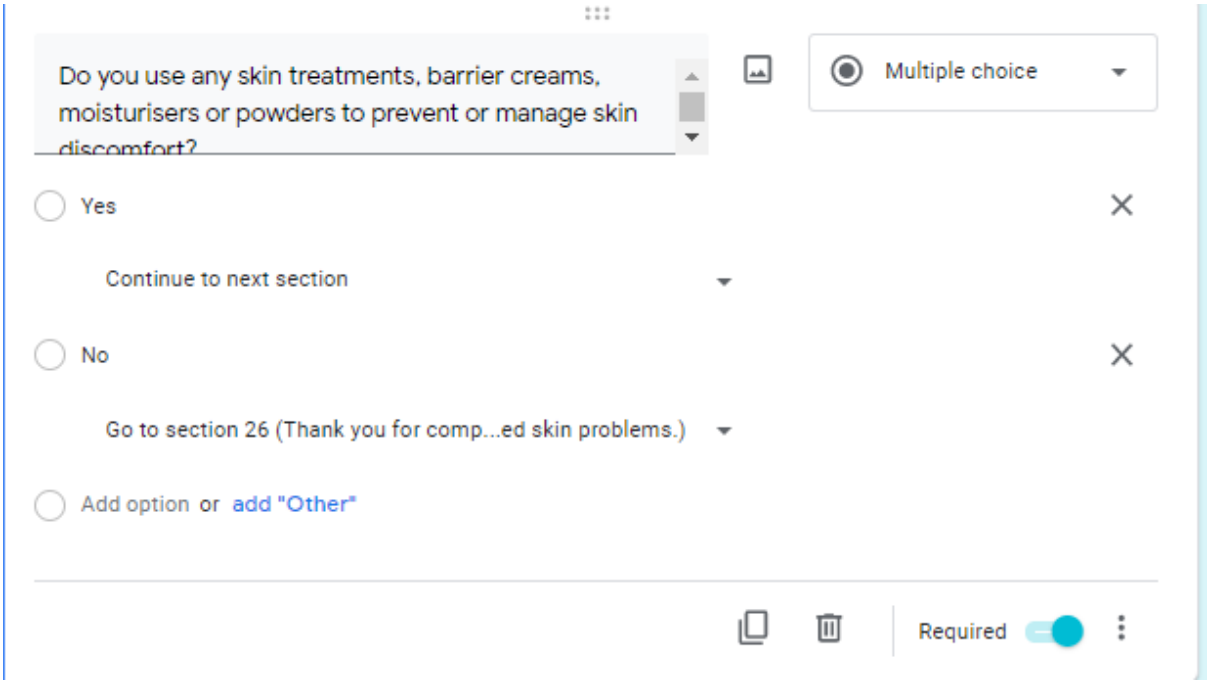
- [ ] Being unable to change garments or pads at regular intervals or soon after an episode
- [ ] Particular activities e.g. walking, sports etc.
- [ ] Particular brand of skin treatment
- [ ] Particular clothing
- [ ] Pad leaks
- [ ] Pad not always large enough for amount of urine
- [ ] Pad not breathable enough
- [ ] Pad too loose
- [ ] Pad too tight
- [ ] Pad rubs
- [ ] Particular type or brand of pad
- [ ] Sitting for long periods of time
- [ ] Sleeping in pad
- [ ] Other: _____

Back Next Clear form

Section 18: Skin Treatments




*Questionnaire Builder View: Showing Multiple Pathways Based on the Answer Selected.*




Section 22: Skin Treatment Usage

## Treatments

Please tick which products you have used to try to treat any incontinence-associated skin problems. If products are not shown below then please list them in the 'Other' box.

Note: The products listed here may not be appropriate for your use

Disclaimer: This research is not funded by any product manufacturers and will not be used for any marketing or commercial purposes.

Select from the drop-down menu your preferred product.

Choose

If the name of your preferred product is not in the drop-down menu, please write the name below.

Your answer

Select from the drop-down menu your least preferred product.

Choose

If the name of your least preferred product is not in the drop-down menu, please write the name below.

Your answer

Participants were asked to tick any of the skin products that they had used before. Treatments were listed with treatment names alongside images, as shown below. In total there were 36 products to choose from, plus an 'Other' box.

Please tick which skin products you have used before

Abeena Zinc Oxide Spray

Abeena Zinc Ointment


Aloe vera


Aqueous Cream

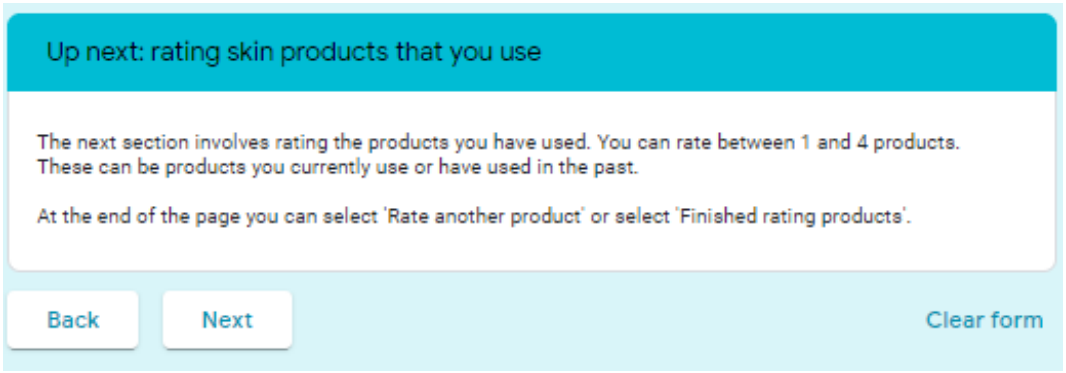

Attends Profession Care Care-Cream


Bepanthen

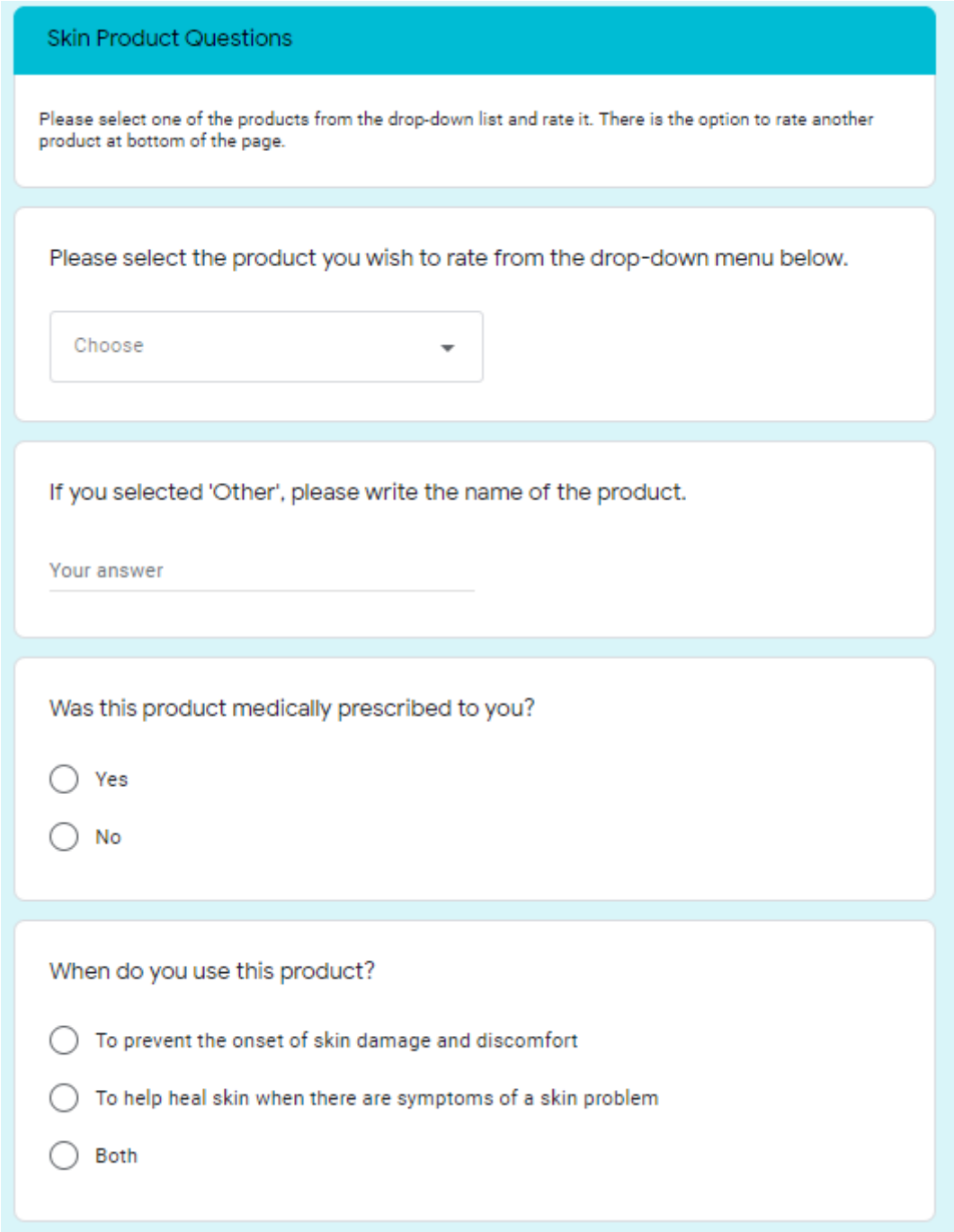

Cavilon Barrier Cream


Cavilon No-Sting Barrier Film

Section 23: Information about upcoming section



Section 24: Skin Treatment Rating



Skin Product Questions

Please select one of the products from the drop-down list and rate it. There is the option to rate another product at bottom of the page.

Please select the product you wish to rate from the drop-down menu below.

Choose

If you selected 'Other', please write the name of the product.

Your answer

Was this product medically prescribed to you?

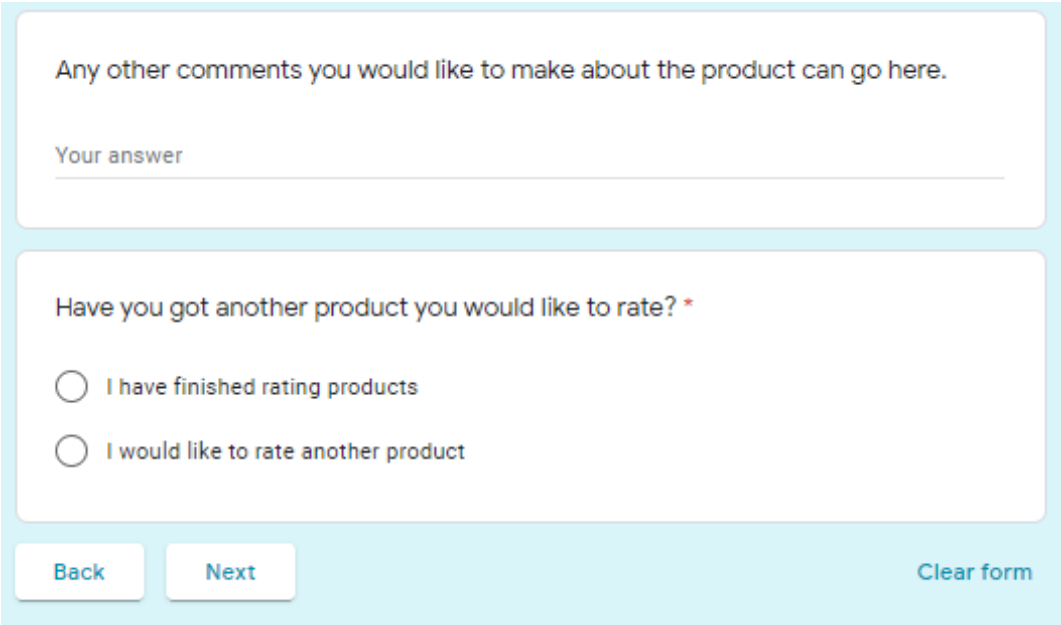
- Yes
- No

When do you use this product?

- To prevent the onset of skin damage and discomfort
- To help heal skin when there are symptoms of a skin problem
- Both

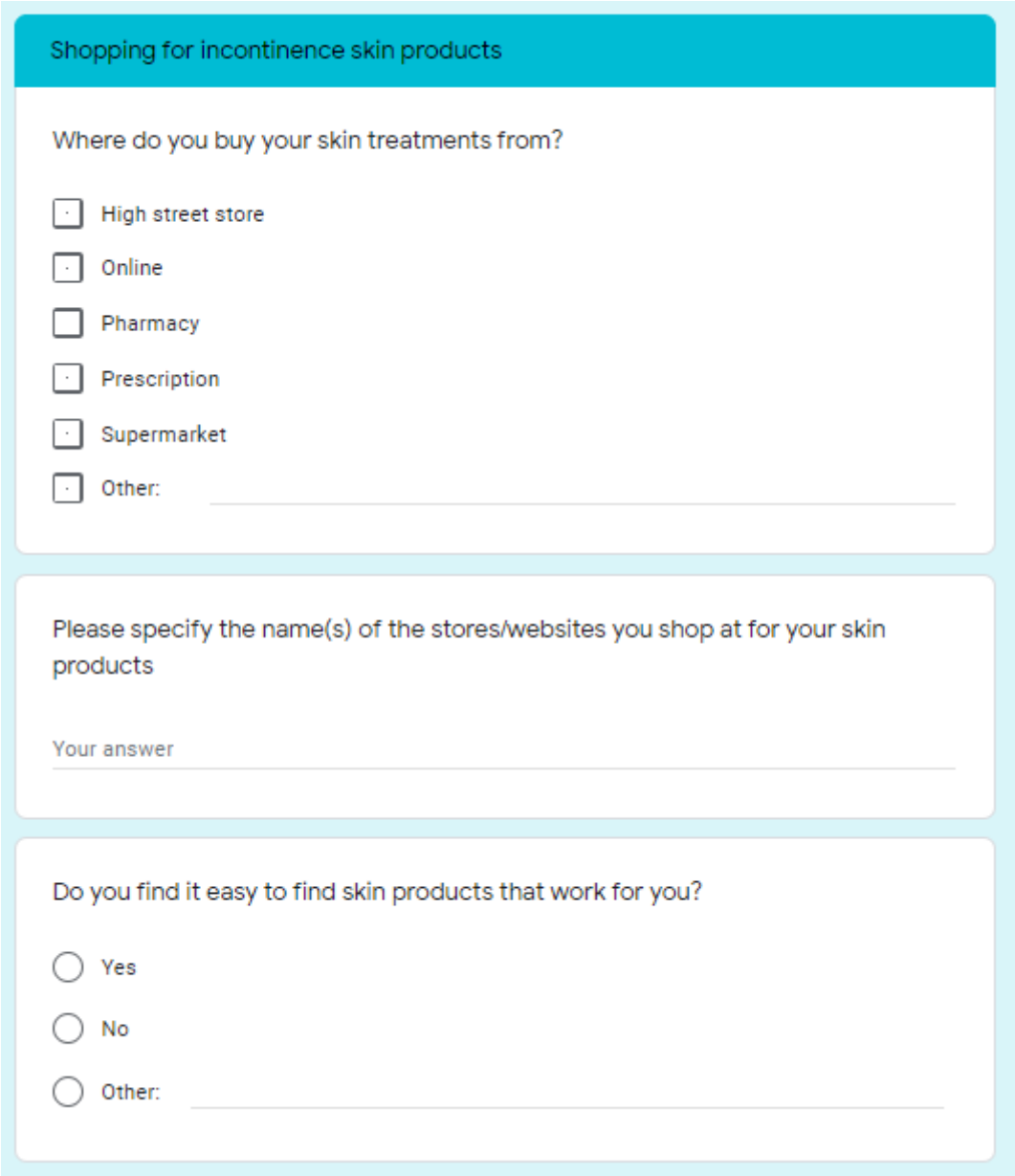
Please select how you feel about these statements relating to the product

| | Disagree | Slightly disagree | Neither agree nor disagree | Slightly agree | Agree |
|---|---|---|---|---|---|
| Reduces redness | ◯ | ◯ | ◯ | ◯ | ◯ |
| Easy to apply | ◯ | ◯ | ◯ | ◯ | ◯ |
| Helps skin to heal | ◯ | ◯ | ◯ | ◯ | ◯ |
| Dries quickly on skin | ◯ | ◯ | ◯ | ◯ | ◯ |
| Stings when applied | ◯ | ◯ | ◯ | ◯ | ◯ |
| Feels sticky | ◯ | ◯ | ◯ | ◯ | ◯ |
| Product is too thick | ◯ | ◯ | ◯ | ◯ | ◯ |
| Product ends up on pad/clothes | ◯ | ◯ | ◯ | ◯ | ◯ |
| Reduces pain and discomfort | ◯ | ◯ | ◯ | ◯ | ◯ |
| I would recommend this product | ◯ | ◯ | ◯ | ◯ | ◯ |




If a respondent chose to rate another product, then the questionnaire would take them onwards to Section 12. People could rate up to a maximum of four skin treatments between Sections 24-27. Therefore, following rating their skin treatments respondents were directed to Section 28 – 'Sourcing of Skin Treatments for Consumers'.

Section 28: Sourcing of Skin Treatments for Consumers



Shopping for incontinence skin products

Where do you buy your skin treatments from?

- [ ] High street store
- [ ] Online
- [ ] Pharmacy
- [ ] Prescription
- [ ] Supermarket
- [ ] Other:

Please specify the name(s) of the stores/websites you shop at for your skin products

Your answer

Do you find it easy to find skin products that work for you?

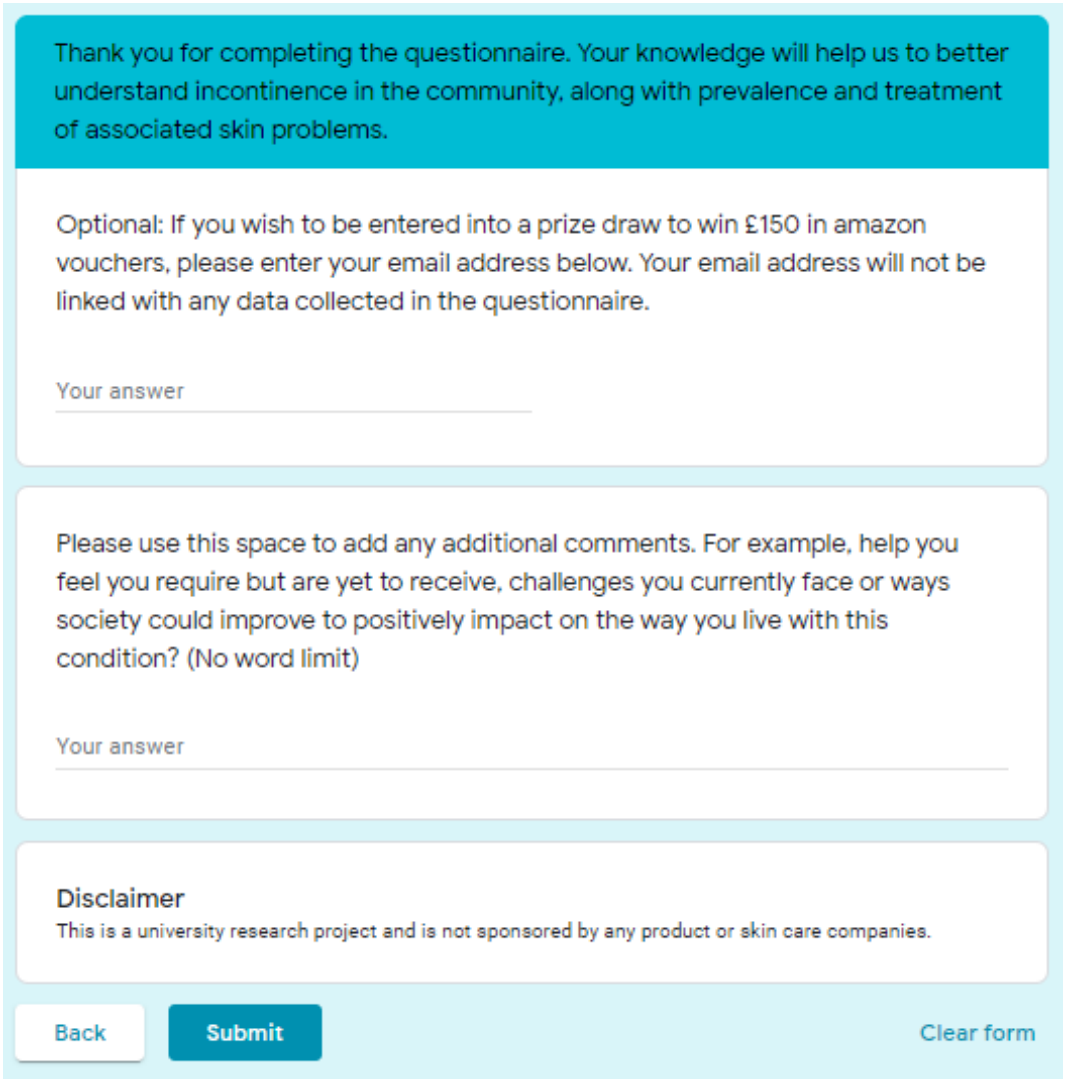
- ( ) Yes
- ( ) No
- ( ) Other:

If you have some difficulty finding products please tick from the reasons below.

- [ ] Contradicting information
- [ ] Lack of samples
- [ ] Cost of products
- [ ] Lack of online reviews
- [ ] It is a guessing game to find right products
- [ ] Lack of ability to get medical help
- [ ] Lack of information when seeking medical help
- [ ] Lack of marketing
- [ ] Restriction of products available on prescription
- [ ] Lack of guidelines
- [ ] Other: _____

Back Next Clear form

Section 29: Ending Statement



# Appendix B



## Appendix B: Skin Treatment Information

Descriptions of the treatments used in the experimental studies are detailed below, alongside the active ingredients of each product.

1. Glycerol 10% in deionised water

*Active ingredients:*
Glycerol

*Category of treatment:*
Humectant

*Description*:
Glycerol is a common humectant used to improve skin hydration and cutaneous elasticity, and offers improved barrier repair. It is well proven in being an effective treatment for xerosis when used in combination with occlusives [1] because they work in conjunction to increase the capacity of the skin to hold water so that the moisture that has been hydophilically attracted into the upper skin layers can then be trapped and preserved in the skin by the occlusive agent, rather than being lost through transepidermal water loss. Humectants are usually present within the top five ingredients of a treatments ingredients list, meaning that they make up a greater proportion of the treatment. Other humectants that are used in skin treatments include hyaluronic acid, glycolic acid, and urea.

2. Vaseline

*Active ingredients:*
Hydrocarbons.

*Category of treatment:*
Occlusive moisturiser

*Description*:
*Vaseline* also known as petrolatum or petroleum jelly, serves a protective function due to the hydrophobic lipid layer which prevents dehydration. Occlusive moisturisers can prevent or reduce transepidermal water loss from the skin by forming a barrier which allows replenishment of the water

content of the stratum corneum by the deeper layers of the epidermis and dermis. Petrolatum is the classic example of an occlusive moisturiser, and it has been found to reduce water loss through the epidermis by nearly 99% [2]. It is a common ingredient in many lotions, creams, and body washes, and it also forms a barrier to protect from moisture and other contaminants from contacting the skin, making it suitable for milder forms of incontinence-associated dermatitis [3].

## 3. Cavilon Barrier Cream

*Active ingredients*:
Dimethicone 1.3%, Acrylate Terpolymer, Diisooctyl Adipate, Coconut oil, Mineral oil, Glycerin/Glycerol, and Paraffin.

*Category of treatment:*
Emollient

*Description*:
The product descriptions below for *Cavilon* have been quoted from the treatment manufacturer (*3M*), and an online retailer of the product:

- '*Cavilon Durable Barrier Cream* provides long-lasting protection of the skin from bodily fluids, and also acts as a moisturiser/emollient. The protective barrier is provided by 1.3% dimethicone and acrylate terpolymer. Together they form a thin, durable, protective film on the skin, which can be used to prevent breakdown of intact skin. It is highly concentrated and should be applied in smaller amounts than traditional barrier creams' [5].
- 'The cream will not transfer to underwear or incontinence pads, and is resistant to washing off, eliminating the need for frequent reapplication. Unusually for a cream, it allows tapes and dressings to adhere and, as with all Cavilon skin care products, it has been tested for hypoallergenicity' [5].
- 'If you suffer from incontinence the chances are you also suffer (or are at risk from) incontinence-associated dermatitis – a condition that can make every movement distressing and painful because your skin is sore. *Cavilon Barrier Cream* has been specially formulated to create a barrier to protect your skin from urine and faeces while also moisturising the affected area. Which means an end to painful movement and the beginning of the life you want to lead' [6].
- *Cavilon* was found to provide moisture barrier effectiveness, over three other dimethicone products [7], and the formulation of *Cavilon* contains far more oils than *Sorbader*m [8]. Figure B.1 shows the mechanism by which *Cavilon* is reported to work, as stated by the treatment manufacturer *3M* [9].

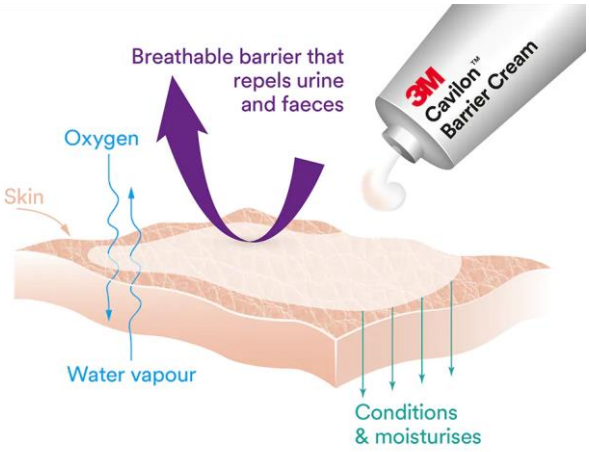



*Figure B.1 - Mechanism of how Cavilon achieves its role as a barrier protection product. Image taken from [9]*

4. Sorbaderm Barrier Cream

*Active ingredients:*

Ethylhexyl Isononanoate, Disiloxane, Acrylate Copolymer, Butylene Glycol, and Allantoin.

*Category of treatment:*

Emollient

*Description*:

The *Sorbaderm Barrier Cream* product sheet contains the following product description: '*Sorbaderm Barrier Cream* is a white concentrated cream that provides the skin with protection from bodily fluids. It also protects dry, chafed, red, or irritated skin by moisturising the skin and providing a long lasting barrier. Use of this cream still allows adhesive products to stick to the skin' [10].

5. Sorbaderm Barrier Spray

*Active ingredients:*

Hexamethyldisiloxane, isooctane, acrylate terpolymer, and polyphenylmethylsiloxane.

*Category of treatment:*

Emollient Spray

*Description*:

Sorbaderm Barrier Spray is 'a polymeric solution which forms a uniform film when applied to the skin. It is a non stinging solvent, transparent and vapour permeable. It is intended for external use as a film forming product that upon application to intact or damaged skin forms a long lasting waterproof barrier.

Acts as a protective interface between skin and bodily fluids, adhesive products and friction' [11]. The clinical applications are for incontinence-associated dermatitis, peristomal skin, and protecting the skin against adhesive trauma [12].

# Appendix C

Friction Profiles from the Chapter 7 Skin-Pad Study

The coefficient of friction profiles for all participants (P1-P8) under the different experimental conditions are shown in Figures C.1 - C.8. These include all different treatments, untreated skin, and wet and dry conditions. All figures are for loading conditions of 3N.

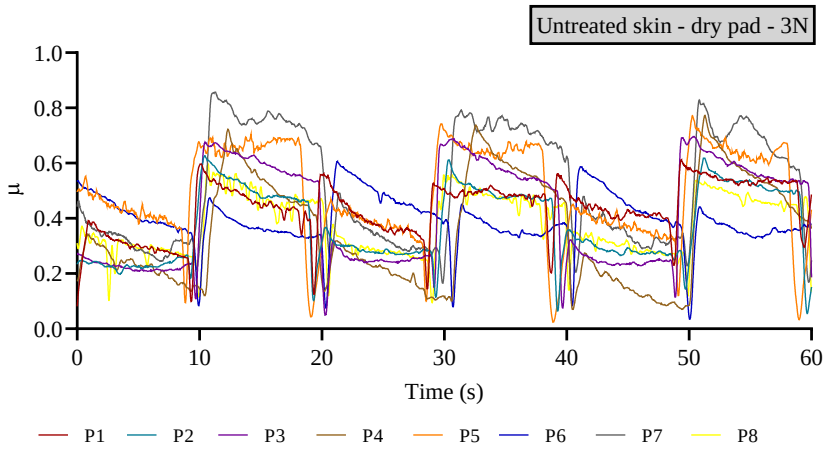



*Figure C.1 - Coefficient of Friction profile for P1-P8 with a dry-pad and an untreated forearm, profile shows the 12 slides over 120 seconds.*

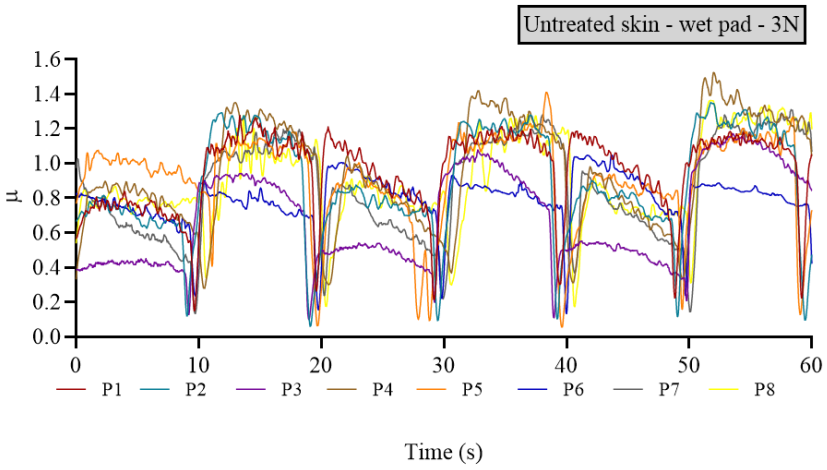



*Figure C.2 - Coefficient of Friction profile for P1-P8 with a wet-pad and an untreated forearm, profile shows the 12 slides over 120 seconds.*

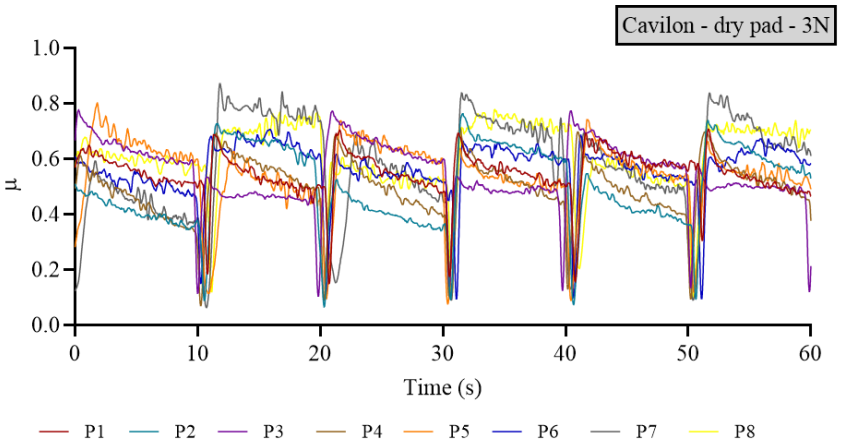



*Figure C.3 - Coefficient of Friction profile for P1-P8 with a dry-pad and Cavilon applied to the forearm, profile shows the 12 slides over 120 seconds.*

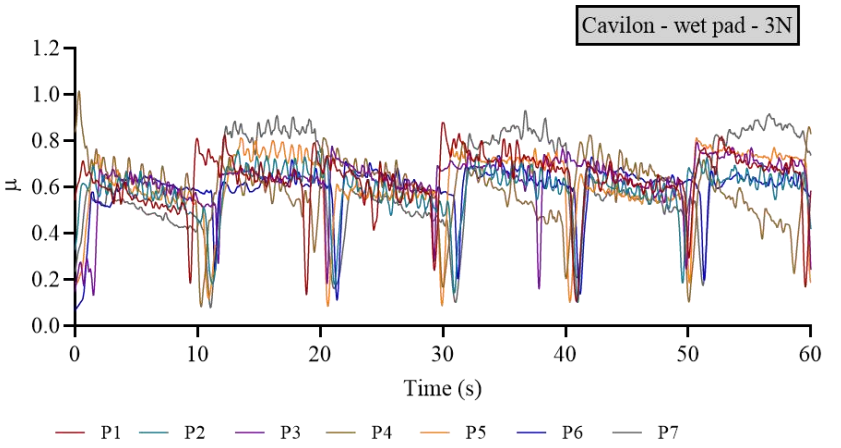



*Figure C.4 - Coefficient of Friction profile for P1-P8 with a wet-pad and Cavilon applied to the forearm, profile shows the 12 slides over 120 seconds.*

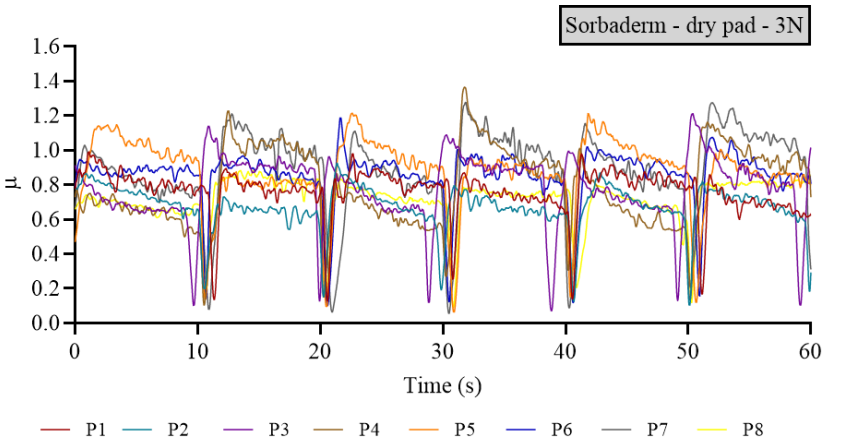



*Figure C.5 - Coefficient of Friction profile for P1-P8 with a dry-pad and Sorbaderm applied to the forearm, profile shows the 12 slides over 120 seconds.*

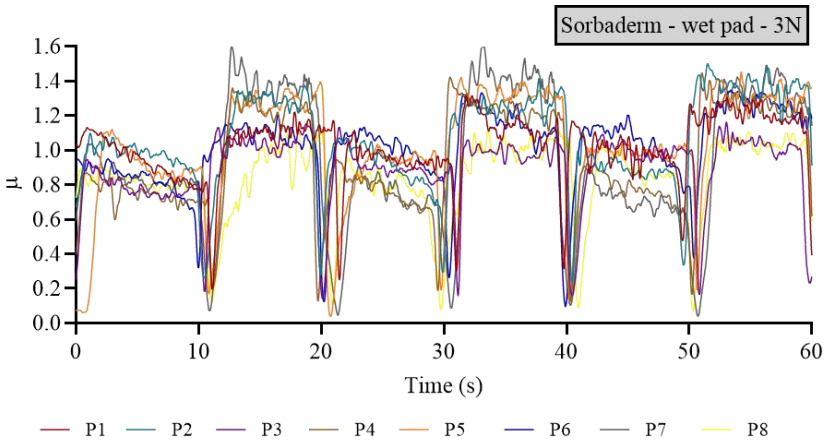



*Figure C.6 -: Coefficient of Friction profile for P1-P8 with a wet-pad and Sorbaderm applied to the forearm, profile shows the 12 slides over 120 seconds.*

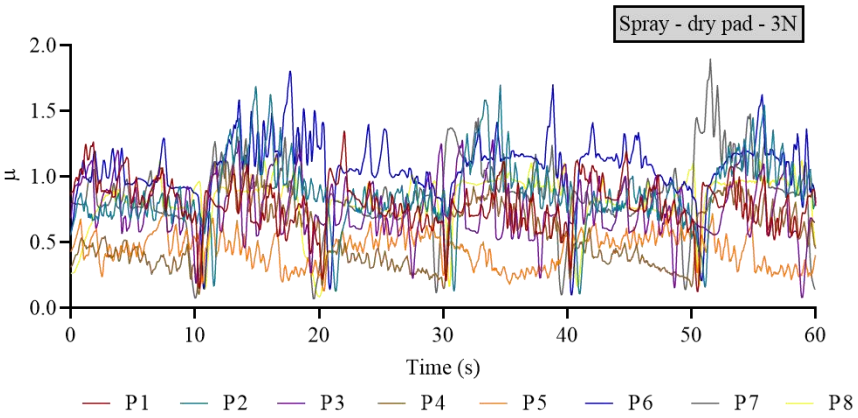



*Figure C.7 - Coefficient of Friction profile for P1-P8 with a dry-pad and spray applied to the forearm, profile shows the 12 slides over 120 seconds.*

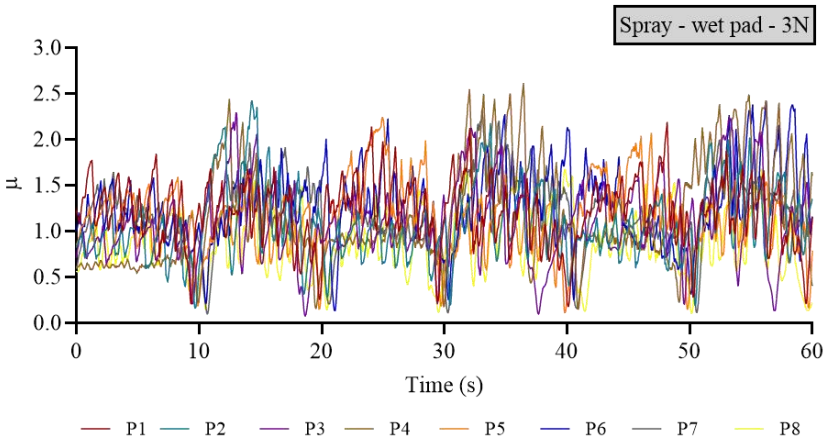



*Figure C.8 - Coefficient of Friction profile for P1-P8 with a wet-pad and spray applied to the forearm, profile shows the 12 slides over 120 seconds.*

# Appendix D

Ethics Applications

The University Of Sheffield.

Downloaded: 23/02/2016
Approved: 15/02/2016

Raman Maiti
Infection and Immunity

Dear Raman

**PROJECT TITLE:** Investigation on the properties of the skin using mechanical and skin characteristic systems
**APPLICATION:** Reference Number 007424

On behalf of the University ethics reviewers who reviewed your project, I am pleased to inform you that on 15/02/2016 the above-named project was **approved** on ethics grounds, on the basis that you will adhere to the following documentation that you submitted for ethics review:

- University research ethics application form 007424 (dated 06/02/2016).
- Participant information sheet 1015207 version 1 (06/02/2016).
- Participant information sheet 1014814 version 3 (06/02/2016).
- Participant consent form 1015208 version 1 (06/02/2016).
- Participant consent form 1014810 version 2 (06/02/2016).

The following optional amendments were suggested:

*The PIS needs the name of the study on it. The PIS and consent forms need dates and version numbers added as a footer / header.*

If during the course of the project you need to deviate significantly from the above-approved documentation please inform me since written approval will be required.

Yours sincerely

Paula Blackwell
Ethics Administrator
Medical School

The University Of Sheffield.

Downloaded: 10/02/2020
Approved: 14/11/2019

Rachel Morecroft
Registration number: 160266799
Mechanical Engineering
Programme: PhD research

Dear Rachel

**PROJECT TITLE:** Interviews and questionnaire to assess prevalence of skin discomfort and damage in people with incontinence in a community-based cohort
**APPLICATION:** Reference Number 031334

On behalf of the University ethics reviewers who reviewed your project, I am pleased to inform you that on 14/11/2019 the above-named project was **approved** on ethics grounds, on the basis that you will adhere to the following documentation that you submitted for ethics review:

- University research ethics application form 031334 (form submission date: 05/11/2019); (expected project end date: 01/06/2021).
- Participant information sheet 1071576 version 1 (22/10/2019).
- Participant information sheet 1071575 version 1 (22/10/2019).
- Participant consent form 1071579 version 1 (22/10/2019).
- Participant consent form 1071578 version 1 (22/10/2019).

If during the course of the project you need to deviate significantly from the above-approved documentation please inform me since written approval will be required.

Your responsibilities in delivering this research project are set out at the end of this letter.

Yours sincerely

Jennifer Rowson
Ethics Administrator
Mechanical Engineering

Please note the following responsibilities of the researcher in delivering the research project:

- The project must abide by the University's Research Ethics Policy: https://www.sheffield.ac.uk/rs/ethicsandintegrity/ethicspolicy/approval-procedure
- The project must abide by the University's Good Research & Innovation Practices Policy: https://www.sheffield.ac.uk/polopoly_fs/1.671066!/file/GRIPPolicy.pdf
- The researcher must inform their supervisor (in the case of a student) or Ethics Administrator (in the case of a member of staff) of any significant changes to the project or the approved documentation.
- The researcher must comply with the requirements of the law and relevant guidelines relating to security and confidentiality of personal data.
- The researcher is responsible for effectively managing the data collected both during and after the end of the project in line with best practice, and any relevant legislative, regulatory or contractual requirements.



Approved: 29/04/2019

Rachel Morecroft
Registration number: 160266799
Mechanical Engineering
Programme: PhD research

Dear Rachel

**PROJECT TITLE:** Improving the understanding of incontinence pad skin friction
**APPLICATION:** Reference Number 026173

On behalf of the University ethics reviewers who reviewed your project, I am pleased to inform you that on 29/04/2019 the above-named project was **approved** on ethics grounds, on the basis that you will adhere to the following documentation that you submitted for ethics review:

- University research ethics application form 026173 (form submission date: 26/04/2019); (expected project end date: 01/09/2020).
- Participant information sheet 1059314 version 2 (26/04/2019).
- Participant consent form 1059315 version 2 (26/04/2019).

If during the course of the project you need to deviate significantly from the above-approved documentation please inform me since written approval will be required.

Your responsibilities in delivering this research project are set out at the end of this letter.

Yours sincerely

Jennifer Rowson
Ethics Administrator
Mechanical Engineering

Please note the following responsibilities of the researcher in delivering the research project:

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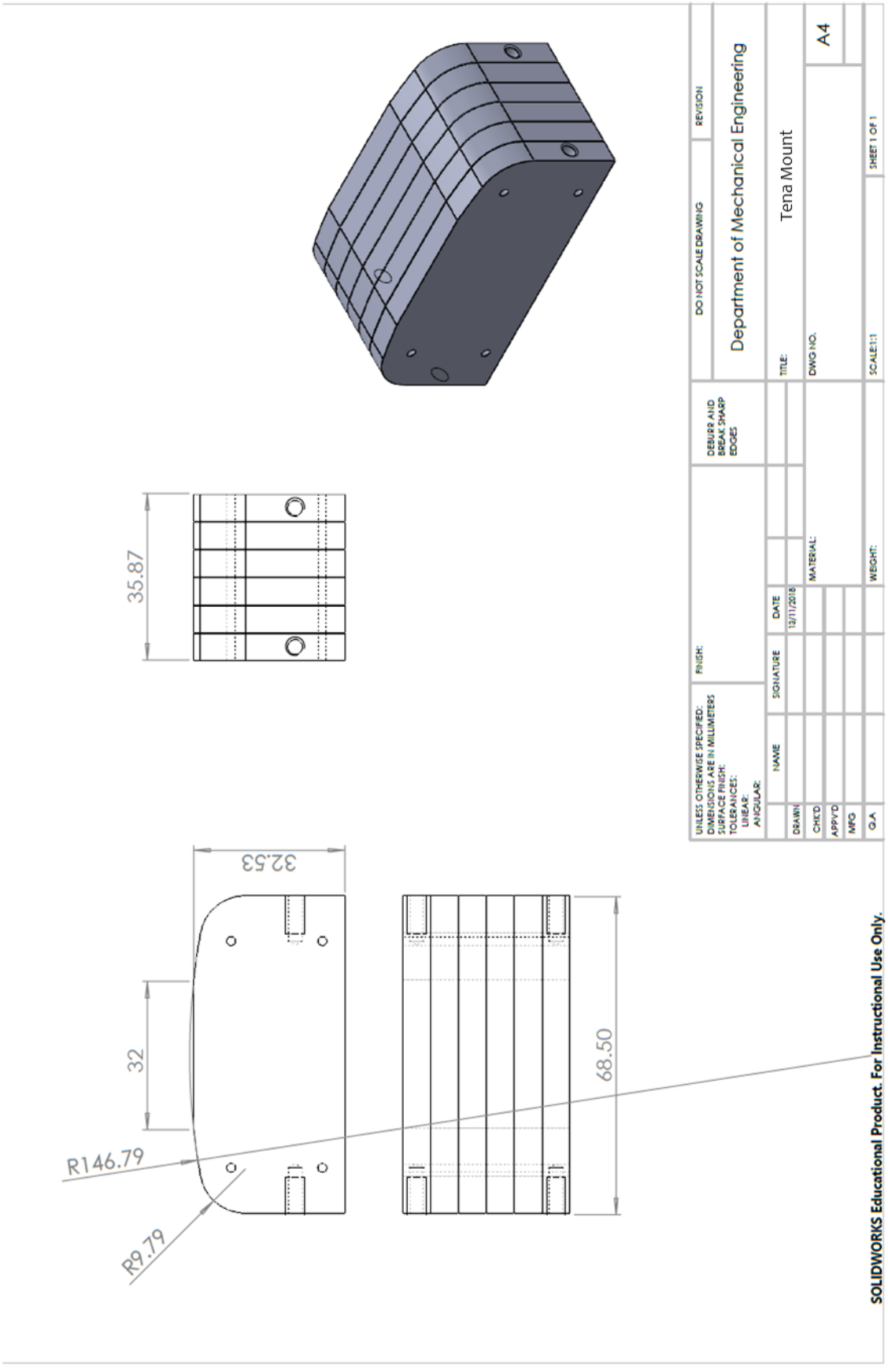
# Appendix E

Friction Rig Mount - CAD Drawing



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