UNIVERSITY OF LEEDS
SCHOOL OF MECHANICAL ENGINEERING
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Tribology of the Plantar Aspect in Relation to Diabetic Ulceration

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Sarah R. Crossland, Heidi J. Siddle, Peter R. Culmer Claire L. Brockett. A Plantar Surface Shear Strain Methodology Utilising Digital Image Correlation, *Journal of the Mechanical Behavior of Biomedical Materials*, 136, 2022.

Sarah R.Crossland*, Alexander D. Jones*, Jane E. Nixon, Heidi J. Siddle, David A. Russell Peter R. Culmer. STrain Analysis and Mapping of the Plantar Surface (STAMPS) - A Novel Technique of Plantar Load Analysis During Gait, *Proceedings of the Institution of Mechanical Engineers, Part H: Journal of Engineering in Medicine*, 237(7), 2023. *Joint first author

Sarah R. Crossland, Heidi J. Siddle, Claire L. Brockett Peter R. Culmer. Evaluating the Use of a Novel Low Cost Measurement Insole to Characterise Plantar Foot Strain During Gait Loading Regimes, *Frontiers in Bioengineering and Biotechnology*, 11, 2023.

Sarah R. Crossland, Francesca Sairally, Jen Edwards, Peter R. Culmer Claire L. Brockett. Mechanical Characteristics of Diabetic and Non-Diabetic Plantar Skin to Inform Development of Physical Models, *Journal of the Mechanical Behavior of Biomedical Materials* [Under Review].

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Finally, thank you to my partner Tom and dog Shinji. You both deserve a medal for putting up with me during this process and beyond. Thank you for all you do to support me and all the wonderful adventures we have had to take my mind off work when it was needed.

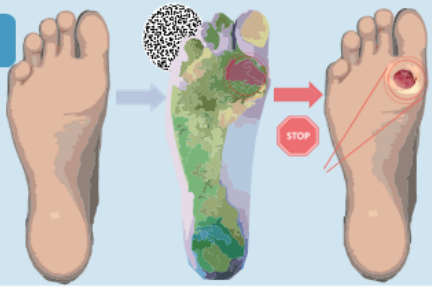
”It is nice to be important, but it is more important to be nice”

Diabetic Foot Ulcer Problem

Spent by NHS England goes to the treatment of the diabetic foot[2].

5 year mortality rate following diabetic ulceration[3].

5 year mortality rate following diabetic ulceration with amputation[4,5].

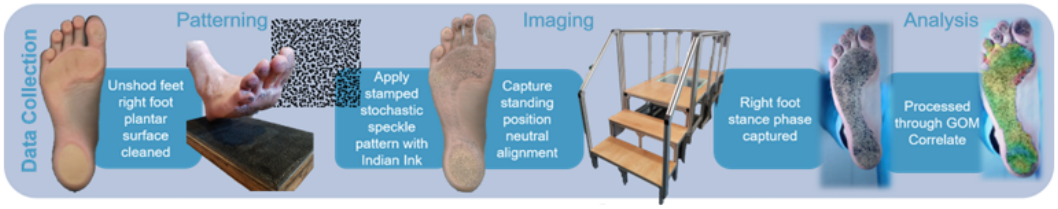


Using DIC plantar strain mapping to work towards identifying pre-ulcerative sites.

Determine at-risk locations prior to diabetic foot ulcer (DFU) formation.

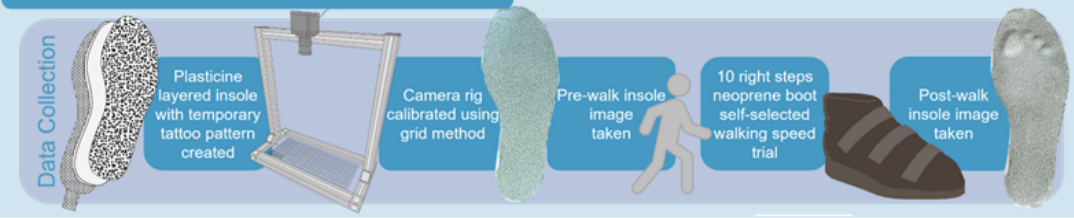
Strain Mapping Method 1: PLOD

Plantar Loaded Observation DIC

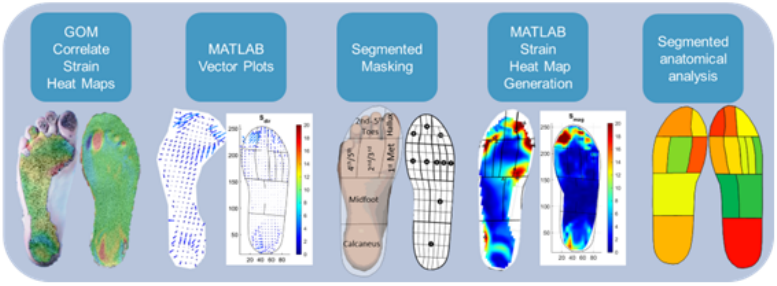


Strain Mapping Method 2: STAMPS

STrain Analysis and Mapping of the Plantar Surface



Data Analysis

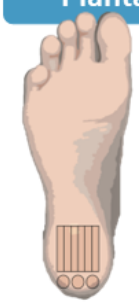


STAMPS Loading Regime Study

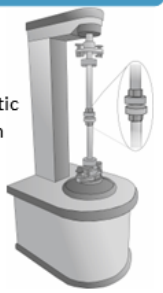
Strain-speed and strain-inclination dependence during gait on the plantar aspect of the foot.

Slow	0.75 m/s
Normal	1.25 m/s
Brisk	2 m/s
Inclination	10 %

Plantar Skin Characterisation



Mechanical characterisation of diabetic and non-diabetic plantar calcaneal skin under representative strain, loading and frequency



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A Plantar Surface Shear Strain Methodology Utilising Digital Image Correlation

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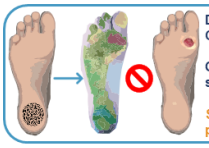
Diabetic Foot Ulcer (DFU) Risk

NHS England spend on diabetic foot[1]

5 yr mortality rate post DFU[2]

5 yr mortality rate post DFU & amputation[3,4]



Digital Image Correlation (DIC)

Optimised stochastic pattern

Strain mapping prior to DFU

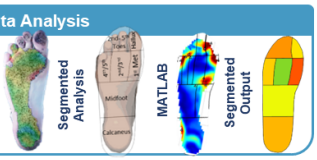
Data Capture

Low-ink transference plantar surface stamping

Single stance phase captured on glass plate platform

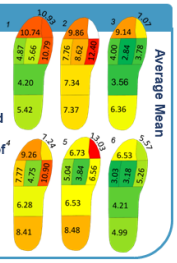
2D DIC capture

Data Analysis



6 participant feasibility study

Results



Varied distributions of strain

Average and peak mean per region of interest

Multi-frame output

Low-cost , high resolution strain capture
Quick to implement DIC
Repeatable and reliable patterning

Crossland et al. 2022

References: [1] Kerr, M. 2017. [2] Jupiter, D.C. et al. 2015. [3] Icks, A. et al. 2011. [4] Ikonen, T.S. et al. 2010.

Engineering and Physical Sciences Research Council

STrain Analysis and Mapping of the Plantar Surface (STAMPS): A Novel Technique of Plantar Load Analysis During Gait

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Diabetic Foot Ulceration (DFU)

Elevated plantar load contributes to DFU risk

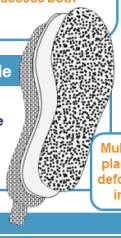
Plantar Load = Pressure and Shear Stress

Currently no in-shoe tool to assess both plantar load components

STAMPS Insole

Strain captured as a surrogate measure for shear and pressure

Digital Image Correlation (DIC) strain analysis



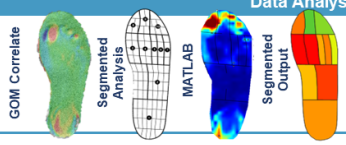
Multi-layer plastically deformable insole

Data Capture

Camera platform used for aligned insole DIC tracking.

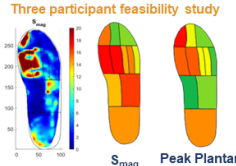
Standardised footwear

Data Analysis



Results

Three participant feasibility study



Repeatable reliable measurement of plantar load characteristics in gait

Jones & Crossland et al. 2023

Engineering and Physical Sciences Research Council

Evaluating the Use of a Novel Low-cost Measurement Insole to Characterise Plantar Foot Strain During Gait Loading Regimes

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Gait Loading Regime Response

Three speeds selected to represent walking paces seen in daily living

Slow	0.75 m/s
Normal	1.25 m/s
Brisk	2 m/s
Inclination	10 %

Inclination selected to assess gait at normal walking pace

STAMPS Insole

Multi-layer plastically deformable insole

Utilising digital image correlation (DIC) for strain response measurement of plantar aspect of the foot

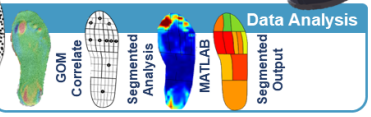
Data Capture

Five participant feasibility study

Treadmill used to control speed and gradient used within the study

Three repeated trials per loading regime

Data Analysis



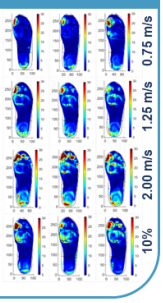
STAMPS captures strain response from controlled speed and gradient changes

Results

Increase in activated strain regions with increasing speed

Increased strain value with increasing speed.

Forefoot translation of strain active regions with increased inclination



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Mechanical Characteristics of Diabetic and Non-Diabetic Plantar Skin

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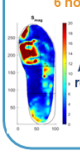
Characterisation

Mechanical characterisation of excised cadaveric plantar calcaneal skin

Cadaveric donors:
6 non-diabetic
3 diabetic



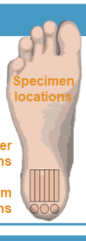
Assess under representative plantar loading

Data Capture

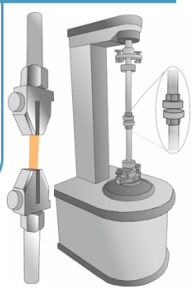
Digital image correlation to assess inherent rearfoot skin pre-tension prior to excision

10 mm diameter compressive specimens

40 mm x 5 mm tensile specimens



1. Tensile Dynamic Mechanical Analysis
2. Tensile Failure Analysis
3. Compressive Dynamic Mechanical Analysis



Data Analysis

- Inherent skin strain
- Stress-strain data
- Young's modulus
- Storage modulus
- Loss modulus
- Tan (delta)

Results

Inherent tissue strain considered low to negligible.

Higher Young's modulus in diabetic cohort reflecting expected soft tissue changes.

Variability in tensile and compressive DMA analysis reflecting small sample size

Disease state and age lead to differing mechanical characteristics, reflecting thickness and stiffness changes

Crossland et al. 2023

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Abbreviations and Nomenclature

Abbreviations

DFU Diabetic Foot Ulceration

DIC Digital Image Correlation

DKA Diabetic Ketoacidosis

FIB Foot Impression Box

HCP Healthcare Professional

HHS Hyperosmolar Hyperglycaemic State

MDT Multidisciplinary Team

MTP Metatarsophalangeal

PAD Peripheral Arterial Disease

PLOD Plantar Loadeded Observation DIC

PPP Peak Plantar Pressure

PTI Pressure Time Integral

ROI Region of Interest

SLIPS Shear Load Inductive Plantar Sensing

STAMPS STrain Analysis and Mapping of the Plantar Surface

TCC Total Contact Cast

TCI Total Contact Insole

Nomenclature

μ Friction

S_{AP} Strain - Anterior-posterior

S_{MAG} Strain - Magnitude

S_{ML} Strain - Medio-latera

S_X Strain - X

S_Y Strain Y

Chapter 1

Introduction

Diabetes and the at-risk diabetic foot is the leading cause of non-traumatic lower limb amputations in the UK, with diabetic foot ulceration (DFU) being linked to high mortality rates and substantial financial burden on the healthcare sector. Current clinical focus of risk assessing the diabetic foot is centred on pressure based measurement techniques due in part to their commercial availability. The effects of shear on the formation of DFU is an emerging focus in the research space, but with limited development of appropriate methods for shear data capture it has not yet translated into the clinical domain for risk assessment. Likewise, treatment pathways for the at-risk diabetic foot are pressure focused, with an increased understanding of the mechanical contribution of shear alongside pressure to the formation of DFU required to support development of more effective orthotic interventions. It has been found that implementing appropriate orthoses is financially proactive, by reducing long term healthcare spend due to effective treatment modalities preventing further progression of prognosis. There is a clear need for the development of methods to capture the contribution of shear in plantar aspect tribological interactions with techniques that offer potential for clinical translation. Whilst characterisation of shear and pressure during loading is fundamental, further research is needed to develop an understanding of tissue response during representative loading approaches when developing future prophylactic orthoses.

1.1 Research Aims

The overarching aim of this research is to and to work towards an improved understanding of the mechanical contribution to the formation of DFU. Current research in the contribution of shear stresses alongside plantar pressures is limited due to reduced access to measurement modalities and a subsequent small literature base. Due to this, the need to investigate the fundamentals of the contributions of pressure and shear at the plantar interface is necessary to build towards an improved DFU formation model. One way to support this is through the creation of biofidelic test beds, which would allow for recreation of plantar interactions under varied exposures to simulated activities of daily living, to assess plantar tissue responses. This research therefore aims to be able to measure and characterise the strain response as a surrogate for shear and pressure forces at the tribological interface of the plantar aspect during gait and activities of daily living, to understand the implications to skin mechanical response. This work can then be used to support future developmental work in biofidelic approaches.

1.2 Research Objectives

In order to achieve this aim, the following research objectives are defined:

Objective 1 To identify and develop a method to capture plantar skin shear strain response during gait events.

Objective 2 To develop and optimise plantar strain capture methods for use in shod environments.

Objective 3 To characterise plantar strain response deviations under differing loading regimes reflecting activities of daily living.

Objective 4 To evaluate the mechanical characteristics of plantar skin under representative tensile and compressive loading.

1.3 Thesis Overview

This thesis is comprised of seven chapters, consisting of content from four papers, and additional appendices, including this introductory chapter, to address the research aims and objectives and summarise with an overall discussion and concluding remarks.

Chapter 2: Literature Review

The literature review chapter covers the diabetic foot and the associated problems, skin and diabetic involvement, clinical evaluations of the diabetic foot and the current methods employed in skin tribology research.

Chapter 3: Methods Development

In this chapter initial development of the methods used within Chapters 4-8 are discussed. This is to provide further context to the published work and underpin the rationale behind their selections and evolution into their implemented form.

Chapter 4: A Plantar Surface Shear Strain Methodology Utilising Digital Image Correlation

This chapter presents research in the development and optimisation of a digital image correlation (DIC) based method to assess the strain response of plantar skin during gait events. This work formed a foundation for understanding the potential of DIC to characterise tribological interactions of the plantar foot.

Sarah R. Crossland, Heidi J. Siddle, Peter R. Culmer Claire L. Brockett. A Plantar Surface Shear Strain Methodology Utilising Digital Image Correlation, Journal of the Mechanical Behavior of Biomedical Materials, 136, 2022.

Chapter 5: STrain Analysis and Mapping of the Plantar Surface (STAMPS) - A Novel Technique of Plantar Load Analysis During Gait

This chapter utilises the DIC approach developed in the previous chapter and builds on this to incorporate it within the development of a novel in-shoe measurement device for strain detection. This chapter concludes with an overview of the coding process to analyse the collected data.

Sarah R.Crossland*, Alexander D. Jones*, Jane E. Nixon, Heidi J. Siddle, David A. Russell Peter R. Culmer. STrain Analysis and Mapping of the Plantar Surface (STAMPS) - A Novel Technique of Plantar Load Analysis During Gait, Proceedings of the Institution of Mechanical Engineers, Part H: Journal of Engineering in Medicine, 237(7), 2023. *Joint first author

Chapter 6: Evaluating a Novel Method to Characterise the Effect of Gait Speed and Inclination on Plantar Strain

This chapter utilises the in-shoe strain measurement device developed in the previous chapter to characterise the response in strain location and value brought about by altered loading regimes, namely controlled speed and inclination changes.

Sarah R. Crossland, Heidi J. Siddle, Claire L. Brockett Peter R. Culmer. Evaluating the Use of a Novel Low Cost Measurement Insole to Characterise Plantar Foot Strain During Gait Loading Regimes, Frontiers in Bioengineering and Biotechnology, 11, 2023.

Chapter 7: Data Processing

This chapter outlines the data processing workflow undertaken for both the shod and unshod DIC analysis approaches.

Chapter 8: Mechanical Characteristics of Diabetic and Non-Diabetic Plantar Skin to Inform Development of Physical Models

This chapter uses the characterised strain interactions from the previous studies to inform mechanical testing criteria for the assessment of excised cadaveric plantar skin under tensile and compressive regimes.

Sarah R. Crossland, Francesca Sairally, Jen Edwards, Peter R. Culmer Claire L. Brockett. Mechanical Characteristics of Diabetic and Non-Diabetic Plantar Skin to Inform Development of Physical Models, Journal of the Mechanical Behavior of Biomedical Materials [Under Review].

Chapter 9: Discussion and Conclusions

This chapter comprises of a general discussion of included studies within the thesis and ends with concluding remarks and future work directions to work towards understanding diabetic foot ulcer (DFU) formation.

Chapter 2

Literature Review

This literature review covers the background of diabetes, the global impact and the impact specifically to the foot. It then expands to discuss plantar skin and ulceration formation pathways, before giving an overview of current clinical evaluation and interventions of the diabetic foot. This is then compared to a research perspective on assessing the at-risk diabetic foot, highlighting the shortcomings in measurement of plantar foot response in tribological interactions.

2.1 Clinical Implications of Diabetes

Diabetes has far reaching implications for the body through its varying manifestations and often associated comorbidities. Whilst a substantial proportion of diabetic healthcare pathways and subsequent funding is focused on the recovery from presenting conditions of diabetes; focus on preventative measures and education is considered lacking in comparison.

Education about the management of diabetes is key to instigating a reduction in those presenting with substantial onset of complications. Regardless of the standard of educational support given to the diabetic community, a portion of the population will present with some complications throughout their lifetimes and addressing these issues once they have arisen is often a costly and laborious process for both the healthcare provider and the patient. Increasingly the NHS, amongst other worldwide healthcare providers, is beginning to take note of preventative action providing a potential cost effective measure in comparison to resolution based treatment pathways. Not only is preventative action a financial incentive to healthcare trusts, but it also is confoundingly beneficial to the patient group concerned through the reduction in often time consuming and substantial interventions.

It is with that in mind, that highlighting the narrative of *prevention is better than cure* that will underpin the focus of the development of this project's research aims.

2.1.1 Diabetes

Diabetes is most notably focused on two conditional types; Type 1 or Type 2, or to a lesser extent gestational diabetes. Other presentations with less prevalence, occurring in a combined approximate of 2% of the population, include monogenic diabetes, diabetes with the causation of rare syndromes and cystic fibrosis-related diabetes [1].

Table 2.1: Population representation of the varied presentation of diabetes in the England and Wales [1]

Type of Diabetes	**Approximate Prevalence in Population (%)**
Type 1	8%
Type 2	90%
Gestational Diabetes	Fluctuating
Maturity Onset Diabetes of the Young (MODY)	<2%
Neonatal Diabetes	<2%
Wolfram Syndrome Diabetic Presentation	<2%
Alström Syndrome Diabetic Presentation	<2%
Latent Autoimmune Diabetes in Adults (LADA)	<2%
Type 3C Diabetes	<2%

Type 1 diabetes is associated with immune response, with the body attacking pancreatic cells that form insulin, restricting production [2]. Insulin is vital to allow glucose generated by the breakdown of carbohydrates to access the cells maintaining the body's homoeostasis. Without insulin present the agglomeration of glucose in the bloodstream means that the kidneys increase their removal of urine from the body, which contains this excessive glucose. The difficulty in effectively utilising glucose caused by the lack of insulin can lead to hyperglycaemic episodes, ranging from the mild with usual diabetic symptoms present, to life-threatening complications such as diabetic ketoacidosis (DKA). DKA is a condition in which the body seeks the energy it is unable to source from glucose due to insulin loss, and attempts to breakdown fats [3]. This can lead to a diabetic coma and must be avoided at all costs by regular blood sugar monitoring and insulin injecting to regulate glucose in the blood.

Type 2 diabetes accounts for the largest population representation of diabetes at approximately 90% [4]. It is a development of the body forming a resistance to insulin or damage to the pancreas which reduces insulin production. In the same way as Type 1 it therefore causes

issues with the processing of glucose in the blood. A severe outcome more often associated with Type 2 is hyperosmolar hyperglycaemic state (HHS) [5]. Successful operation of the kidneys to remove excess glucose within urine can lead to HHS, which is in effect severe dehydration [5].

Unlike the unknown onset of Type 1, Type 2 is associated with varying risk factors. These factors include: being overweight, primary distribution of fat around the abdomen, inactivity, familial history of the condition, increased age, signs of prediabetes, previously having gestational diabetes, polycystic ovary syndrome and race (though unclear why, those of Caucasian ethnicity do not develop Type 2 as often as other populations, as found in North American studies [6]) [7].

Symptoms and Complications

Symptoms of all forms of diabetes are derived from the residual glucose that remains in the bloodstream and is not converted to energy for the body. The body looks to flush out this excess glucose via urination. In turn this can lead to fungal infections around the urinary tract due to the high glucose content of the urine [8]. Other common symptoms shared by all variants of the condition include, but are not limited to: increased frequency of urination, increased thirst, fatigue, unexpected weight loss, extended duration of wound healing and visual distortion.

Reduction of excess glucose is the clear goal of insulin injecting, but controlling quantities supplied is also important to ensure that blood glucose does not drop too low, leading to hypoglycaemia [9]. Hypoglycaemia attacks can present as the sufferer appearing fatigued, pale, confused and shaking and can come on rapidly. Sufferers often carry high glucose containing food/drinks on their person to be administered in such a situation. It is vital that a person suffering from hypoglycaemia is treated quickly due to the potential for loss of consciousness [9].

Diabetic presentation can vary between patients due to their personal management of the disease. These variations are often not seen in the classical symptoms of diabetes, which in general present with common frequency, they are more likely to be noted in complications associated with the condition. Diabetic complications can manifest in a plethora of forms, each of which can have a significant long term impact on patient health if not dealt with in an appropriate and timely manner.

Retinopathy instigated by diabetes is one of the major complications. In retinopathy the high blood glucose levels cause damage within the back of the eye, specifically the retina. Whilst retinopathy is often slow in its development requiring a long time period to lead to threat of sight loss, the risk it poses if going untreated and undiagnosed is possible blindness for the patient concerned [10]. Symptoms include: gradual vision deterioration, sudden loss of vision,

floaters in the field of view, blurred vision or pain and redness of the eye [10]. Understanding the symptoms of this complication and attending appropriate screening interventions can ensure it is monitored correctly and adequate intervention is in place to implement treatment pathways for vision loss.

Cardiovascular disease is also prominent in the diabetic community [11]. This is due to the gradual damage inflicted to the blood vessels of the heart due to a period of raised blood sugar. To manage this complication, patients are encouraged to monitor their blood sugar levels closely and have regular blood pressure and cholesterol checks to ensure overlapping damage caused by high cholesterol and blood pressure do not exacerbate the prognosis.

Peripheral neuropathy is another key complication of diabetes. Much as with the damage caused to blood vessels of the heart by high blood glucose levels, the sugar can damage the blood supply to the nerves [12]. Damage usually begins in the capillaries supplying nerves of the extremities, especially seen in the lower limb. Supply damage to these nerves can leave the patient with numbness, tingling or burning sensations [12]. Without intervention this can cause complete loss of sensation in the affected area.

The complication on which this research is focused is that of damage to the feet. The aforementioned complications can all impact the effect of diabetes on the foot and alter the pathway of foot problems which arise. Section 2.1.2 will further discuss this overlap and the developments occurring in the diabetic foot.

2.1.2 Diabetic Effects on the Foot

Issues present at the diabetic foot are due to the damage subjected to it by peripheral neuropathy and peripheral arterial disease (PAD). PAD occurs due to narrowing or atherosclerotic plaque occlusions in the arteries. Decreased blood circulation in this manner can lead to intermittent claudication in the affected limbs from the reduction in supply of oxygenated blood [13]. Without a good blood supply, healing of any wounds can also be reduced and any high blood sugar content at these sites can attract strong bacterial concentrations, leaving potential infections at the site difficult to treat.

The combination of PAD with neuropathy can mean that the occurrence of foreign objects within the shoe or external interference with the skin, such as burns, go unnoticed by the patient. Where this happens, wound sites can propagate to ulceration, see Fig.2.1, without being identified by the diabetic.

Some of the complications presented in section 2.1.1 appear to have little overlap with the diabetic foot, but difficulties with sight and cardiovascular health can impact the foot directly and indirectly. Poor cardiovascular health, leading to reduced circulation, links with PAD and the reduced blood flow to the foot, which affects ulceration risk and impairs wound healing [13, 11]. Visual impairment and sight loss mean that those suffering from reduced sensation brought about via peripheral neuropathy, may not only have difficulty sensing wound creation occurring, but also lack the ability to check the foot for wound development. This lack of continual checking can be a key complication in ulceration treatment, as patients who attend as outpatients in the hospital may be unable to monitor wound healing or progression of severity in order to liase correctly with the diabetic multidiscplinary team (MDT).

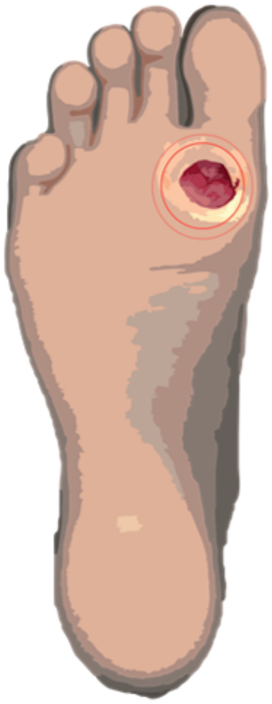

Figure 2.1: Depiction of ulcer located on the plantar 1st metatarsophalangeal (MTP) joint.

2.1.3 Impact of Diabetes and the Diabetic Foot within the NHS

Foot ulceration presents as a complication in approximately 15% of the diabetic population in their lifetimes [14], forming a key medical concern. The annual incidence in the population is between 1-3.6% worldwide [15], with 2-2.5% of the diabetic population in England presenting with foot ulceration in any given week [16]. While this incidence may seem a small percentage of

the overall diabetic population, due to ever increasing diabetic prevalence in general, the number effected by ulceration is significant. In 2013, 3.2 million people across the UK were diagnosed with diabetes, with 2.7 million of those in England [17]. Extrapolating the data to the weekly ulceration incidence lower bound value of 2% in England, equates to around 54,000 patients requiring treatment at any one time. This high incidence rate, coupled with the requirements of involvement from a substantial MDT comprising of orthopaedic consultants, diabetic nurses, podiatrists, orthotists and plaster technicians, means that the pressure placed upon the NHS by diabetic foot complications is extensive, in terms of both financial and physical burden. It is estimated that at least £1 in every £140 of NHS spend is directed to diabetic foot care [16].

The role of the MDT in diabetic foot treatment and the numerous positive outcomes cannot be ignored, but the high incidences of ulceration and amputations occurring from this must be addressed. Diabetic foot ulceration is the leading cause of non-traumatic lower limb amputation in the UK population, with approximately 80% of cases occurring due to ulceration [18]. Post- amputation, while the need of the diabetic to remain monitored by the MDT for further complications and remaining foot issues is present, the care provided to the patient extends beyond the diabetic foot MDT. The involvement of prosthetists, physiotherapists and occupational therapists in the treatment pathway adds further pressure to an already stretched NHS workforce and budget.

It must be noted that care beyond the outpatient/inpatient environment, undertaken in the community teams and through council funded care for those with the most severe complications of diabetes, is an often overlooked cost to the public budget. Earlier detection of ulceration risk is therefore a linchpin in the reduction of physical and financial pressure taken by the NHS in dealing with the at-risk diabetic foot. Identification and intervention in early stages of presentation could reduce ulceration incidence and prevent the most severe cases, leading to potentially reduced treatment times and amputation rates.

2.2 Skin and Diabetic Involvement

The structure of the skin and the differences presented with plantar skin must be understood in order to thoroughly assess the breakdown brought about via ulcer formation. However, beyond the skin structure itself the tissues and bony anatomy also contribute to the interactions which occur when the skin is in contact with another surface.

2.2.1 Skin Structure

The outer skin and underlying tissue can be thought of as a structure containing three principle layers: the epidermis, dermis and hypodermis. The epidermis is the outermost layer which offers protection to the underlying tissue and organs. Within plantar and palmar skin, due to their increased thickness comparative to the rest of the body, the epidermis can be thought of as five distinct layers as opposed to four elsewhere.

The key characterising features of plantar skin, which distinguishes it from other skin sites, are the thickness of the epidermis [19], and the close binding of the dermis to the epidermis [20]. Table 2.2 highlights the additional stratum lucidum layer present in the epidermis, only present in palmar and plantar regions, see Fig.2.2. This presence does not contribute greatly to the thickness of the epidermis as much as the increased depth of the stratum corneum seen in plantar regions. Within diabetic populations with foot complaints, the stratum corneum thickness is generally increased as a result of elevated pressure plantar regions. This increase in thickness of the stratum corneum is in direct contrast to the decrease in thickness seen in the epidermis as a whole. Compared to control populations, those with diabetic foot ulceration and peripheral neuropathy have been shown to present with a 15% and 9% decrease in plantar epidermal thickness, respectively [21].

Table 2.2: A brief overview of the epidermal layer structure and function from superficial to deep.

Epidermal Layer	**Structural Features**
Stratum Corneum	Layer formed of keratin sheets in which dead cells are periodically shed and replaced by cells provided from the stratum lucidum beneath. This layer typically accounts for much of the epidermal depth, but variations due to skin site and conditional influence occur [22].
Stratum Lucidum	Only present within the plantar and palmar regions, this layer contains keratinocytes derived from the stratum granulosum and formed of incomplete keratinised cells [22]. Mackie (2003) poses that this layer might be an artefact of histological specimen processing [23].
Stratum Granulosum	Keratinocyte cells in this layer initiate keratinisation in the structure. Cellular secretions at this layer form a barrier for water permeability and prevent ingress of foreign matter [22].
Stratum Spinosum	The desmosomes and keratinocytes at this level present in a polyhedral shape, hence the 'spiny' name which characterises their appearance. Through basal cell division in the stratum basale, keratinocyte layers are formed. This layer's role is to provide strong intercellular connections and structural stability [22].
Stratum Basale	A single layer of basal cells, which begin division to keratinocytes to provide replacement to those superficially lost in the layers above [22].

Table 2.3: Presentation and function of the Dermis and the dermal-epidermal junction.

Dermal Layer	**Structural Features**
Dermal-Epidermal Junction	Provides a permeable barrier and mechanical support between the epidermis and dermis, ensuring anchorage to one another through collagen bundles [22].
Dermis - Papillary Layer	A loose structure of fibroblasts dispersed within the elastin and collagen fibres of areolar connective tissue. Via the dermal-epidermal junction, dermal papillae interdigitate with the stratum basales' epidermal ridges [22].
Dermis - Recticular Layer	Comprised of a mesh of collagen and elastin fibers. Fibrocytes are responsible for the collagen bundle formation which extend into the hypodermis and papillary layer, making this layer not easily distinguishable . The collagen provides strength and structure to the skin, it also binds with water to maintain adequate skin hydration. The elastin present confers limited elastic properties to the skin [22].

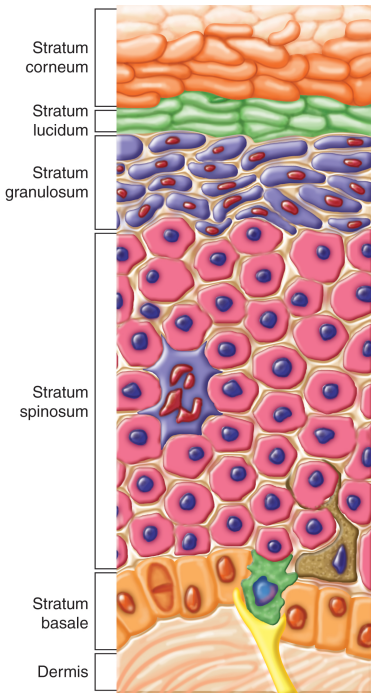

Figure 2.2: Schematic showing the arrangement of the dermal and epidermal skin layer structure, as seen in plantar and palmar regions [24]

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2.2.2 Plantar Skin Topography

Understanding of the unique topography formed by the epidermal ridges found on the plantar and palmar aspects is an in-depth research topic. Whilst not seeking to trivialise skin topography, the complexity of its development and the variation in formation across human subsets [25] means that translation of skin topography is often idealised when considering human skin equivalents for a variety of research approaches to allow for variable control. Consideration of skin topography is important to tribology, but tribological study into epidermal ridges is often confined to the palmar surface and fingertips. Van Kuilenburg (2013) looked to further understand the asperity contacts between interfaces and epidermal ridges, applying a consistent annulus on the meso scale to approximate the ridge formation and the shape of each ridge to be trapezoidal. They proposed the contact area is a summation of the ridges involved rather than deformation of the ridges [26]. Epidermal ridges can appear in loops, spirals and other formations of less consistent presentation in close proximity to one another, causing varying interaction and changing real contact area when interacting with interfaces.

To work towards understanding the mechanical formation of diabetic ulceration, biofidelic test bed approaches can be used. It is important then, to determine suitable anatomical sites for analysis. Skin topography can help identify sites for analysis. The juxtaposition of fingertips and the calcaneal region, on the scales utilised for tribological testing, would indicate that whilst annulus presentation suits the former, a repeating linear pattern may best approximate the latter, see rearfoot region of Fig.2.3. Choosing to focus on this area of the foot, alongside reduction of interference from underlying bony morphology, provides a comparative simplicity in ridge pattern with the forefoot that may be advantageous when analysing the tribological effects on the plantar aspect.

For any development of skin equivalents for testing, the same trapezoidal shaping and geometrical positioning should be assumed consistent across all epidermal ridges. Van Kuilenburg (2013) established, through 3D confocal microscopy, ridge widths of 300-400 µm and furrows of 210-280 µm based on analysis of synthetic finger pad replicas [26]. Generation of a synthetic elastomer plantar skin replica could be established in a similar fashion going forward to assess comparative ridge and furrow widths, to ensure approximations taken are in line with the skin region being considered.

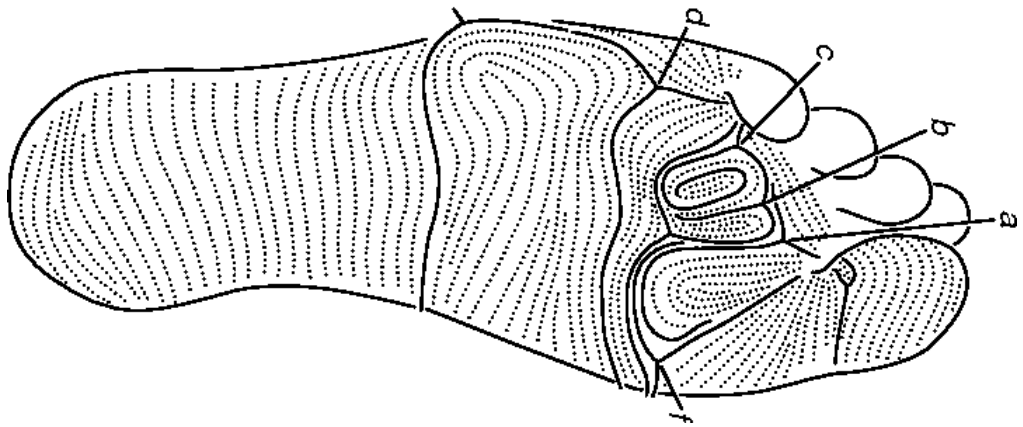


Figure 2.3: Plantar prominent epidermal ridge alignment. Noting complexity in flow pattern at the distal aspect with alignment reducing to a near linear flow proximally [27].

2.2.3 Skin Tribology and External Influence

The tribological properties of skin vary with intrinsic and external influence. Table 2.4 covers some of the factors which must be considered when evaluating the skin interactions [28]. This

list is not exhaustive and provides an overview of general considerations which may be made upon initial skin evaluation. Beyond this, further consideration in a diabetic context could be given to the presence of sweat and vascularisation status also for example. Whilst these factors vary readily within the patient population, some controls can be implemented in laboratory tests, particularly in terms of experimental inputs. Intrinsic factors can be harder to determine and control with as much precision, but should be understood to alter the tribology of the interacting surface. Protocols such as skin cleaning prior to any in vivo analysis can help to reduce the effects of some surface conditions.

Table 2.4: List of factors contributing to skin mechanics which should be considered [28].

Intrinsic Factors	**Experimental Factors**
Skin layer concerned	Loading type and period of loading
Skin region	Loading direction (shear)
Patient age	Strain (rate)
Hydration level	

2.2.4 Ulceration Locations

Understanding of the location prevalence of ulceration will be used to inform selection of tissue from cadaveric samples for tribological evaluation. The Eurodiale study of diabetic foot ulceration within Europe found 48% of ulceration to be plantar, of which 23% presented on the plantar toes, 22% was contained to the fore and mid-foot region and 3% on the hindfoot [29]. With an approximate half-and-half incidence on either aspect of the foot, the decision to focus on the plantar aspect has been taken to compare the varied tribological environments encountered by the plantar aspect compared to the dorsal foot, e.g. insoles. Although approximately 75% of plantar ulceration occurs on the toes and forefoot region [30], see Fig.2.4, the bony anatomy of the foot in this region (such as sesamoid bones and joint prevalence) and the underlying biomechanics during gait, may adversely affect the tribological interaction beyond replication capabilities in initial laboratory testing protocol. For this reason, focus will be given to the hindfoot area for biofidelic test bed developmental protocols, even though reduced ulceration incidence occurs here. Whilst this scope of this study does not extend to the development of a biofidelic test bed, it is important to be reflective of the anatomical regions of interest to allow for future expansion of this research.

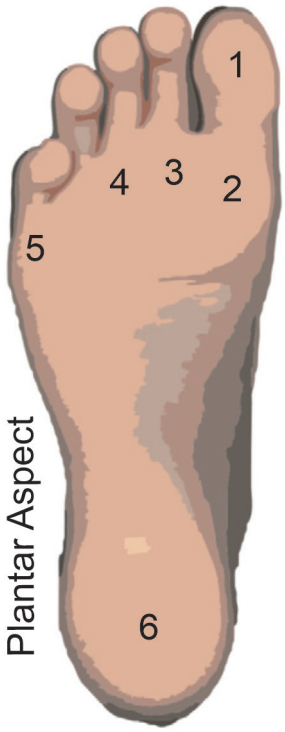


Figure 2.4: Prevalent ulceration locations on the plantar aspect of the foot showing; 1) Plantar hallux, 2-5) 1st,2nd,3rd and 5th MTP joints respectively and 6) calcaneus [31].

2.2.5 Properties and Topography of Underlying Tissue

Whilst tribology is the study of interacting surfaces, the characteristics of the subcuteanous tissues during plantar interactions should be considered for their impact on surface dynamics. Whilst the scope of this study focuses on the plantar skin response, previous research groups have investigated the calcaneal fat pad due to the varied role it plays plantar biomechanics and changes it undertakes as a result of disease progression.

Research of the calcaneal fat pad has often focused on modelling the geometry rather than the detailed surface topography [32, 33]. Surrogate development of the calcaneal fat pad is limited in incidence, with Chanda (2018) identifying this limited research alongside oversimplified mechanical characteristics within the current surrogate market and utilising this to develop a surrogate with a realistic viscoelastic response [34].

2.2.6 Ulceration Pathways

Unlike traditional pressure ulcers across the rest of the body and at the heel and malleoli, diabetic foot ulcers are graded on their own scales. This is due to the additional co-morbidities or pathogenic factors present alongside pressure that can lead to ulceration in the diabetic foot [35]. Due to these existing pathogenic factors, and population variances, there can be a wide spread in the presentation of ulceration in the diabetic community worldwide [36]. To establish comparison across all diabetic populations, grading systems are required as a way to establish appropriate treatment pathways, inform research and satisfy the requirements of clinical audit [37].

There has been little consensus in the clinical community about which of the various grading systems supports the best classification of all ulcers presenting, with many systems not validated successfully [36]. Developing countries often see less vascular-related complaints and may have a greater incidence of infection than European countries for example, so the need for a system which can reflect this variance is clear [38]. The validation of the systems used often does not extend beyond the population it was initially developed with in mind, which reduces global application.

Whilst this study does not set out to define a chosen or new grading system for ulceration, it is important to consider the factors for classification to understand the formation of ulceration presenting from various pathogenic sources and external factors, in order to aid in quantifying the influence of tribological contacts in the development of diabetic foot ulcers. With this knowledge it may aid us to inform future classification or support select classification systems which can be used functionally within a time-burdened healthcare setting.

Table 2.5 highlights the complexity of presentation possible with diabetic ulceration that can be assessed. Game (2016) shows [37], through this analysis, the consideration which must be given to how easy the assessment is to operate, due to complexity and special equipment requirements, within a healthcare setting. These factors share equal importance with scoring the progression of the ulcer and co-morbidities present, as they rule out some systems which would only be practical in a research setting. The balance between complexity and neglecting key features provides the main challenge in selection of an appropriate system. Regardless of the system chosen for ulcer classification, the aetiology of the ulcer is not always clear. For instance, the presence of ischaemia can show poor vascular supply, but current grading systems cannot divulge significant information over the external involvement in ulcer generation. The

most apparent information that can be gleaned from such assessment, regarding external factors, is the prevalence of locations across the foot. Once compiled and compared, such information can provide clear mapping of areas of high incidence, which can suggest pressure involvement due to prevalence in weight bearing aspects of the foot.

Table 2.5: Game (2016) evaluation of differing published classification systems developed to grade the presentation of ulceration in the diabetic foot [37]

	Foot										Limb			
Diabetic Ulcer Grading System	*Score Given*	*Area*	*Depth*	*Infection*	*Duration*	*Site*	*Multiple Ulcer*	*Oedema*	*Local Gangrene*	*Ulcer Phase*	*Ischaemia*	*Neuropathy*	*High Complexity*	*Special Equipment Required*
The Megitt-Wagner System	x		x	x[b]					x					
University of Texas System	x[a]		x	x							x			
S(AD) SAD System	x													
The SINBAD System	x	x	x	x		x					x	x		
The PEDIS System	-[c]	x	x	x							x	x	x	x
Foster and Edmonds	x													
The DEPA System	x		x							x	x			
Van Ackers/Peters	x[a]		x	x					x		x	x	x	
DUSS	x		x			x	x				x			
MAID	x		x		x		x				x			
CHS System	x		x	x[b]					x					
Margolis 2003	x	x	x		x									
Saint Elian Wound Score System (SEWS)	x	x	x	x		x	x	x		x	x	x	x	
The Wound, Ischemia and Foot Infection Classification (WIFI)	x		x	x							x	x	x	x

[a] No numerical value or score applied, grid and scale increase predict worsening outcome regarding lower limb amputation.

[b] Infection only classified with deep ulceration.

[c] Can be used to determine a derived severity score from PEDIS assessment.

Table 2.6: Depth-Ischaemic grading and concurring suggested treatment options according to Brodsky, reproduced from Robinson (2009) [39].

Classification	Definition	Treatment
Depth		
0	At-risk foot, no ulceration	Patient education, accommodative footwear, regular clinical examination
1	Superficial ulceration, not infected	Off-loading with total contact cast, walking brace or special footwear
2	Deep ulceration exposing tendons or joints	Surgical debridement, wound care, off-loading, culture-specific antibiotics
3	Extensive ulceration or abscess	Debridement or partial amputation, off-loading, culture-specific antibiotics
Ischaemia		
A	Not ischaemic	
B	Ischaemia without gangrene	Non-invasive vascular testing and vascular reconstruction with angioplasty/bypass
C	Partial (forefoot) gangrene	Vascular reconstruction and partial foot amputation

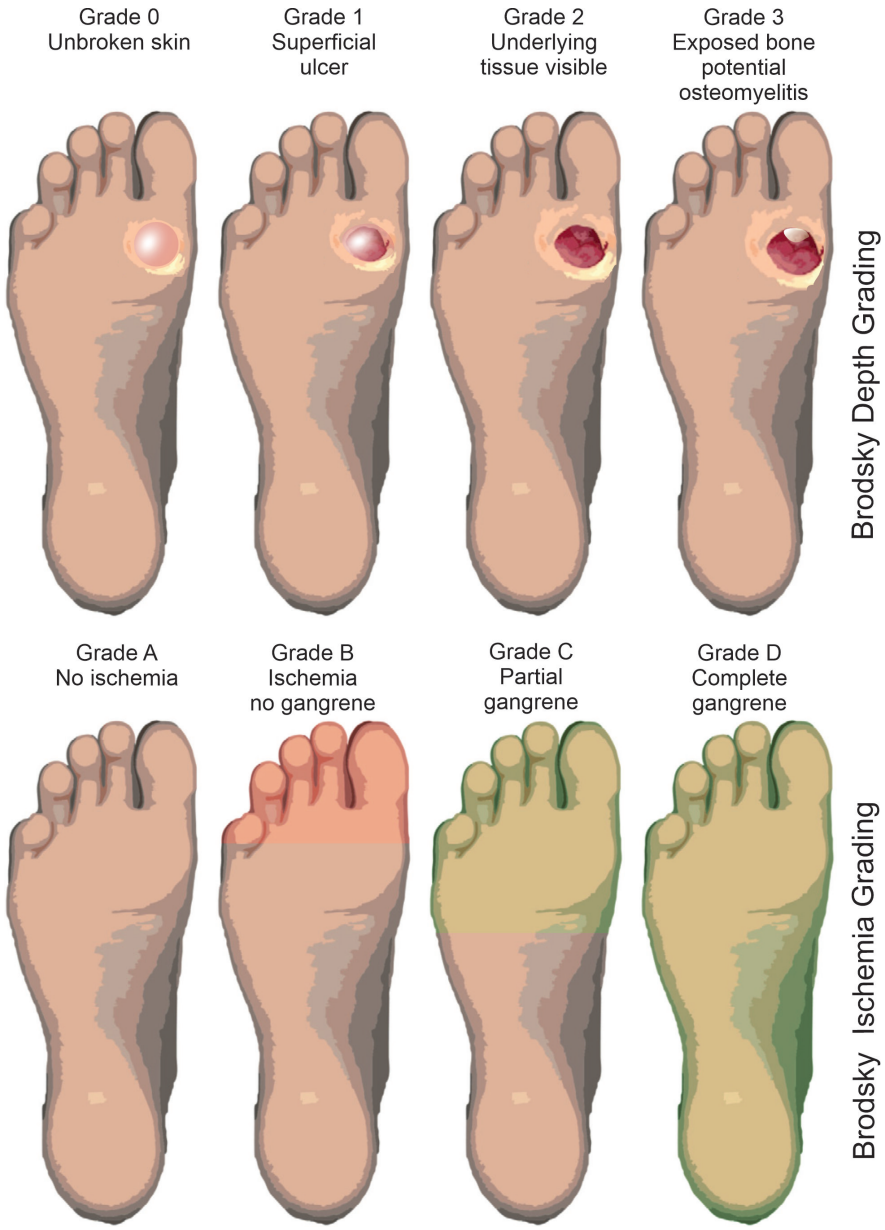


Figure 2.5: The Brodsky depth-ischaemia grading of diabetic foot lesions [39].

The Brodsky depth-ischaemia grading [39], Fig.2.5, is a clear example of the overlap between vascular health and ulceration severity and can be used to simplify understanding of the risks associated with ulceration/ ischaemia and the respective treatment options, see Table 2.6. Other systems overlap the two classification profiles, ulcer depth and ischaemia, which can cause confusion during diagnostics of a patient with limited vascular dysfunction. Separation of

the ulcer grading is clear and consistent for all cases presenting. The treatments specified for such cases are however very generalised and the requirements of 'off-loading' offer a breadth of techniques and interventions dependent on location and comorbidities. As such, treatment of any patient should be assessed to ensure off-loading measures are personalised to their requirements.

Formation mechanics of the diabetic ulceration have often centred solely on the contribution of pressure, due to the ease of measurement offered from the variety of pressure measurement systems available in a clinical capacity. Whilst pressure plays a key role in DFU formation, shear strain on the skin is thought to contribute also, but with a lack of clinically viable toolkits to measure shear in plantar interactions, it is not quantified in clinical guidelines. Pressure measurements for the diabetic foot are comprehensively researched in literature, with elevated pressure values of 600 kPa seen often in the diabetic neuropathy population as opposed to 400-500 kPa for the foot pathology free diabetic cohort [40, 41]. Some disparity is seen between the peak plantar pressures achieved and location of subsequent ulcer formation [42]. Shear stresses are postulated to be the additional component in plantar interaction that leads to ulcer formation. A recent systematic review identified sixteen studies of shear stress at the diabetic foot, which was reduced further to three when consideration of in shoe assessment was considered [43]. The limitations presented by these studies, including sensor size leading to reduced plantar coverage and sensors as third bodies within the shoe complex [44, 45], lead to a reduced understanding of shear stress at the plantar surface and the role it plays in diabetic ulcer formation.

Plantar tissue shear stress is thought to subject the tissue to faitgue due to subsurface failure and lead to and precipitate the formation of callusing prior to ulceration [46, 47, 48]. Improved techniques to assess the plantar aspect for the contribution of shear would work towards greater understanding of the at-risk diabetic foot.

2.3 Clinical Evaluation of the Diabetic Foot

Evaluation of the diabetic foot is a continual process throughout the lifetime of the patient. The frequency of intervention is determined by the risks posed to the patient which predispose them to complications of the foot. Regardless of risk factors, all diabetic patients should undergo at least an annual foot inspection to ensure they are managing their diabetes effectively and monitor any signs of ulceration developing [49]. Alongside this, patients are advised to check their feet daily and report any changes in foot health to their clinical team. This places a large onus on the patient, who may struggle to meet this requirement due to range of social and physical factors. Moving diabetic foot care towards a preventative rather than responsive model, means that technological advances in monitoring may become more prevalent and reduce patient self-reporting of ulceration.

2.3.1 Interventions for the Diabetic Foot

Post-symptomatic treatment is the norm for the 'at-risk' diabetic foot. The gold standard recommended treatment upon presentation of an ulcer is total contact casting (TCC) [50, 51], see Fig.2.6. TCC works to offload the foot to promote healing. This method promotes a non-removable cast with fixed parameters [51], which ensures that the patient does not remove or mis-align the device, such as is possible with other offloading treatments such as an adapted shoe, insole or aircast walker [51, 52]. This lack of adjustability means that the practitioner can be sure of the adherence to treatment and remains in control of the treatment pathway, this is partially supportive of why the results seen from TCC promote such high rates of healing in infection-free, neuropathic ulcers [53]. The downsides to such treatment over other methods are numerous; lack of mobility to the joint and potential of atrophy, lack of access to the wound for regular care and potential for new ulceration to occur undetected being some of the key issues [51]. The contraindications for casting are infection presence and PAD, meaning that a large population of those with diabetic ulceration are not suitable for this favoured treatment pathway [54].

Figure 2.6: A total contact cast for off-loading of the at-risk ulcerated diabetic foot [55].

Alternative interventions such as removable aircast walkers, or CROW walkers for Charcot patients, do not offer the same sustainable offloading as TCC, due to the possibility of removal by the patient [51, 52]. These methods, alongside adapted footwear and insoles, require continued wear to work successfully. These devices, whilst maintaining mobility for the patient, can lead to increased mobility comparative to TCC, which results in slower healing times [51]. The hygiene inside the device can still also be an issue, even though regular wound maintenance is possible with this approach. Fabric linings can often come into direct contact with the wound and not be cleaned with regularity. Patient education is essential to provide [56], but adherence to the advice given with removable devices is also often limited.

Regardless of the chosen intervention, post-symptomatic treatment and the longevity of the healing process, median healing times being seen in the range of 63-77.7 days [57, 58, 59, 60] is not ideal. However, it is a reactionary treatment pathway to the usual presentation of patients only being addressed or visiting diabetic foot services upon formation of an ulcer. In an idealised approach early or prophylactic intervention to prevent ulceration occurrence would be preferred. The protocols instigated post-ulceration, whilst far from ideal are also time consuming, labour intense and expensive. If risk assessment procedures can be adapted to more objective measures, it is hoped that the interventions applied could be used to prevent ulceration, rather than for healing purposes. Such intervention would reduce the need for TCC and direct treatment to a more orthoses based approach.

Orthotic Intervention

It is reported that for every £1 spent on orthotic intervention produces a saving of £4 for the NHS in the long term due to the relief this provides on other aspects of the service [61]. This statement highlights the importance of orthoses as an intervention in patient care. Whilst orthoses offer a useful function in the treatment pathway of ulcer healing, utilising them at an early stage of intervention prior to presentation is of clear benefit to both the patient's care and the burden on the NHS.

Diabetic foot orthoses work to offload the foot in a general capacity through total contact principles [62]. To achieve this the first stage of orthotic intervention is often a diabetic specification [63]. Such insoles can be custom made or adapted from generic total contact insoles (TCI), see Fig.2.7b, dependent on the level of foot deformity with which a patient presents. The idealised situation would be a custom moulded insole, taken from impressions of the patients foot using a Foot Impression Box as shown in Fig.2.7a, but in practice their use is reduced due to associated costs. The principle of total contact insoles is to conform to the foot along the entire plantar aspects in order to distribute the load applied across a greater surface area and reduce point pressure. They are made of compliant materials, such as high or medium density poron, as to ensure tolerance for the diabetic foot [64]. To compound this, sinks of softer materials, often lower density poron, are used in areas of prominence for ulceration (see Section 2.2.4), to provide relief to significant areas of pressure as denoted from pressure mapping.

(a) (b)

Figure 2.7: (a) Foot impression box used to capture the foot profile for generation of TCI [65], (b) TCI used diabetic footcare for weight profile distribution across the plantar aspect [66].

Insoles alone may be enough to offer pressure relief and prevent ulceration in some of the diabetic population, but those with more complex presentations or poor condition management may need further support. Education of foot care is vital and though patients are told that footwear should be kept appropriate [56], in real terms this can be hard for some patients to rationalise or impossible to achieve if there is foot deformity present. Unsuitable footwear is a contributory factor in ulcer formation, this can be through improper fastening, poor sizing and poor donning/doffing or a combination of these factors [67]. By providing orthotically adapted footwear and guidance on wear, it is hoped that some of these issues can be overcome. Generalised diabetic footwear adaptations that are done in a bid to ease donning, reduce pressure and control shear risk include; leather uppers, lace ties, low openings, rocker soles, shank support, close fits and no internal seams. Whilst the offloading can be modified by footwear and tracked with pressure mapping, there is currently no quantification of the effects of shear undertaken on the foot. Establishing an understanding of the shear applied to the surface of the skin and the implications of this in ulcer formation would potentially improve the design and prescription of orthotic intervention to better stabilise and support the 'at-risk' diabetic foot to reduce chances of ulceration, comparative to pressure offloading alone. Current prescriptions based on pressure offloading do not account for the interactions of the skin and its opposing surface, as little of the interaction beyond pressure is widely researched. This means that the evidence-based practice

model favoured in healthcare cannot be actioned in the instance of shear.

Whilst there is clear benefit to quantitatively assessing shear strain to provide a greater evidence base on which to develop treatment protocols, most current orthotic intervention is focused on post-symptomatic treatment. As aforementioned orthotic treatment produces a long term financial relief on the health service, but with most intervention focusing on treating symptoms rather than prophylactic intervention there is room to increase this saving by working towards prophylactic orthotics being normalized. To achieve this risk assessment processes for the diabetic foot need to advance to ensure early stage recognition of potential ulceration sites. Combining shear strain data with existing pressure information is one method of analysing the breakdown potential of varying skin sites.

2.3.2 Diabetic Foot Assessment - Clinical Approaches

The assessment of the diabetic foot is often undertaken by a combination of the MDT depending on the patient risk and ulceration prevalence. Yearly assessment is indicated for low risk patients and would usually be conducted by a diabetic nurse and/or podiatrist [49]. Medium risk patients may also see the same MDT members, but also an orthotist to inform preventative insole and footwear measures, and seen on an increasing frequency [49]. Those patients who are determined as being at high risk of diabetic foot complications would additionally be monitored by an orthopaedic consultant, alongside the usual MDT with a higher frequency and rapid initial intervention [49]. Patients with active diabetic foot complications are urgently seen and the treatment pathway includes increased frequency of observation to monitor prescribed interventions.

Whilst this system offers the opportunity to identify ulceration risk at varying stages of progression to instigate a treatment pathway, due to the complexity and cost and time limitation of the MDT involvement in this system, there is limited opportunity for those who are not currently presenting with an ulcer, but are developing one, to be seen with enough regularity to address concerns. The number of patients who self present with ulceration is low, at approximately 30% [68]. This disproportionate imbalance to those only diagnosed with ulceration during routine hospital assessments is poor and results in a delayed treatment response for the patient. Establishing protocols that improve detection of the 'at-risk' diabetic foot prior to ulceration presentation must be a key concern for the NHS. Preventative measures rather than post-symptomatic treatment could reduce patient distress, improve patient quality of life and

reduce long term costs to the NHS [69].

Risk Assessment

Risk assessment of the diabetic foot currently takes the form of input from varying healthcare workers and a range of physical and observational assessments of the patient's current health. The protocols put in place should ensure that the practitioners liaise with one another to minimise the chances of a patient slipping through the cracks of the system before intervention can be put in place.

To achieve this, the MDT often operates from a central diabetic clinic service in which the patient can be seen by all required MDT practitioners in one setting simultaneously [70]. Whilst in practice this offers good care to patients who have already been highlighted as at risk or who suffer from ulceration, it does not necessarily offer the environment to screen from foot risk.

The care accessed prior to this service by diabetic patients is predominantly through general practitioners and community nursing with only yearly access to the diabetic MDT service for a foot assessment, if the patient is considered low risk. This allows a significant period of time in which a patient's condition could change dramatically through poor diabetic management. During this time the patient and their GP would be responsible for noting any foot changes or predictors of risk, for which they are not experts.

Risk factors that should be considered when assessing the feet of a diabetic patient include; neuropathy, PAD, ischameic symptoms to the limb, ulceration, callus formation, inflammation and infection, deformity, oedema gangrene and Charcot arthropathy [49]. Previous history of ulceration and/or foot problems is also considered a significant risk factor to consider additional assessments and intervention.

Once the diabetic foot care service is accessed, a variety of methods are used to assess the foot depending on the MDT member seen. Diabetic scoring systems are used to identify an observational score of risk of ulceration, see Table 2.5. Though consideration is given to many contributory factors affecting patient health, little is supported by objective results in primary observations where other health practitioners are not included in the assessment.

If presenting to a podiatrist, monofilament and doppler tests may also be used to aid the risk assessment with tangible results to support diagnosis of peripheral neuropathy and vascular complications respectively.

These risk assessment protocols enable the practitioner to understand the contributory effects of overall diabetic health to ulceration risk, but give little focus to the interaction of the

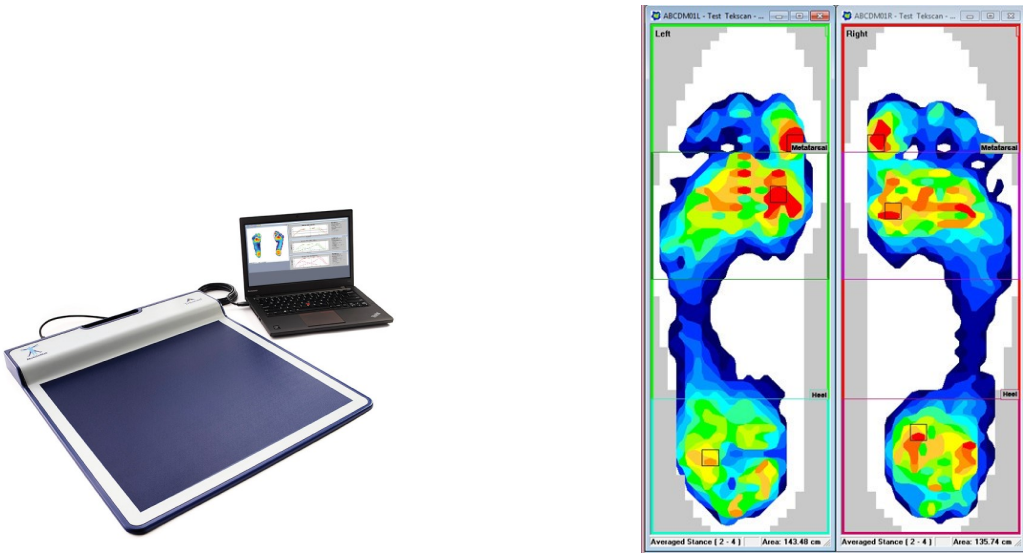
skin itself in the ulceration pathway. For example, The Braden Scale, although making note of the role of friction, shear and activity level, only cover these factors in terms of observable movements of the patient, e.g. can they move themselves freely and how long do they remain inactive? Whilst this highlights the combination of external influence thought to predispose ulceration risk, pressure and applied time, it is too generalised and lacks objectivity.

Involving an orthotist in the risk assessment pathway often leads to the inclusion of pressure mapping technologies to identify areas of high pressure and allow some understanding of the risk profile of the diabetic foot.

The generalised primary care assessment protocol for the diabetic foot to inform health-care professionals (HCP) of risk profiling and associated follow-up intervention periods [49], is complex and may involve interventions from numerous members of the MDT to be achieved successfully. This may lead to HCPs not forming a full holistic view of what is presented and could lead to inappropriate risk assignment. The combination of these tests in parallel, provide a semi-comprehensive assessment of baseline risk, but still lacks the inclusion of the understanding of shear or quantifiable long term profiling of condition.

Pressure Mapping

The ability to pressure map the plantar aspect of the diabetic foot provides an objective measure of the risk of the foot to ulceration. Without an understanding of the contribution of pressure to the formation of ulceration the effectiveness of the mapping becomes limited. Ulceration formation is often considered to be simplified to a combination of pressure and the applied duration [71]. If only this is considered, then mapping offers an effective way to plot areas of high pressure beyond normal limits and can be negated for, with offloading of these areas [72]. If ulceration is thought of as a more complex process combining the pressure and duration with shear forces and neuro-vascular complications, the effectiveness of offloading the high pressure areas without further consideration to these other predisposing factors may be limited.



(a) (b)

Figure 2.8: (a) Tekscan mobile force plate for pressure mapping [73], (b) Example plantar pressure map data capture using Tekscan force plate [74].

Pressure plates are often used in diabetic orthotic assessment to form pressure mapping profiles of the foot, see Fig.2.8, but the limitation of time and space often reduces the measures to one incidence of static readings before creating an offloading prescription. This means that the duration of loading in the noted areas of high pressure and the transfer of pressure during gait are not often available. Gait laboratories containing multiple pressure sensors and in-sole sensors offer a solution to provide long term and gait appropriated data to better inform orthoses prescription. However, as aforementioned, obtaining these in a traditional NHS environment is often not possible due to the requirements of space, time and money to invest in these technologies. The prescription change may be indiscriminate between static and gait/long term sensing, and not enough investment/research has been conducted in this area to support the funding of more involved technologies for pressure mapping.

The timing of this stage is critical if the orthoses provided are to be used prophylactically, but due to budget constraints, patients are often not referred to this step until they present as a high risk foot and often already suffer from ulceration or visible damage to the foot such as redness, swelling or distortion of the foot. If early intervention can be achieved through interim pressure maps and orthoses prescription, a reduction in ulceration prevalence may be possible. However, as the Braden Scale alludes to [75], shear is also often considered a key contributory

factor to the development of plantar ulceration.

Currently, no stages of the risk assessment or treatment of the diabetic foot successfully include measurement, understanding or application of the knowledge of shear with any objectivity [76]. If pressure and shear could be mapped simultaneously over a set time period, a more holistic view of the predisposing factors of ulceration could be noted to inform orthoses supply.

2.3.3 Evaluation of Clinical Protocols

Presentation of ulceration in clinic by patients themselves is relatively low [68], with ulceration often being spotted by HCPs during routine inspections. Budget and time pressures on the NHS limit the amount of HCP inspections possible, with annual inspections reserved for low risk diabetics [49]. Generation of a quick and effective way to profile the mechanical interactions of the foot, besides pressure alone, could support uptake of such protocols in the risk assessment pathway to allow for an increase in assessment numbers without severely proving a burden to time, labour and cost resources.

Current risk assessments of the diabetic foot are comprehensive in approach but often subjective, failing to address objective requirements to profile the foot which would allow for improved understanding of the foot condition when looking to enact interventions for healing [37]. Whilst biological factors contributing to ulceration can be monitored through interventions such as blood sugar measurement and monofilaments tests for neuropathy, the assessment protocols for mechanical factors rely on observations and pressure plate studies. Being able to successfully quantify the shear would be of obvious benefit to further the current risk assessment protocols and provide an additional objective measure to support treatment pathway decisions.

Orthotic intervention is based on the foot profile and pressure data, with the current gold standard treatment being TCC to isolate and provide weight relief to promote healing [50]. The obvious downside to this is reduced access for treatment during the healing process [51]. The use of prophylactic orthotics such as custom shoes and insoles, is advancing due to the potential benefit to the patient and NHS budget, which in the long term may reduce the quantities of TCC being required [63]. The downside to shoes and insole prescription is the lack of quantifiable information which is used in development of customised orthoses. Shear profiling may provide further data in understanding the ulceration pathway in order to generate a prescription which can counter the negative effects of both pressure and shear for diabetic patients.

2.4 Research Approaches for Diabetic Foot Assessment

Clinical approaches to the assessment of the diabetic foot follow an evidence based practice model, with the evidence base provided from a research literature data. A non-clinical environment allows for the trial of techniques which may initially be beyond the scope of the healthcare environment, but can offer insight into future assessment techniques and provide valuable quantifiable data to establish new treatment pathways.

2.4.1 Pressure Monitoring

Beyond their use in clinical environments, pressure plates offer a standardised way of collecting foot pressure data in the research environment also. The utilisation in this environment allows for further technological integration, such as combining pressure readings with motion capture kinematic data. This overlap provides a more expansive analysis of how the body is working in order to exert the pressures seen at the force plate and can be vital in establishing aetiology of ulceration [77]. Whilst this data would be relished in a healthcare setting, the time consuming nature and high capital cost push such technology out of the realms of in clinic assessment. Consequently small cohort research data sets are often extrapolated and interpreted to guide new treatment approaches for population subsets which are not representative for the individual patient. Individual patient analysis to this extent in clinic could help to provide a personalised treatment approach and ensure reduction in ulceration rates and reduced healing times. Treatments must look to engage in personalisation to meet the future demands of medicine and look for proactive ways to reduce incident rates of ulceration in the diabetic population [78]. Conversely, the vast data taken from this method is unlikely to be analysed sufficiently in the time-pressured NHS environment, so does not offer a realistic approach to achieve a personalised treatment pathway.

Another data collection approach for pressure, is via in shoe pressure sensors, such as the F-Scan by Tekscan (Fig.2.9), allowing for understanding of the interface between the foot and shoe complex. Pressure plates do not allow for an understanding of the foot-shoe complex, so this method is seen as gaining further insight into the patient's foot behaviour beyond a laboratory setting. In reality they are less widely used due to high cost, hygiene protocols for re-use, and entrusting the patient with the device outside the clinic and queries on the effectiveness of in-sole sensors such as these to provide insightful data for intervention are often raised [79]. Whilst information captured in this way can be useful to portray the pressure exerted on the patient in

activities of everyday living beyond the clinic, difficulty in ascertaining gait events comparative to kinematic and pressure plate data[80], meaning that transference of the pressure knowledge to meaningful intervention is more complex. Validation of such devices, shows that exposed temperatures, surface conditions and loading speeds in use can all effect the readings procured [81], which queries the use of such technology in the 'real-world' setting it is desired for use, as control measures must be in place to ensure suitability of measurement.

The improvements in pressure sensing technologies, have lead to a renewed growth in the market for in shoe sensing techniques. Start up companies are driving this charge, and integrating approaches such as inertial measurement units to overcome the limitations of traditional pressure measurement insoles. The market focus for such technology expands beyond diabetic foot analysis and are geared towards healthcare and sporting activity, with an emphasis on remote monitoring and alerts [82, 83, 84]. Remote monitoring, will improve patient empowerment in their health monitoring, and is a key area of research for the implementation of health behaviour tools in diabetic foot care [85].

Figure 2.9: F-scan in shoe pressure mapping system by Tekscan [86].

Textiles is a growing field of interest for foot measurements, with optical-fibre based technology allowing for the combined capture of plantar pressure and temperature alongside foot posture angle in the diabetic population [87]. Whilst not widely adopted due to the early stage

of development and the high initial associated costs, this technique offers a good alternative to capturing multiple aspects of data from inside the shoe complex. The limitations of sensing textiles in understanding the tribological properties of the interface is the movement artefacts that will be created in the sock within the shoe comparative to sensing insole which are stable within the complex. Research on pressure sensing textiles, such as socks, is growing. Sensoria [88], utilises a limited sensor array based within a sock, rather than weaved into the fibres. This approach reduces the capacity for capturing the complete plantar aspect and can only focus on set locations. Translation of such technology into home monitoring environments could provide a false sense of security for the user if they receive no high pressure warning, but actually have high pressure in an area not covered by the sensors.

Exploring pressure profiling beyond the medical setting, criminology has provided a differing approach to data capture. Tread patterns left at a crime scene host a bed of information about pressure profiles of the implicated. Needham (2016) have used glass plates and frustrated total internal reflection of light to image pressure data from tread patterns and in turn the plantar foot aspect [89]. In this instance, pressure information is proportional to the light emitted and provides a low cost, low technological requirement way to give data on the foot [89, 90]. The initial development process of this technique is complex, but beyond this can be repeated with relative simplicity. Whilst incomparable to force plate data, it does offer an introductory and accessible way to capture relatively high resolution plantar information quickly in both a research and clinical environment [91].

2.4.2 Strain Monitoring

Strain, in relation to the plantar aspect of the foot, is considered as the resultant deformation from normal pressure and shear stresses combined. Both shear stress and strain are illusive in the clinical environment at present, but advances to capture the data in a research setting are been explored widely.

The foot-shoe complex offers difficultly in recording shear strain due to the lack of inaccessibility to the interacting surfaces. To overcome this, textiles and insole based approaches are a growing area of development.

Infused fibre technology, strain sensing socks, ingrain piezo-resistive sensing threads into the weave of the textile to measure applied strain [92]. This technology could potentially allow for full foot strain measures and long term tracked analysis, but is highly limited in

providing reliable and useful data. The current development of applied strain technology is focused on smaller anatomical site coverage and currently developed with understanding namely foot drop through ankle angle determination [92]. However, this applied strain sensing using this technology has also shown promise in identifying gait events, which would be useful when combined with strain in providing greater understanding of the foot complex in relation to diabetes.

Poor fit of socks and movement between the foot-sock-shoe complex can create artefacts that do not align to the direct strain of the skin. They also offer poor resolution when compared to other strain capture techniques such as DIC and are costly to create. Due to the nature of the textile base, this option cannot be reused in a medical environment due to hygiene and cross infection risk, further adding to the continual associated costs.

A more practical approach is in-shoe insole shear sensors, such as the Shear Load Inductive Plantar Sensing (SLIPS) by Wang et al. (2022) [93]. Their approach is to generate an insole in-bedded with low cost strain sensors, which it is hoped will allow for NHS uptake. This technique allows for analysis beyond the clinic for in-situ measures during the activities of daily living, but it can be difficult to compare this data to the phases of gait the strain profiles were taken in. The understanding of the need for capturing both shear stresses on the plantar aspect, alongside pressures has lead to a growing interest in creating in shoe measurement devices.

2.5 Translational Research for Diabetic Foot Assessment

To fill the emerging need to capture shear stress and normal pressure response on the plantar aspect cumulatively, alongside translation of the tissue response to work towards improved understanding of ulcer formation mechanics scoping of translational research techniques is required.

2.5.1 Digital Image Correlation Approaches

Digital image correlation (DIC) is the tracking of an applied stochastic speckle pattern using image analysis. The positional changes of the speckles relative to one another are tracked comparative to an initial reference image [94]. DIC has predominately been employed for use on hard materials, but the increased translation to biomaterials in the past 30 years has seen an expansionto biological tissue use also [95]. The simplicity of the technique and wide availablity

of high quality imaging options mean that a renewed interest in in-vivo tissue analysis is an emerging focus [96].

To bridge the gap between traditional hard material DIC and in-vivo soft tissue work, attention must be given to the method of application of the speckle pattern itself. The stochastic pattern is central to the success of the technique and reducing failure is of key importance. To be considered successful, the pattern must meet the basic requirements of having a stochastic nature, good material adherence to ensure that the strain being tracked is representative of the material, offers a clear contrasting background to ensure consistency of tracking, not crack, not alter the material properties and offer an average speckle size of 3 -7 pixels on the acquired image [97, 98, 99, 100].

Liu (2017) fingertip study enacted DIC as a means of determining in contact strain [101]. To achieve this, a stochastic speckle pattern of contrasting colour to the skin was applied to the fingertip. Whilst undergoing application of strain, imaging the pattern allows for the analysis of the deformation of the pattern and thus the skin to map length changes between speckles to plot the strain. This analysis is easily done with clear images at set intervals over the deformation of the fingertip. These can be used alongside software such as GOM Correlate [102] or NCORR [103], to quickly assess strain comparative to the initial reference frame.

To image the fingertip undergoing these interactions, a clear contacting surface is used, through which the images can be obtained. To achieve this in a laboratory setting is relatively simple in terms of required equipment, due to a small glass surface being required and the dexterity of the finger to position in a table set-up of equipment.

Translation of DIC to the plantar aspect and the foot in general obviously requires scaling of the equipment and techniques used to be successful, but poses a great option for in-vivo analysis of the foot's interactions and the corresponding skin response. DIC has already been implemented as a method to characterise the foot. Blenkinsopp (2015) employed DIC as a methodology for measuring and monitoring the size and deformation of the foot during gait [104], as a way to track changes of foot shape with improved accuracy comparative to common modalities used to follow the foot in gait such as motion capture. Blenkinsopp (2015) realised the potential of DIC to also track deformation of the plantar aspect of the foot [104], by implementing a glass footplate alongside a six camera set-up to allow for 3D DIC analysis of the dorsal and plantar aspects during gait. Ito et al. (2017) also noted the potential of DIC for plantar deformation and strain analysis, and the overlap with diabetic foot complications [105]. Their study of plantar surfaces was limited to a five participant laboratory-based trial potentially

restricted to ensure suitability for purpose and also due to the substantial size, complexity and cost of the equipment used for this trial. Disregarding what could be seen as limitations, plantar DIC shows strong potential for establishing strain profiles of varying populations to inform tribological study.

To utilise DIC in an effective way for large population assessment, in order to create generic strain profiles of the foot, the technique and equipment used must be simplified and made accessible to implement outside a laboratory environment in order to attract a large research sample and process them with ease.

The main challenges to overcome when utilising DIC for large scale plantar study are: equipment cost, rig development, and speckle pattern generation and application. Reducing the set-up from 3D to 2D allows for a reduction in cost due to the lower specification of equipment required to achieve meaningful results. 3D DIC of the plantar aspect alone requires a synchronised minimum two camera set-up which alongside associated software can be financially unsuitable. Reducing to 2D analysis, means only one camera operating at a suitable frame rate can be used to capture the data, and by coinciding this with the use open access software, simple analysis of deformation and strain in both axes can be achieved at a very reasonable cost. The downside to 2D DIC is the loss of data during gait when the plantar aspect is out of contact with the interacting glass surface. To overcome this, frames should be analysed in segments as directed by the period of gait the foot is in; e.g. the heel should be assessed from initial heel contact to the heel off phase of gait alone. Assessing the foot in these segments also allows focus to be directed to the contacting aspects of the foot with greater prevalence of ulceration to provide strain data relevant to each important anatomical site.

Speckle generation for DIC has its roots in applications on non-organic materials. The transferal of such techniques to organic material can often require a change of tact due to the adherence properties and the delicacy of the tissue, but when considering in-vivo application, skin reaction and participant health and safety can be at the forefront of consideration. Coinciding with this is the need to produce a reliable pattern that can consistently be applied to users with ease and will ensure significant coverage when retrospectively analysing the associated images.

Speckle generation techniques across all subsets of application are most notably linked with diffuse spraying of the intended target area. Blenkinsopp (2015) when analysing their feet opted to apply a contrasting white base coat prior to spraying the black speckle to ensure the speckle could be easily distinguished [104]. Whilst this technique proved successful, it is easy to see that applying this on a large scale could prove both difficult to ensure spray consistency,

not be suitable for time poor large scale participation and also be difficult to achieve relatively cleanly when asking for participation of the general public. Quino et al. (2021) have addressed the need for pattern application to reflect the evolving market for DIC and implement temporary tattoos as a thin film medium for which to apply a successful speckle pattern for use on soft materials [99].

Computer software, such as Correlated Solutions Speckle Generator [106], allows the user to define a randomised speckle pattern, with control over the size, density and variation of pattern present. Temporary tattoos with a computer generated stochastic speckle, provide high repeatability and a good degree of guaranteed pattern suitable for analysis compared to the uncontrolled nature of diffuse spraying.

This flexibility in creation of the computer generated speckle, can also allow for testing of the idealised pattern for shear skin strain assessment. Skin strain when measured ex-vivo is often via compression or shear. Both applications apply to the foot under loading during gait, so it is important that tests can reach the average expected strains from studies of plantar skin undergoing these tests. Pai (2010) found that under compression excised diabetic plantar skin reached strains between 0.46-0.54 across a range of plantar locations, with a similar range of 0.44-0.55 seen in non-diabetic skin excised from the same locations [107]. This marginal difference between strain values, shows that accessing non-diabetic skin for strain studies has limited impact on the strain profiles expected. Boyle (2019) correspondingly found similar values for compressive strain in a two sample study following an applied compression of 300 seconds, with strain values of 0.1-0.2 for initial compression [108]. They also found that values between 0.1 - 0.5 were achieved for initial shear strain, reducing to 0.1-0.3 creep strain after 300 seconds [108]. Long term creep shear strain may not directly occur during gait, but repetitive shear may be applied to the foot, so it is important to understand the effects of shear strain. Translating these values to bench test studies of computer generated speckle patterns is important to assess for loss of tracking.

When generating these varied speckle patterns, it is important to consider that current pressure plates are expected to have a minimum spatial resolution of 5 x 5 mm when considering sensor distribution in the plate [109]. In line with this, the current International Working Group for Diabetes Guidelines suggest sensing technology should have a sensor spread of every 2 cm^2 [110]. DIC can improve on this spatial resolution greatly due to the dense spread of speckles required for tracking. As such, it poses as an important technique to consider for us in assessing strain in the diabetic foot.

2.5.2 Tribological Evaluation and Test Bed Approaches

The plantar aspect of the foot comes into contact with a variety of surfaces daily. To characterise these interactions we must think about how the properties of the skin and underlying tissue impact the contacts which occur and also about their responses to differing contact surfaces. Formulating methodology to characterise the skin under loaded and shearing interactions during gait is of primary importance to be able to ensure the damage profiling of the skin to assess tribological interaction is well informed.

The mechanical properties of plantar skin are characterised to an extent, but the focus on characterisation is rooted in excised cadaveric skin profiling, such as Boyle (2019) [108], or through non-weighted study of the plantar surface with devices like the Cutometer [108, 111]. While both of these methods provide important information about the sole of the foot that can inform how it interacts, they do not provide in-vivo information of the reactionary response of the tissue to interaction during stance and gait.

In-vivo study of skin undergoing similar tribological interactions is not a new field of study, with various study focusing on differing anatomical locations such as the fingertip. Interactions of such sites, can provide useful ideas for expansion to the plantar surface, but consideration must be given to the factors at play in each setting which differ greatly. The fingertip during contact with surfaces is exposed to much lower levels of pressure due to not being loaded by the entire weight of the body, as the plantar surface is. It is also much smaller in size, and presents with greater ease of manipulation when looking to examine the interactions in a laboratory environment. None the less the profiling procedures produced can inform plantar methodology significantly.

As discussed in Section 2.5.1, DIC offers an option for determining skin strain characteristics in-vivo that can be adapted for use on the foot, coupling such information with pressure profiles can support the characterisation of input properties for tribological test rig study. Tribological test rigs, allow for the recreation of in-vivo measurements, without the reliance on participant involvement and allow for increased accessibility and repeatability of testing a range of plantar interactions to work towards expanding knowledge on ulcer formation mechanics in the at-risk diabetic foot.

To ensure that the strain profiles achieved are representative of in-shoe strain, work must be compared not only to excised mechanically tested strain values, but also be supported by further in-vivo measurement. Comparatively little research has been conducted into the effects

of shear at the plantar surface due to limited technological scope in this area [44]. Investigating these research areas should provide improved datasets from which to underpin future studies.

The understanding and analysis of an interaction of the plantar aspect with a surface is only relevant to the surface alone which is being considered.

Assessment of the breakdown and damage profile of skin undergoing an interaction with a set surface is important to understand the proportional formation of ulceration which may be mechanical in origin. Initial tribological assessment must adhere to simplifying the interaction to allow for focus on the key elements at play. Pin-on-plate is a widely used experimental technique for tribological assessment of the characterisation of differing interactions. In other biotribology focussed assessment, such as prosthetic hip implant development [112], it is often adhered to as an initial test step in the suitability profiling stage. This suggests that pin-on-plate may offer suitability of implementation for characterising plantar interactions and should therefore be investigated further.

The influence on tribology is not merely the skin and external material in contact, but a combination of intrinsic and experimental factors which affect the interaction, see Table 2.4 [28]. Controlling the experimental factors can be achieved with relative simplicity, but must be informed via further literature data and relevant testing for suitability of application in a tribological test, such as strain studies of the skin to inform requirements.

2.5.3 Tissue Studies

The focus of existing mechanical characterisation on plantar tissue, whether in vivo or ex vivo, is often compressive shear studies, to invoke replication of expected plantar interactions [113, 114, 115, 116, 117, 118, 119, 120]. Studies predominantly focus on bulk properties of the plantar tissue rather than isolation of the skin and subcutaneous layers [121, 122, 123]. Whilst this helps to underpin the fundamental response of plantar tissues in tribological interactions, it tells us little about the individual tissue responses. Isolating the skin from the subcutaneous tissues in ex-vivo approaches, would allow for greater understanding of the specific mechanical responses which may lead to tissue breakdown and ulcer formation. Having an improved understanding of the mechanical characteristics beyond compressive shear studies alone is also fundamental in the development of improved surrogates for triboligcal assessment and finite element analysis approaches.

Measurement of the stiffness and thickness of plantar skin variation between diabetic and

non-diabetic populations has been widely researched to assess for potential reasoning behind ulcer formation. Ultrasound offers an in-vivo assessment approach, allowing for a greater population sample than ex-vivo cadaveric study. In vivo studies have shown increased skin thicknesses in the diabetic population, with thickening stratum corneum, and epidermal thickness reduction in ulcertative and neuropathic groups [124, 125, 21]. A range of plantar skin heel thicknesses ranging between 2.34$\pm$0.33 mm to 2.86$\pm$0.40 mm have been measured using ultrasound approaches dependent on the disease state of the tissue [21, 126]. Conversely, ex-vivo histomorphological assessment places this value closer to 2.06$\pm$0.66 mm, but with an approximate 0.2 mm thickness increase in diabetic than non-diabetic skin [127]. This is contrasted by other ex-vivo optical measurement of calcaneal skin showing 1.70 mm average thickness regardless of disease state [128]. This variance in the value dependent on measurement technique across all populations, highlights the difficulty in accurate measures due to measurement precision and potentially issues in distinguishing the skin layers alone. Cadaveric assessment allows for separation of skin from the subcuteanous layers, but with difficulty in determining complete separation of all tissues from one another. It also allows for increased mechanical assessment to determine skin specific characteristics comparative to non-destructive in-vivo studies.

Whilst current research on the differences in plantar tissues between the two populations agrees on the fundamental skin changes, further understanding of the tissue mechanical characteristics beyond the bulk properties are required. Tensile and failure testing, alongside compressive analysis can support this aim.

2.5.4 Human Skin Equivalents and Surrogates

Whilst cadaveric tissue is important for use in tribological assessment of the diabetic foot, it is limited in supply and removes the ability for repeat studies. The use plantar skin equivalents would allow for repeated experimentation without the additional difficulty of obtaining testing samples and the associated ethical requirements. Human skin equivalents (HSE) are developed with a limited range of use in mind [129, 130], and can be subdivided by their intended purpose for use: as clinical skin replacements and grafts, or for use as in vitro permeation and toxicity screening models [131]. Bostan (2016) review of equivalents for use as tribological equals provides good evidence of the opportunity HSEs present. In contrast their focus is given to abdominal skin, which is non-weightbearing tissue with differing topography to that expected of plantar tissue [129]. The requirements of tribological equivalents for plantar skin need to satisfy

further differential requirements due to the load bearing nature of the tissue and its structural variance from non plantar and palmar skin predominantly.

Table 2.7: Potential HSE currently on the market that can be considered for tribological testing [131].

Clinical Skin Replacements and Grafts	**In Vitro Permeation and Toxicity Screening Models**
Integra DRT	SkinEthic Rhe
Apligraf	Episkin
Epicel	Epiderm
Transcyte/Dermagraft	StrataTest
Orcel	Epidermal Skin Test 1000
Alloderm	Advanced Skin Test 2000
Stratagraft	EpidermFT

Due to the aspect of the skin chosen for tribological testing, the mechanical properties of the skin surrogate must align with those of the cadaveric sample. Skin behaves as a nonlinear viscoelastic material and cannot be aligned to Amonton's laws of friction. The friction must be summated by a combination of analysis of the force required to break the adhesive bonds at the skin interface on an asperity scale and the forces related to the contacting points deformation, as with an elastomer [132, 133]:

$$\mu_{total} = \mu_{adhesion} + \mu_{deformation}$$

Previous studies have shown that in dry friction, adhesion components play a greater role in the total friction coefficient [134]. Assessment of plantar skin under wet conditions has noted a rise in the deformation component [28, 135] and the overall coefficient of friction (CoF). Skin in this instance was moist/wet and may not align with friction behaviour of sebaceous saline conditions. Friction also reduces with contact pressure and differs with the age of the skin [135]. This must be used to inform test development and assessment of the friction properties and HSE selection, alongside comparison to the skin structure requirements. The behaviour of skin replacements and grafts may not align to these desired properties due to reduced structural dimension and oversimplified bulk properties and so screening models may provide a better alternative to mimic plantar skin [136]. The need to reduce reliance on bulk properties has been recognised and must play a key role in the next generation of surrogates for tribological

assessment [34].

Mimicry of the tissue underlying the skin must be taken into account due to the potential role it may play in affecting the skin's surface tribology. Within the plantar aspect this means alternatives for the calcaneal fat pad should be assessed to compare and contrast their biofidelity. Elastomer compositions have been investigated for their potential to replicate the calcaneal fat pad of both healthy and diabetic cohorts [137]. Chanda and McClain (2019) developed four-part mixed composition elastomers; see Table 2.8, of varying hardness in order to assess their compressive mechanical properties. Cyclic and dynamic loading tests were conducted, with strain rates noted due to the high impact loads taken by natural calcaneal tissues [137]. Compared to literature data of in vivo testing by Tong, Lim and Goh (2013), mock diabetic elastomers achieved $R^2 = 0.86$ with mock healthy elastomers achieving $R^2 = 0.92$ over congruent tests, showing strong correlation to expected values [138].

Table 2.8: Elastomer compositions generated to replicate healthy and diabetic calcaneal fat pads [137].

Diabetic Elastomer	**Healthy Elastomer**
45-50% wt Part A Shore 00-10	60% wt Part A Shore 00-10
15-20% wt Part B Shore 00-10	20% wt Part B Shore 00-10
20% wt Part A Shore 30a	10% wt Part A Shore 30a
15% wt Part B Shore 30a	10% wt Part B Shore 30a

Structure, shape and thickness all contribute to the mechanical efficiency of the calcaneal fat pad [139], and should be taken into account in design developed when it may influence tribological conditions.

2.5.5 Evaluation of Research Protocols

Tribological assessment of skin from in-vivo sources is simplified when the anatomical location chosen is non-weight bearing and easily manipulated for assessing the chosen interaction. The plantar aspect of the foot does not lend itself for easy assessment due to both the location and weight bearing requirements of the foot. In-vivo interactions also lend themselves to studies profiling skin properties during interaction, such as Liu (2017) fingertip DIC study [101], but are obviously unsuitable for damage inflicting studies. Ex-vivo assessment of plantar tissue interaction allows for damage profiling such as required for understanding the mechanical

triggers of skin ulceration. Though methodologies can be extracted from such in-vivo studies, such as utilising DIC analysis, which would enable the profiling of the skin strain to allow for tuning of inputs when pin-on-plate trialling excised skin interactions. This ensures that the skin is adjusted suitably to mimic in-vivo conditions as closely as possible. Adaptation of existing DIC methodologies will be required to create a low cost, repeatable, reliant method which can be extended to profiling large populations.

Pin-on-plate is already a well established technique in tribological assessment, including that of biological models such as hip prosthesis [112]. It therefore is indicated for initial characterisation studies of plantar damage interactions. Adapting the pin-on-plate set-up to design a suitable method of holding and stabilising skin and underlying tissues under in-vivo replicative inputs, is of key importance to ensure that the analysis undertaken is suitable to understand ulcerative breakdown from a mechanical perspective.

Human skin and tissue equivalents are usually generated for the grafting and dermatological markets and not for their mechanical similarity during tissue damage. Through this study it is also hoped that testing, design and formation of alternative tissue options will be possible as pin-on-plate can offer a methodology to test appropriateness for use in further research of plantar skin interactions. This analysis can provide a guide of suitability beyond the current indications of use provided with tissue equivalents.

2.6 Summary of Literature Review

Diabetic foot care is heavily invested in, in terms of labour and resources, but with significant median healing times for ulceration at present [57, 58, 59, 60], and a rise in the diabetic population, it is clear that there is still room for improvement in the treatment pathways implemented to reduce the NHS burden and improve patient health.

Early intervention and prophylactic treatment options provide an obvious benefit to the at-risk diabetic foot, but informing the decisions that risk assess the foot and lead to orthotic prescription is not necessarily fit for purpose for identifying mechanical involvement in ulceration. Risk assessment is focused on many subjective decisions and biological pre-disposing factors [37], whereas orthotic prescription is solely governed by pressure and foot shape at present. It is clear that providing further measures to understand the at-risk foot and improve prescription decisions, such as quantifying plantar shear involvement, could be beneficial to both the patient and HCPs.

Skin mechanical properties and profile across a range of anatomical sites are well noted from numerous in-vivo and ex-vivo studies, but the application of this knowledge in regards to plantar interactions provides more complexity, that is inefficiently understood in the context of ulcer formation. From a tribological aspect, understanding the interaction and mechanical damage to the skin and underlying tissues during this process is of clear benefit to the medical industry. The variation of interactions and loading profiles the foot undergoes during daily living, alongside inaccessibility to extract measures from the foot in-vivo, provide complexity to establishing tribological investigation of note. Whilst pressure is quantifiable easily from external pressure plate analysis, what is happening to the skin within the shoe complex is much harder to ascertain, such as the shear profile during gait. Profiling shear strain can aid understanding of the foot's role in interaction, to inform future tribological test bed development. Initial tribological testing is often conducted via pin-on-plate analysis, and this aligns itself well to assessing multiple surfaces against plantar tissues and available equivalents.

Shear strain profiling of plantar skin in-vivo offers a key area of development in understanding foot interactions. DIC, which is widely used in a variety of applications, offers an easily implementable method to map deformation and strain of skin. Comparison of the attained shear profiles by DIC is important to verify this method of strain measurement for use as a risk assessment/prescription development tool. DIC as a protocol for use on in-vivo and over a wide population, must also be streamlined for repeatability and reliance.

Pin-on-plate assessment of plantar tissue interactions, could provide a useful method to simulate mechanical factors in ulceration development. How to characterise the damage profile in this instance is a main area for development of this process. Further work is also required to adapt the pin-on-plate set-up to ensure suitability of purpose for holding soft samples as required.

Human skin and tissue equivalents currently on the market were initially created for use in grafting and dermatological testing, with mechanical properties designed to reflect those uses. Whilst through further testing, suitability of existing alternatives for use in damage profiling might be evident, the development of materials with properties designed purposefully for damage profiling may be required.

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Chapter 3

Methods Development

DIC was identified as the key technique to be implemented for the use in strain tracking throughout the applied methods (Chapters 4,5,6,8). As DIC is a method traditionally used on hard materials, refinement of the technique for application and pattern tracking was required to ensure fitness for purpose. DIC can be considered a three stage process: pattern application, pattern tracking and data analysis. Each stage must be successful in turn for the following stage to succeed. Key criteria for the success of each stage were outlined as below for the application of DIC on human soft tissues with the potential for translation to clinical environments.

Pattern Application Success Criteria

- Application technique which is repeatable to apply, relatively clean process to administer, skin safe medium

Pattern Tracking Success Criteria

- Pattern which can be tracked to expected skin strains reliably
- Tracking at frame rate appropriate for movement of target object in dynamic strain studies
- Tracking with relative high resolution

Data Analysis Success Criteria

- Negligible loss of tracking across entirety of target area during static and dynamic studies

From these criteria, focus to the application and optimisation of the pattern was identified as the areas requiring refinement prior to use.

3.1 Pattern Application

3.1.1 Direct Skin Application

The initial focus of the DIC technique was for application directly in-vivo, as seen in Chapter 4. Traditional DIC stochastic pattern creation and application is derived from diffuse spraying of often enamel paint onto the desired target, which is often non-biological in origin. On such materials diffuse spraying offers rapid and wide spread coverage of the intended target with a highly randomised stochastic pattern. If further contrast between the spray and target colours is required to ensure clear imaging, a base colour contrast spray is often applied. This is a time consuming process, limiting the amount of repeated tests conducted in a given period. Diffuse spraying offers rapid coverage, but does not allow for repeatable spray distribution, or spraying which guarantees a consistent spatial resolution. To ensure the pattern covers all areas sufficiently during the test, without blank spaces, post-spray analysis would be required following each trial. This current method was not suitable for use in human soft tissue studies when considering use of the eventual method in a clinical environment.
The requirements of the application technique for the applied studies include:

- A low or no allergenic skin response to the chosen medium
- A repeatable method with a clear and consistent pattern.
- A fast and simple technique to reduce time constraints of analysis in both laboratory and clinical settings.

Methods

A range of speckle pattern application ideas were trialled for their suitability to meet the aforementioned requirements for use on direct foot application:

Diffuse Spray - Indian Ink
Diffuse spray techniques are commonly associated with DIC. Indian ink was chosen instead of enamel paint to reduce the risk of allergic skin response.

Fine Coarse Sponge - Indian Ink
This technique is the recommended process for soft materials [1], indicating potential for use on skin.

Fine Coarse Sponge - Acrylic Paint

Trialled as an alternative to Indian ink to assess adhesion, pattern quality and drying response times.

Temporary Tattoo

A temporary tattoo with a Correlated Solutions computer generated stochastic pattern [2]. A speckle size 1.25mm diameter, 75% pattern density, 75% pattern variation was arbitrarily chosen to represent this technique as focus was given to the application technique and pattern quality alone. This technique was chosen for the ability to cover a large varied surface area quickly and offer a pattern with consistent spatial resolution.

Rubber Stamp - Indian Ink

A customised rubber stamper, 300 x 150 mm, using the same computer generated pattern [2] and application of Indian ink using a rubber roller. The technique of transferring a stamped pattern with a roller was developed for lino printing art [3].

Results

Fig.3.1 shows the pattern outcome of each technique with Table 3.1 discussing the merits and limitations of each technique. Diffuse spraying showed coverage of all areas of the foot and a range of pattern densities leading to an undefined variable stochastic pattern. Fine coarse sponge with Indian ink and acrylic paint showed good coverage but inconsistent densities as seen in the diffuse spray. Temporary tattoo showed a clear consistent pattern but poor coverage at the forefoot due to the reduced size of the tattoo and difficulty with smoothing into shaping of the foot. Rubber stamping showed a clear consistent pattern with coverage to all weight bearing aspects of the plantar surface.

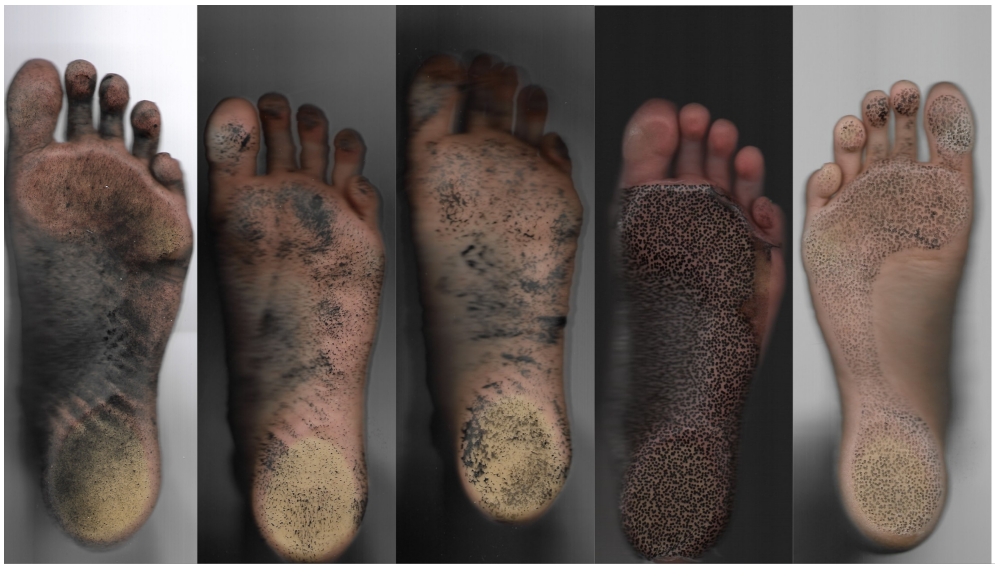

Figure 3.1: Trialled stochastic pattern application techniques: a) Diffuse Indian ink spray, b) Fine Coarse Sponge - Indian Ink, c) Fine Coarse Sponge - Acrylic Paint, d) Temporary Tattoo, e) Rubber Stamp - Indian Ink.

Table 3.1: DIC Pattern application techniques advantages and disadvantages for plantar skin shear strain analysis.

Application Method	Advantages	Disadvantages
Indian Ink Spray	Skin Safe Fast Large area coverage Low cost	Non-repeatable Low pattern control Bleeding of pattern Messy procedure
Fine Coarse Sponge - Indian Ink	Skin safe Fast Medium area coverage Low cost	Non-repeatable Low pattern control Bleeding of pattern
Fine Coarse Sponge - Acrylic Paint	Skin safe Fast Medium area coverage Low cost	Non-repeatable Low pattern control Bleeding of pattern
Temporary Tattoo - Computer Generated Pattern	Computer generated pattern Repeatable Pattern control Fast Clean procedure	Additional interface High cost
Rubber Stamp - Computer Generated Pattern	Computer generated pattern Repeatable Pattern control Fast Relatively clean procedure Low cost	Non-weight bearing areas not covered

Discussion

Each technique offered limitations, but by prioritising the desired outcome of the pattern the most suitable method was selected. A clear, consistent pattern which can be repeated is the key component of successful DIC. Low allergic response is required to protect the participants. Fast coverage of a large area is desirable to reduce application time. Low cost is desirable but not vital to success of the pattern. Table 3.1 provides an overview of the advantages and disadvantages of each method. The method which most supported the prioritised outcomes was rubber stamping. The computer generated pattern provides the clarity and repeatability of the stochastic pattern [2]. This clarity and repeatability of pattern is not seen in the techniques other than temporary

tattoo and rubber stamping. For this reason the other methods were excluded for consideration for the purpose of this study. Both temporary tattoo and rubber stamping with Indian ink have a low allergic response and are skin safe. They also offer a high area coverage, but the reduced possible size of the temporary tattoo limits the ability to cover all possible foot shapes and sizes. Temporary tattoos do provide coverage of non-weight bearing regions which would be beneficial in 3D DIC, but the focus of this study is solely 2D. The high cost and additional film interface created by temporary tattoo application mean that this technique is undesirable on direct skin application due to potential for causing wrinkles in the pattern upon application. The limitation of rubber stamping is that the pattern is not transferred to non-weight bearing aspects of the foot. However, this is not important in 2D DIC as the strain is only tracked when the foot is in contact with the glass platform. Whilst this leads to a loss of information on how the surrounding skin responds to the strain of the in contact regions, diabetic ulceration occurs in weight-bearing regions predominantly on the plantar aspect so was the key area of observation for this study.

3.1.2 Plastically Deformable Insole Application

During the refinement process for the direct skin pattern application technique, it was noted that temporary tattoos offered a beneficial approach in terms of allowance for a repeatable, tuneable stochastic patterning approach. It was therefore decided that it would be trialled as the method of pattern application for the plastically deformable insole (Chapters 5, 6). It had already met the requirements of use, but was previously deemed unsuitable for the contoured surface of the foot. Translating this to the initially flat surface of the deformable insole however was successful and provided a low cost and quick method of consistent pattern application.

3.2 Pattern Optimisation

Use of a computer generated pattern provides a pattern which is repeatable, unlike patterns generated by diffuse spraying. This type of pattern generation also provides the opportunity to refine the pattern in terms of speckle size, distribution density and variance. Refinement of the pattern provides the opportunity to meet the desired criteria for use needed for plantar strain tracking:

- Match or exceed spatial resolution of existing plantar sensors e.g. pressure plates.
- Track DIC sufficiently to expected plantar surface skin strains.

- Meet the size machining requirements for rubber stamp creation for direct skin application.

3.2.1 Method

Instron extension tests were used to trial a variety of computer generated patterns to expected peak plantar skin strains. The 50 x 50 mm pattern areas were laser cut into an acrylic sheet to form stencils, see Fig.3.2. To reduce use of cadaveric skin, a sheet of EcoFlex 30 ™ silicone with an embedded spandex layer for stability was created to approximately represent skin tissue. The stencils were lacquer spray painted onto the silicone sheet and individual test samples cut. The final samples were approximately 55 mm in total length accounting for a 50 mm pattern height and additional border.

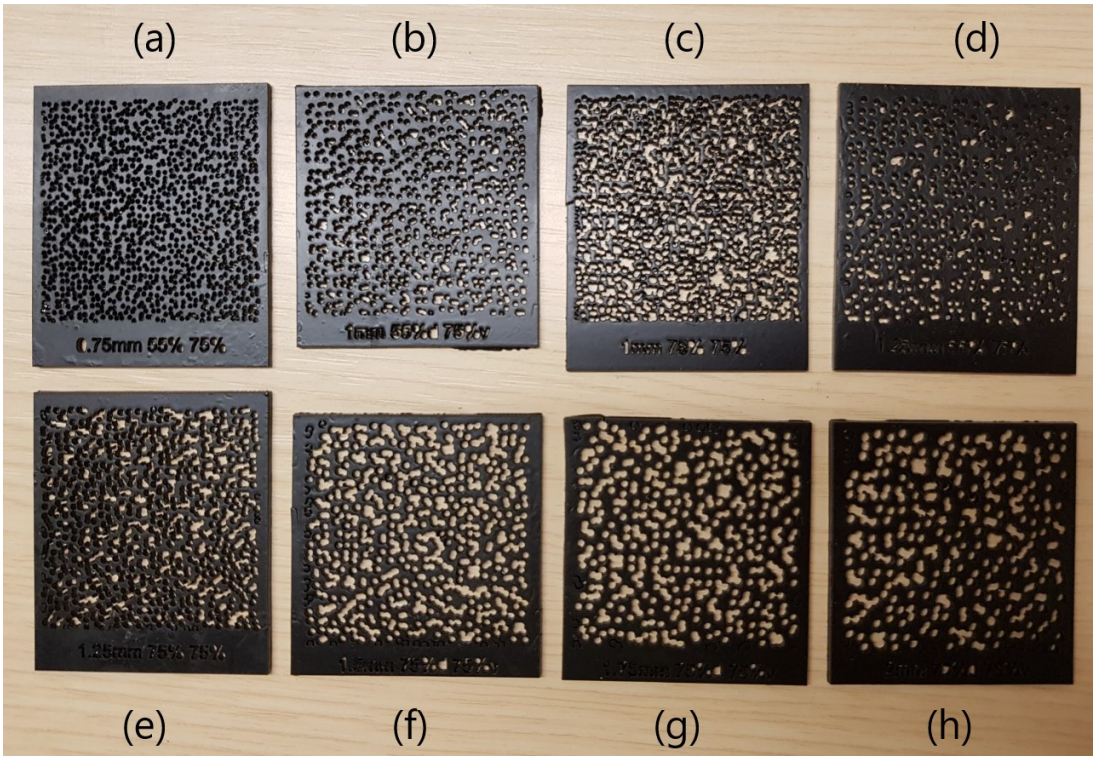

Figure 3.2: Laser cut stencils of computer generated stochastic patterns: (a) 0.75 mm diameter 55% density 75% variation, (b) 1 mm diameter 55% density 75% variation, (c) 1 mm diameter 75% density 75% variation, (d) 1.25 mm diameter 55% density 75% variation, (e) 1.25 mm diameter 75% density 75% variation, (f) 1.5 mm diameter 75% density 75% variation, (g) 1.75 mm diameter 75% density 75% variation, (h) 2 mm diameter 75% density 75% variation.

Data on the strain properties of plantar skin were used to inform the strain used in Instron studies. Data exists of peak tissue strain, but not surface shear strain in tribological interaction. Pai and Ledoux [4] determined the compressive tissue strains of excised plantar diabetic and non-diabetic skin in ulcer prevalent locations. The peak compressive strains were found to be 0.54 and 0.55 respectively. Boyle et al. [5] focus on shear strain in plantar skin, determining initial peak shear strain of 0.5. This value is in close agreement with the compressive strain properties found by Pai and Ledoux [4]. The Instron jaws were set at 55 mm apart to hold each silicone sample without excessive pretension. 30 mm total extension, 0.545 strain, was applied per sample applied at a rate of 5 mm per second, leading to a total test time per sample of 6 seconds recording at 8 fps. The recorded data per sample was then processed using GOM Correlate software to perform DIC analysis [6]. The pattern quality function in the software was used to assess pattern suitability for DIC in the reference image prior to extension, Fig.3.4. GOM Correlate was then used to run DIC analysis across each 6 second test [6]. The software is able to detect the stochastic pattern, quantify detected reference points and monitor changes in distance between respective points. The quantity of detected reference points was used to plot changes in pattern detection during increasing strain application to the silicone samples. Detected reference point loss during testing shows a reduced quality of pattern detection, which is undesirable. 5% reduction in points was set as the acceptable loss beyond which the pattern is not suitably representative of the initial pattern. The strain rate at which a 5% loss of detected points occurs was documented for each pattern sample, Table 3.2.

3.2.2 Results

Fig.3.3 shows the silicone samples prepared from the stencils for the Instron test. Clear and defined speckle patterns with limited bleeding were produced as required, by use of lacquer spray. The pattern quality assessment of the samples prior to straining, Fig.3.4, shows a mostly high quality pattern (green) across all samples. The samples which show areas of sub-par (yellow) and poor (red) quality, (a), (d), (f) and (h) are predominantly low density speckle distribution. Apart from (f) which has higher density distribution but notable spaces in the pattern due to the large speckle diameter pattern chosen.

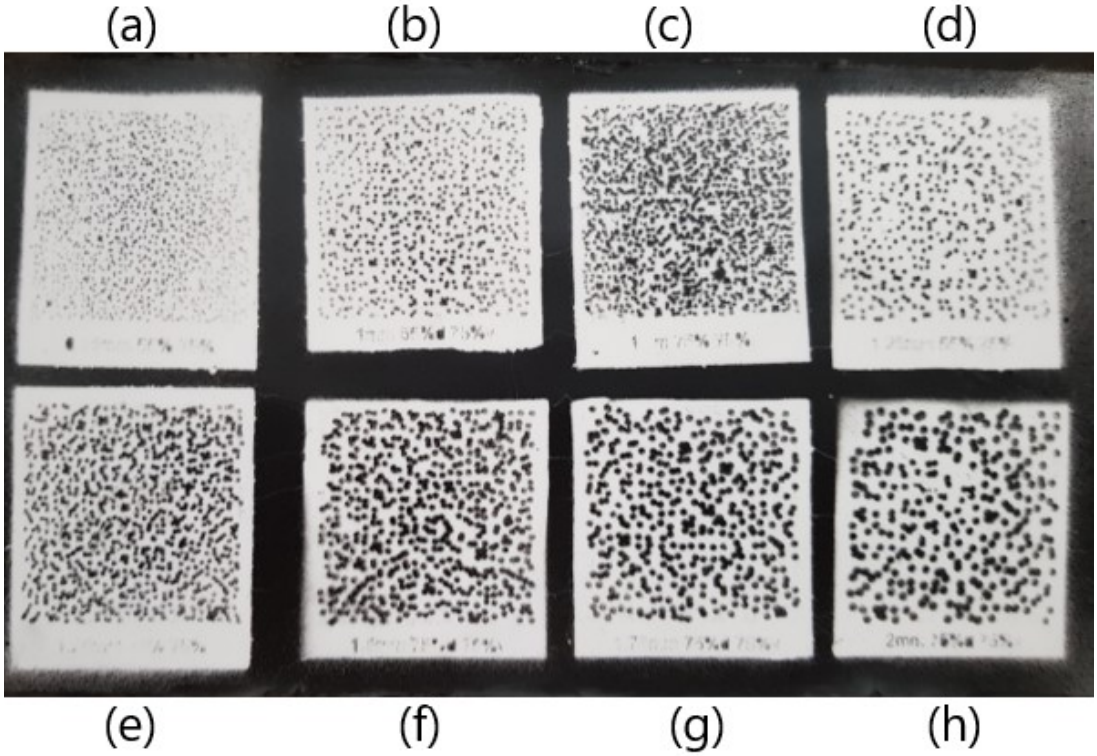

Figure 3.3: Silicone stenciled pattern outcomes of computer generated patterns, as listed in Fig.3.2.

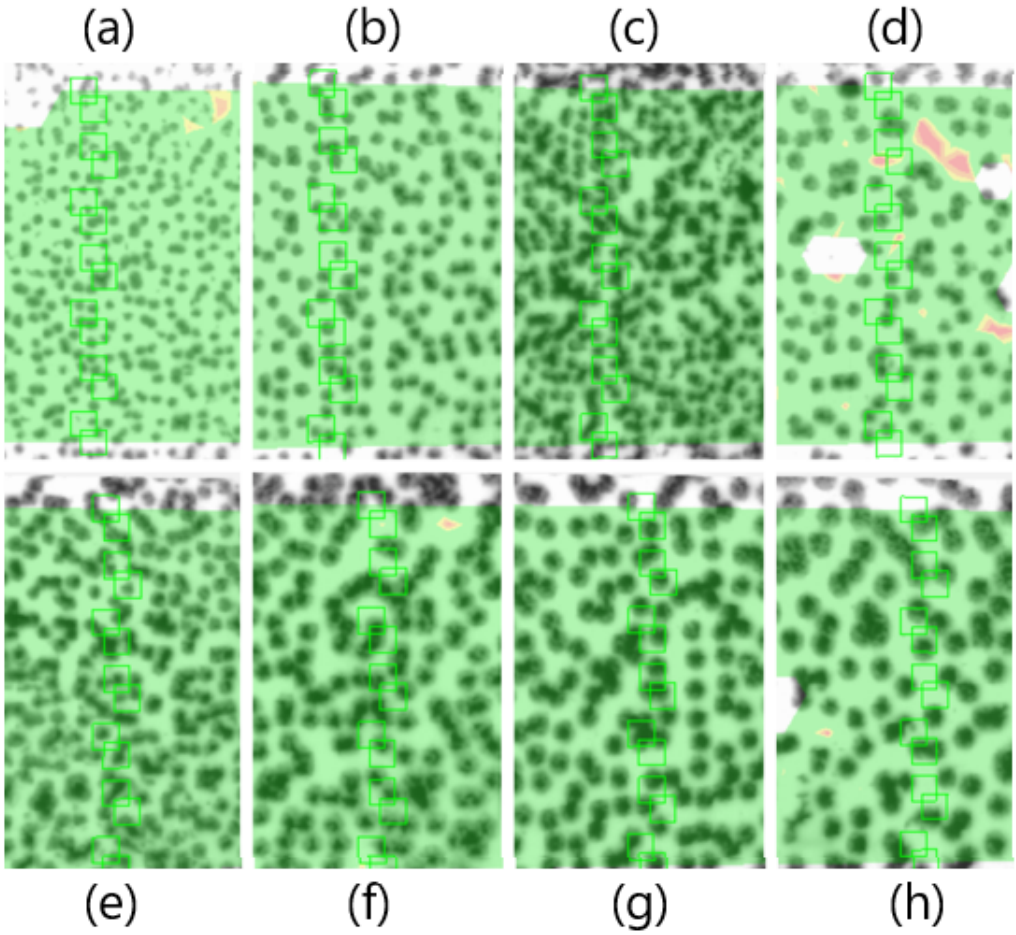

Figure 3.4: Pattern quality tests for the stochastic pattern variations, as listed in Fig.3.2. Green indicates high pattern quality, yellow sub-par quality and red poor quality [6].

The tracked 5% reduction in detected reference points seen is shown in Table 3.2. It is compared to the extension and subsequent strain to the silicone sample applied when the detected 5% reduction occurred. Only two patterns achieved 95% remaining reference points above 0.3 strain, the 1 mm diameter 75% density 75% variation and the 1.25 mm diameter 75% density 75% variation patterns. All patterns were recorded until a strain of 0.545 was placed on the silicone samples. At the strain only two patterns exhibited detection of over 50% of the original detected reference points. The 0.75 mm diameter pattern shows the greatest remaining detected reference points at 71.2%, with the 1.25 mm diameter 75% density 75% variation pattern detected 52.8% remaining. When assessing the machining requirements of the rubber stamp for speckle size, the pattern quality, the strain achieved at 95% reference point detection

and high final detected reference point percentage, the pattern which best met this criteria was 1.25 mm diameter speckle, 75% pattern density and 75% variation. The temporary tattoo is not bound by the same machining requirements of the rubber stamp so a smaller speckle pattern can be implemented in this instance of use.

3.2.3 Discussion

Current pressure plates are expected to have a spatial resolution from a sensor distribution of 5 mm^2 [7]. DIC patterns are tracked from the spacing of any two speckles relative to one another. To achieve a distribution of similar spatial resolution, only two speckles per 5 mm^2 are required. All the patterns trialled fit this spatial resolution criteria. The selection of the trialled patterns were dictated by the limitations of the laser cutter used for forming the stencils. Smaller speckle sizes with higher variation and densities were investigated but could not clearly be distinguished in machining. Patterns which could be laser cut successfully were continued with and are also suitable for machining the rubber stamp used in the application technique. Initial pattern quality was used to reduce the number of viable patterns, Fig.3.4. This excluded (d), the 1.25% diameter 55% density and 75% variation pattern, due to the large areas of low pattern quality and gaps in the detected pattern. Other patterns showing only limited areas of poor quality, (a), (f) and (h), were not discounted completely at this stage and all were continued to Instron strain studies.

The expected strain achieved by the best performing patterns, when assessed for 5% detected reference point reduction, was around 0.3 (Table 3.2). The test was conducted to the higher property strains of plantar skin, 0.5 [4, 5]. It is expected that surface strain on the plantar aspect would not reach characteristic peak strain of the tissue. This offers justification for selecting patterns which maintain a high quality 95% pattern at a reduced strain of 0.3. A study limitation is that the spray paint used on the silicone, whilst offering good initial adhesion compared to Indian ink, cracks during extension of the silicone sample. This damage to the speckle integrity leads to reduced detection by the GOM software [6], as the software works by tracking the intact speckles relative to one another. This leads to reduced pattern tracking capability at higher strains within this study, which may not be seen when the method is transferred to Indian ink and skin where pattern cracking is less likely. The chosen speckle pattern (1.25 mm diameter, 75% density, 75% variation) to form the stamp is not hindered by machining requirements, provides a well spaced pattern with reduced risk of bleeding between the speckles, tracks well at expected strains and offers good pattern quality for successful DIC.

Table 3.2: GOM Correlate DIC self-identified reference point changes throughout silicone Instron trials to test pattern capabilities under expected skin strain values [6].

Trialled Pattern	Initial Frame Reference Points	Frame at which <95% Reference Points Remain	Silicone Extension by Frame <95% (mm)	Strain at Frame <95%	Final Frame Reference Points	Percentage Remaining Reference Points (1dp)
0.75 mm 55% Density 75% Variation	504	21	12.7	0.23	359	71.2
1 mm 55% Density 75% Variation	552	19	11.5	0.21	23	4.2
1 mm 75% Density 75% Variation	532	29	18.5	0.34	132	24.8
1.25 mm 55% Density 75% Variation	546	12	6.4	0.12	20	3.7
1.25 mm 75% Density 75% Variation	527	27	17.1	0.31	278	52.8
1.5 mm 75% Density 75% Variation	568	24	14.9	0.27	80	14.1
1.75 mm 75% Density 75% Variation	560	20	12.1	0.22	92	16.4
2 mm 75% Density 75% Variation	573	19	11.4	0.21	109	19.0

Both applications of use have successful pattern tracking with low instances of pattern dropout as seen in Chapters 4,5,6.

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Chapter 4

A Plantar Surface Shear Strain Methodology Utilising Digital Image Correlation

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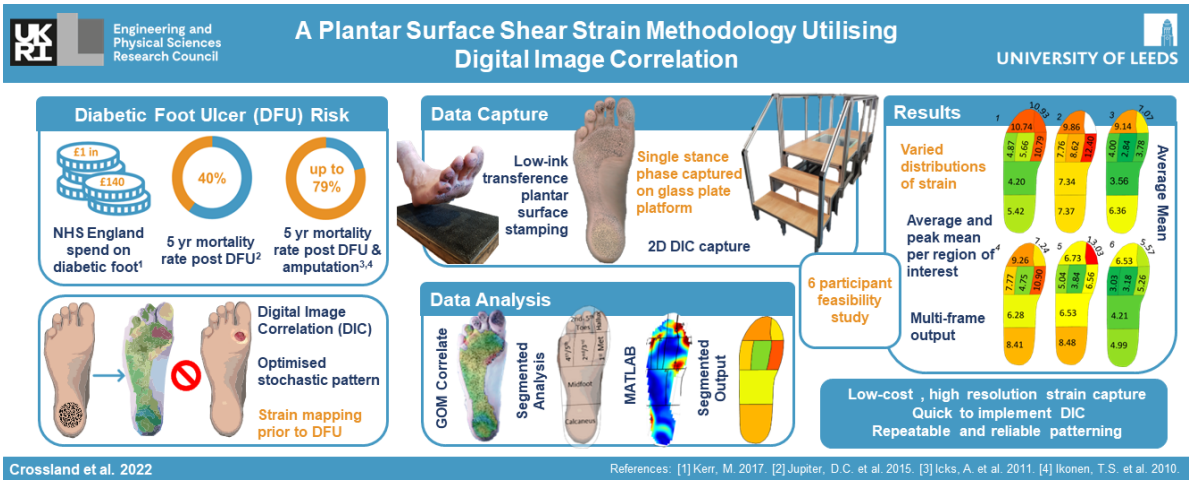

Figure 4.1: Graphical abstract for the paper A Plantar Surface Shear Strain Methodology Utilising Digital Image Correlation.

Preface

To understand the tribological interface of the plantar aspect in relation both normal and shear forces, this study was designed to meet the research objective of capturing the strain response of the skin during gait in lieu of shear. Current investigations of this interface have traditionally focused on the contribution of normal forces and neglected shear due to reduced availability of appropriate technology. This study utilises a 2D DIC method, with integrated glass platform walkway, to pattern the plantar aspect of the foot to enable the tracking of surface skin strain response during gait in comparison to a neutral stance position. Chapter 7 outlines the data analysis protocol employed for the strain data collected during in this study.

4.1 Abstract

The increase in the global diabetic population is leading to an increase in associated complications such as diabetic foot ulceration, associated amputations, morbidity, which substantial treatment costs. Early identification of DFU risk is therefore of great benefit. International guidelines recommend off-loading is the most important intervention for healing and prevention of DFU, with current research focused on pressure measurement techniques. The contribution of strain to DFU formation is not well understood due to challenges in measurement. The limited data available in the literature suggest that plantar strain is involved in ulcer formation. As a consequence, there is a need for plantar strain measurement systems to advance understanding and inform clinical treatment. A method was developed to determine plantar strain based on a Digital Image Correlation approach. A speckle pattern is applied to the plantar aspect of the foot using a low ink transference method. A raised walkway with transparent panels is combined with a calibrated camera to capture images of the plantar aspect throughout a single stance phase. Plantar strain is then determined using 2D DIC and custom analysis summarises these data into clinically relevant metrics. A feasibility study involving six healthy participants was used to assess the efficacy of this new technique. The feasibility study successfully captured plantar surface strain characteristics continuously throughout the stance phase for all participants. Peak mean and averaged mean strains varied in location between participants when mapped into anatomical regions of plantar interest, ranging from the calcaneus to the metatarsal heads and hallux. This method provides the ability to measure plantar skin strain for use in both research and clinical environments. It has the potential to inform improved understanding of the role of

strain in DFU formation. Further studies using this technique can support these ambitions and help differentiate between healthy and abnormal plantar strain regimes.

4.2 Introduction

Approximately 7% of the UK population have diabetes [1], with this population alone predicted to increase from 4.8 million today, to to 5.5 million by 2030, and of which 1 million are currently thought to be undiagnosed [2, 3]. Associated diabetic foot ulceration (DFU) affects approximately 34% people with diabetes [4], with an expected five year mortality rate of 40% following the development of a DFU [5], which rises up towards 79% following a diabetes related amputation is required [6, 7]. Diabetic foot care accounts for £1 in every £140 spent in NHS England [8], with an upper estimate of £962 Million spent annually on DFU in 2014/15 [9]. The need to improve diabetic foot treatment pathways is clear.

Current interventions for the at-risk diabetic foot are centred on prevention and wound treatment [10], with pressure redistribution being considered the most important intervention [11, 12]. The key clinical challenge is early identification of at-risk sites prior to ulceration developing, allowing preventative action. Plantar ulceration accounts for 48% of all DFU and is the focus for most analysis techniques [13]. Both plantar pressure and shear strain are understood to play a part in the aetiology of diabetic ulcers, thus providing the opportunity to inform prophylactic or reactive treatment options [14]. Unfortunately, current technology is limited to measurement of plantar pressure and excludes shear stress and/or strain. This restricts clinical utility because pressure alone is not a good predictor of ulcer formation [15]. Figure 4.2 shows the potential role strain analysis of the plantar aspect could contribute to risk assessing the diabetic foot prior to ulcer formation.

Clinical pressure assessment can be undertaken using a wide variety of methods ranging from carbon transfer foot impression sheets for quick, low cost, pressure information, to pressure plates and insole sensors providing digitised pressure data [16]. Comparatively, plantar strain sensing technology development is in its infancy with only a range of early prototypes reported and which focus on evaluating the efficacy of different sensing approaches, including magneto-resistors, strain-gauges and capacitive sensors through to piezoelectric materials [17, 18]. Most of these methods are developed for research use and there are currently a lack of viable commercial options for clinical use [19][14]. Choosing an appropriate technology for future use in clinical settings requires consideration of factors including cost, space and time requirements, in addition

to the core ability to generate clinically relevant measures. In this respect, imaging techniques have significant potential, with growing interest in analysis of static images of the foot to detect underlying abnormalities [20, 21]. Our interests are focused on measuring the dynamic aspects of strain, as it develops across the plantar aspect during gait, through the use of accessible imaging techniques.

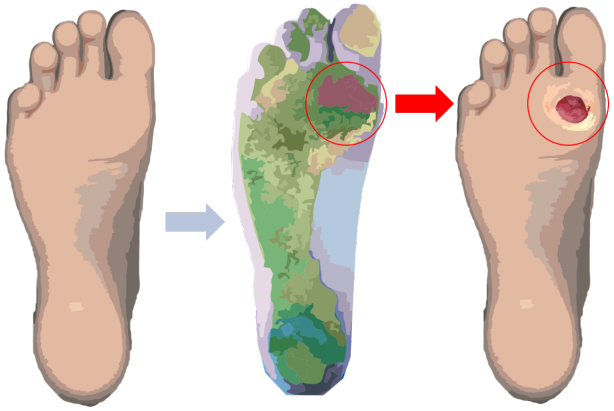

Figure 4.2: Schematic showing how plantar surface strain analysis could be used to assess diabetic ulceration risk site prior to ulcer formation.

Digital Image Correlation (DIC) is an image-based strain measurement technique. It operates by tracking positional changes of points on the patterned surface of a material as load is applied, comparing image frame(s) with a reference to determine the strain across the surface [22]. DIC emerged as a technique to track the strain of materials and started translating to biomaterials in the 1990s, with regular application after the turn of the century [23], and with increasing recent use in the field of soft materials. The use of DIC to examine strain properties within biological tissue studies is a growing field [23, 24], with in-vivo tissue studies emerging as a particular focus[25]. A key challenge with soft tissues is applying an appropriate pattern to support reliable DIC analysis. Patterns should be stochastic in nature, with good adherence to the material and clear contrast to the base material to allow for consistent pattern tracking [26, 27]. Understanding the surface strains undertaken by the skin during interactions of daily living is a pertinent topic for many applications within the field of healthcare. The foot's plantar aspect is regularly in contact with external surfaces during gait, providing an ideal measurement opportunity to investigate its strain characteristics during loading.

Liu et al. [28] measured strain at the fingertip using DIC by imaging through a transparent glass contact surface. Similar approaches of using glass contact surfaces have been extended

to observe the foot's shape during ambulation [29]. Ito et al. [30] employed this approach with 3D DIC analysis to further investigate the feasibility of palmar and plantar surface strain tracking under laboratory conditions. These studies highlight the potential of DIC as a promising application for analysing plantar strain and informing DFU treatment. However, the methods have been developed for research purposes, requiring complex equipment and calibration which may prohibit use in a clinical environment. Typically they employ spray application of a speckle pattern onto the foot's surface for DIC tracking. This is challenging to perform in clean clinical environments and reduces the reproducibility of coverage [27]. While laboratory studies provide a wealth of information, ensuring the technique has potential for translation to clinical utility is important.

The aim of this work is to develop a clinically suitable method to employ DIC for the measurement of plantar strain and use this to advance understanding in DFU formation. In the Methods section we first describe development of a measurement technique based on 2D DIC analysis. We then report a feasibility study used to evaluate the efficacy of the technique. Outcomes of the study are reported in the Results section employing analyses to derive a range of clinically-focused outcome measures. The paper concludes with a discussion on the advances made in this work, its relevance to research and clinical practice, and future development of the technique.

4.3 Methods

Our approach was developed through close clinical guidance to determine a set of over-arching clinical needs. These were then used to develop and refine a concept based on technical requirements for best practice in DIC imaging and analysis.

4.3.1 Clinical Needs

- Capture a single complete phase of stance during walking at a self-selected normal walking speed.
- Provide progressive tracking across the entirety of stance phase from heel strike to terminal stance.
- Preparation of the foot for imaging should be a quick procedure taking less than five minutes.

- The measurement area should be large enough to allow the entire plantar aspect to be imaged (over 95% of foot length distribution [31]) with a margin that allows for the varied placement due to stride length on to the plate.
- The method and output measures should be repeatable and linked to clinically relevant metrics.

Clinical metrics currently available to clinicians when assessing the diabetic foot include those obtained from technology such as pedar® [Novel GmbH, Munchen, Germany] in-shoe pressure mapping, providing an intuitive outlook of data to help inform treatment decisions.

4.3.2 Concept and System Overview

A concept was developed to satisfy the clinical needs, using methods informed by the literature. Our approach, shown in Figure 4.3, centres on an elevated walkway within which a reinforced glass visualisation plate is embedded. The glass plate represents the target measurement area upon which the foot is placed during gait. Preparation involves patterning the plantar aspect of the foot with a speckle pattern. A high-resolution camera is then used to capture a stream of images of the patterned foot throughout the stance phase. Images are processed using 2D DIC to determine strain across the plantar aspect during contact with the glass plate and subsequent analysis to determine clinically relevant descriptors related to the foot anatomy. The following sections describe the development of each of these aspects prior to evaluation in a feasibility study.

4.3.3 Platform Development

The platform is designed to enable 2D DIC analysis of the plantar aspect of the foot, which enables a single camera configuration, in contrast to use of 3D DIC methods (e.g. [30, 29] which require more complex multi-camera setups). To achieve successful 2D DIC the target object should remain planar during the trial otherwise corresponding errors in measurement must be considered [26]. Our platform therefore focuses data capture on the contact phases of gait, whilst on the glass plate, to ensure planar conditions are achieved.

Ideally the target region should almost fill the imaging field of view [26]. For a moving target, such as the plantar aspect of the foot during gait, the field of view may be slightly larger to ensure it is easy to correctly position the foot on entering stance. An appropriate depth of field to allow the target to remain in focus during the trial is also required [26]. To meet the system

requirements a 2 x 1 m walkway was created with an integrated 0.8 x 0.6 x 0.033 m reinforced glass plate to capture plantar stance images. Half the glass plate was set as the field of view, with the plate created larger than required for single foot analysis to consider future use for imaging of either foot.

Glass refraction was considered negligible based upon the outcomes of the calibration routine. In addition, reference and active stance images are subject to the same configuration and the differential between these images is used to calculate strain, thus minimising the effect of any residual distortion.

Selection of a camera and lens should allow the user to obtain the desired field of view, depth of field, frame rate and spatial resolution for clear imaging [26]. A frame rate should be determined that reduces the chance of large displacements taking place unrecorded between frames [26]. A single high-resolution webcam (1080 x 720p) operating at 30 fps was situated beneath the glass plate to meet these needs. The camera was positioned to maximise the field of view across the measurement area and provide a narrow depth of field centred on the top surface of the glass plate.

Diffuse lighting was directed at the underside of the glass plate to enhance speckle-skin contrast without introducing glare to ensure consistent pattern tracking [26]. During testing, room lighting was dimmed to minimise specular reflection.

The imaging system was calibrated using a multi-image chequerboard process to determine the real world image size for subsequent analysis (MATLAB [R2021a]). The calibration process (termed intrinsic calibration) determines and corrects for lens distortion for a single camera with a standard lens by transforming the real world points in x,y,z using a matrix of the determined camera parameters [32, 33, 34].

4.3.4 Pattern Application

The quality of DIC measurement relies upon application of a repeatable stochastic speckle pattern, for which speckle movement can be tracked and post analysis performed [26]. The selected pattern must consider speckle-pixel ratio, variance in pattern and pattern density to ensure it can be appropriately tracked [26].

To pattern the plantar aspect of the foot, a range of application methods were trialled, with selection criteria being 1) ease and speed of application to different foot shapes, 2) pattern quality after application 3) repeatability of the method. Methods included hand patterning,

spray patterning (commonly optimised for use in DIC [24, 23]) and temporary tattoo transfers (as employed in wearable electronic sensors [35]). A low ink transference rubber stamping method was selected because it offers quick, consistent and high quality patterning whilst being a relatively clean process compared to spraying techniques. This comprises of a 300 x 150 mm rubber stamp with a wooden base to prevent bowing during full weight transference onto the stamp. Indian ink was applied,as it is skin safe and has a low allergenic response, with a rubber roller to reduce the quantity of ink transferred to prevent pooling on the stamp. The stochastic speckle pattern used was computer generated using Correlated Solutions Speckle Generator [v1.0.5].

Patterns of varying speckle diameter and pattern density were trialled from 0.75 - 2 mm based on recommendations from best practice [26, 27], with a standardised pattern variation set at 75% for a stochastic distribution. Trialled speckle diameters were selected to meet machining requirements for stamp creation. To optimise the pattern for the output, 55 x 55 mm skin representative samples Smooth-On Ecoflex™ 00-30 with an embedded spandex layer were patterned to undergo strain testing. Tensile testing studies were conducted to expected peak mechanical plantar skin strains of 0.55, using an Instron® 5943. This strain was chosen in line with the mechanical properties of excised healthy and diabetic cadaveric plantar skin samples [36, 37]. This given strain should exceed peaks seen for surface strains of in-vivo tissue sufficiently to assess pattern tracking consistency. GOM Correlate 2020 [v2.0.1] was used to track pattern quality throughout the extension to peak strain. We considered the optimal pattern would be able to track to the peak strain implemented with a loss of 5% or fewer tracked points, as pattern degradation should be minimised to reduce decorrelation during analysis [26]. A 1.25 mm speckle with 75% density and variation of pattern, see Figure 4.3, was found to be optimal for the output and used to form the rubber stamp. Simplification of the speckle pattern application method was required to ensure ease of translation to potential clinical environments for DIC.

4.3.5 DIC Plantar Strain Analysis

A commericial DIC software package was used to perform the DIC post analysis of images and thus form a time series of strain maps for the plantar aspect of the foot (GOM Correlate). First, high-resolution surface technical strain maps were generated for the stance phase. Strain maps were then generated for each image frame captured, to provide a detailed picture of the variance

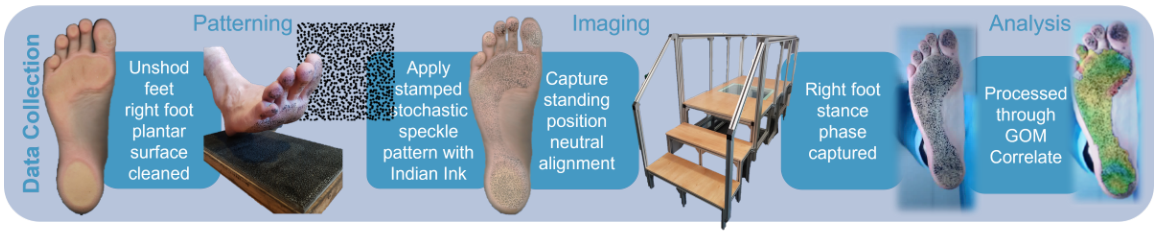

Figure 4.3: Visualisation of the data collection process for plantar surface strain assessment.

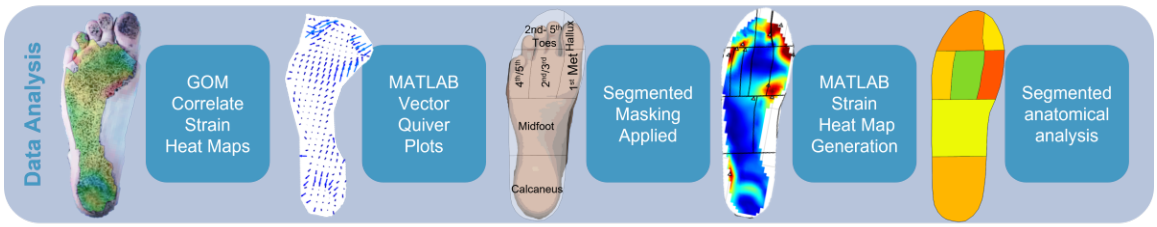

Figure 4.4: Visualisation of the data analysis process for plantar surface strain assessment.

of surface strain throughout individual phases of stance with respect to a neutral standing position. An equidistant point spread was applied across the surface of the strain maps to derive strain and positioning data sets for post-processing. Strain data within a 3 σ distribution from the mean were selected for export, to minimise outliers and artefacts caused by out of plane motion [26] from skewing the data distribution and display in the generated quiver and heatmap plots, as shown in Figure 4.4.

4.3.6 Regional Summary Analysis

The exported strain map data determined through DIC were then post-processed for visualisation and to derive summary metrics using custom scripts in mathematical analysis software (MATLAB). A seven region mask segmented with continual borders was linearly transformed and overlaid onto the reference images by a qualified orthotist using anatomical landmarks, as shown in Figure 4.4. Segmented masking of the plantar aspect enabled comparative analysis of strain across the foot and particularly in areas at high-risk of ulceration. 75% of plantar DFU occurs at the forefoot regions [38], with a near even concentration between the toes and metatarsal regions [13]. The defined regions were determined based on these known ulceration prevalent anatomical regions, in known regions of interest for DFU [39], to define regionalised surface

strain data. This is consistent with similar plantar masks used to report pressure in other systems such as Novel's® Automask which divides the foot into anatomically significant segments for zonal analysis [40]. The anatomical regions are segmented into the hindfoot, midfoot, individual metatarsal heads, hallux, second toe and combined third to fifth toes [40]. Initial masking was defined to cover these regions and divide the midfoot, which was then simplified to the chosen seven region mask when analysing data output to consider difficulty in mask tracking during gait. Through this segmented approach the highest recorded (peak) mean strain seen in one frame within stance phase and the averaged mean strain across all recorded frames in each region were determined.

4.3.7 Participant Study

A feasibility study was conducted to evaluate the efficacy of the proposed methodology. In particular it aimed to assess the ability of the experimental set-up to meet the requirements for effective data collection, analysis and the clinical needs outlined. The study was designed to use the DIC methodology to collect right foot single stance phase surface strain analysis of the plantar aspect of a subset of six non-diabetic participants, see Table. 6.1. Ethics were obtained through the University of Leeds Engineering and Physical Sciences joint Faculty Research Ethics Committee (LTMECH-001) to meet the requirements of testing. The experimental protocol for data collection is shown in Figure 4.3.

Each participant underwent the patterning process, which required the right foot to be wiped clean and then stamped using the low ink transference stamping method. Camera calibration was performed prior to each participant using the system. A reference image was taken to provide a baseline for the surface strain of the skin to be compared to following standing and walking. This image was captured when a full weighted neutral stationary standing position was adopted on the glass plate of the walkway. This alignment was chosen for the reference image instead of midstance to allow comparison in strain relative to a stationary position. It was also concluded that differing gait biomechanics and subsequent progression over the foot in stance would render it challenging to identify a neutral midstance position.

Following this a single step was taken from a standing start on to the glass at a self-selected normal walking speed and images were captured from the camera at 30 Hz.Three repeats were taken.

Table 4.1: Six participant profile data.

Gender	Weight	Shoe Size
3 Male 3 Female	61.6 - 96.9 kg	8-12 UK Male 5.5-7 UK Male

4.4 Results

All six participants completed the data collection process successfully. Figure 4.5 shows an example of a multi-frame heat map output generated by the DIC analysis software (GOM Correlate) throughout stance comparative to a neutral standing position. Figure 4.6 shows a single frame of data after post-processing to produce a strain quiver plot and segmented heatmap for region specific analysis. A variation in the number of frames to complete stance phase was seen across the participants due to variations in the biomechanics and speed of gait. In general, the magnitudes and direction of strain were observed to vary greatly across the aspect of the foot and throughout gait for each participant.

The regional analysis of mean strain and standard deviation for each frame of stance phase per participant was conducted. From this, the peak mean value that is seen in each anatomical region during stance was determined. Figure. 4.7 shows a graphical representation of the distribution of peak mean strain and standard deviation per region for each participant. Across the participants a relatively large standard deviation can be seen around the mean, showing the substantial spread of strains seen within localised regions during stance. Comparatively the range of peak mean strains is relatively consistent between the group. Although the distribution of strain is varied per participant a pattern can be seen in the colour spread with higher mean values often focused around the calcaneus and forefoot with lower means seen in the midfoot.

Figure. 4.8 shows the averaged mean strains occurring in each region throughout the entirety of stance. The segmented foot maps colour distribution shows in which regions the highest and lowest strain occurs respectively across all participants. The range of the averaged means is relatively low, but the distribution of strain across the plantar aspect between each participants is again pronounced. Similar participant strain distributions at the forefoot and calcaneus are seen between the peak mean and averaged means. It can be noted a few participants displayed moderate to high midfoot means comparative to the entire plantar aspect.

Variation in peak mean and averaged mean patterns for each participant reflects the variation in foot contact and loading during stance seen in the participant trials. Typical biomechanical

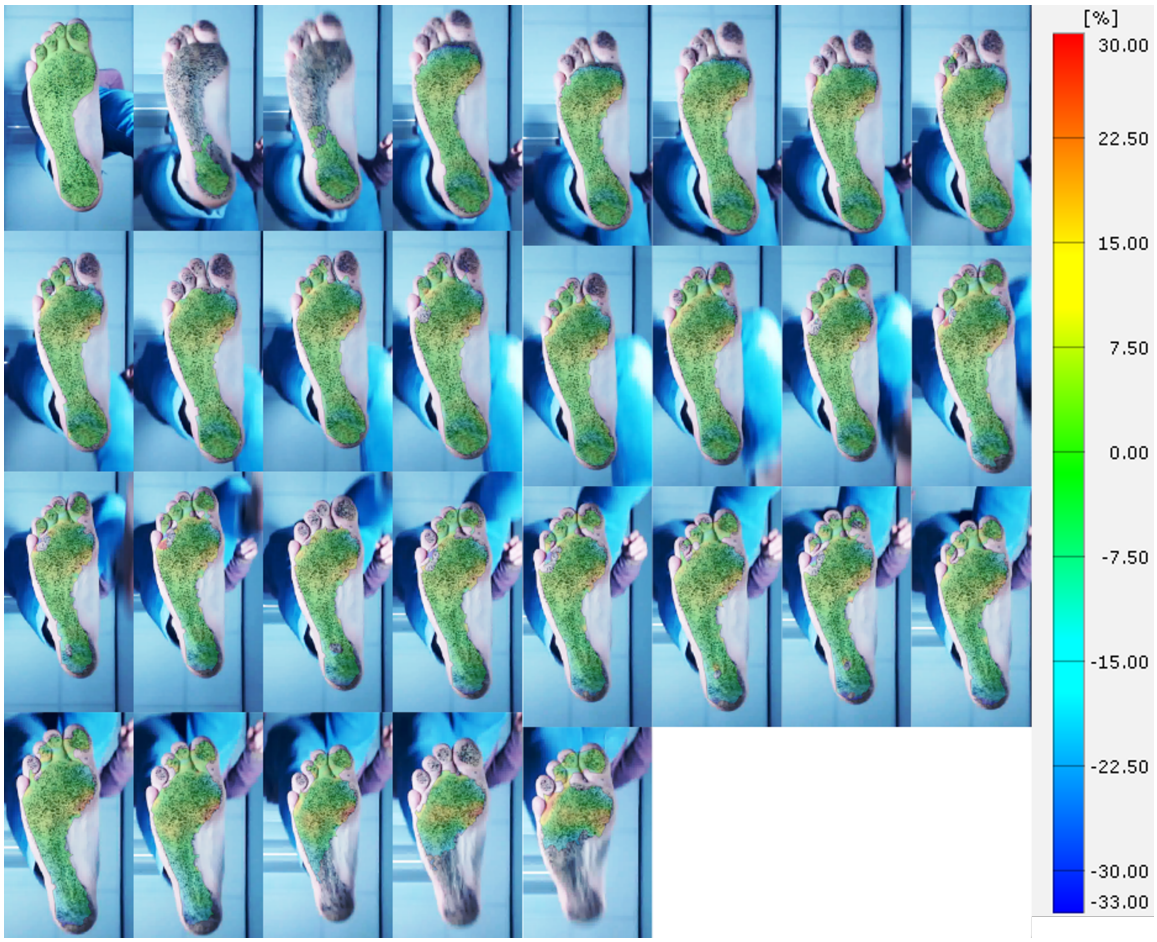

Figure 4.5: Example surface strain GOM Correlate heat map comparative to standing throughout stance.

positioning of the foot throughout stance is considered as progressing from the lateral hindfoot through to the medial forefoot [41], this is reflected in the higher strain regions for both peak and mean strain values generally across the participant group. Participant 2 did not register any DIC tracking in the hallux segment, as seen in Figures. 4.7,4.8. This indicates a potential lack of contact during stance phase within the plane of tracking.

4.5 Discussion

Our principle aim in this work was to develop a robust methodology to assess plantar surface skin strain in gait using DIC. This was developed and successfully trialled through a six-participant

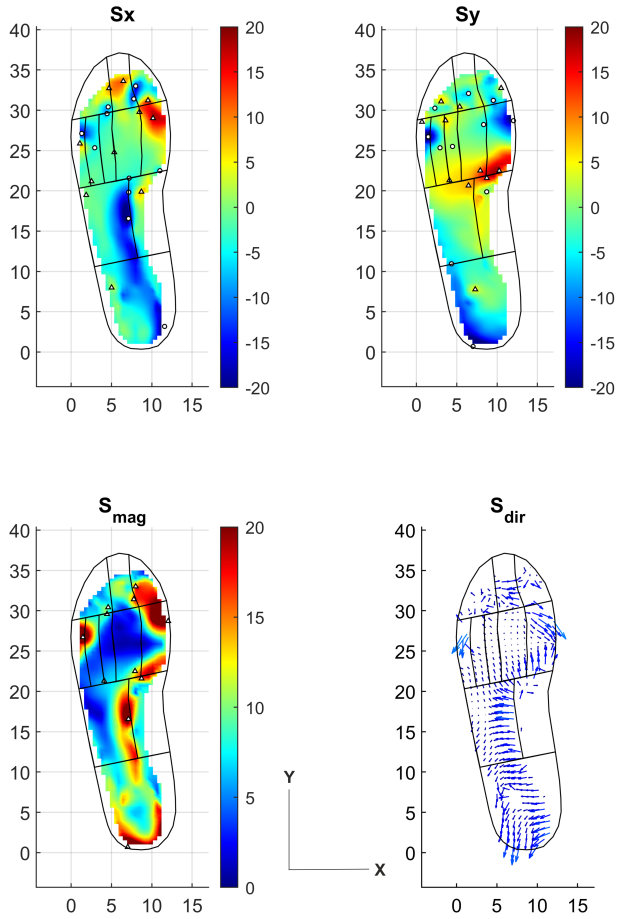

Figure 4.6: Example surface strain of a MATLAB generated heat map from one frame of stance. Showing strain independently in x and y, the combined magnitude and comparative quiver plot.

study of the stance phase in gait. Our emphasis was on developing methods appropriate for use in clinical practice. Using an ink stamp for the speckle pattern application allows for a quick and uniform patterning of the entire plantar aspect. The pattern is pre-determined and consistent which increases the reproducible nature of the method comparative to traditional pattern spraying techniques. It also affords comparatively clean application, which would be beneficial within both clinical and research environments. The walkway, camera and lighting set-up offered a regulated environment in which to conduct repeated studies under the same environmental conditions to meet the system requirements for successful DIC. By operating a 2D data capture method, there is a reduction in equipment required, which costs less and removes the need to run cameras in stereo. Removing the complex set-up 3D DIC requires for the stereo process, saves time and associated errors, making it much more accessible in the clinical environment.

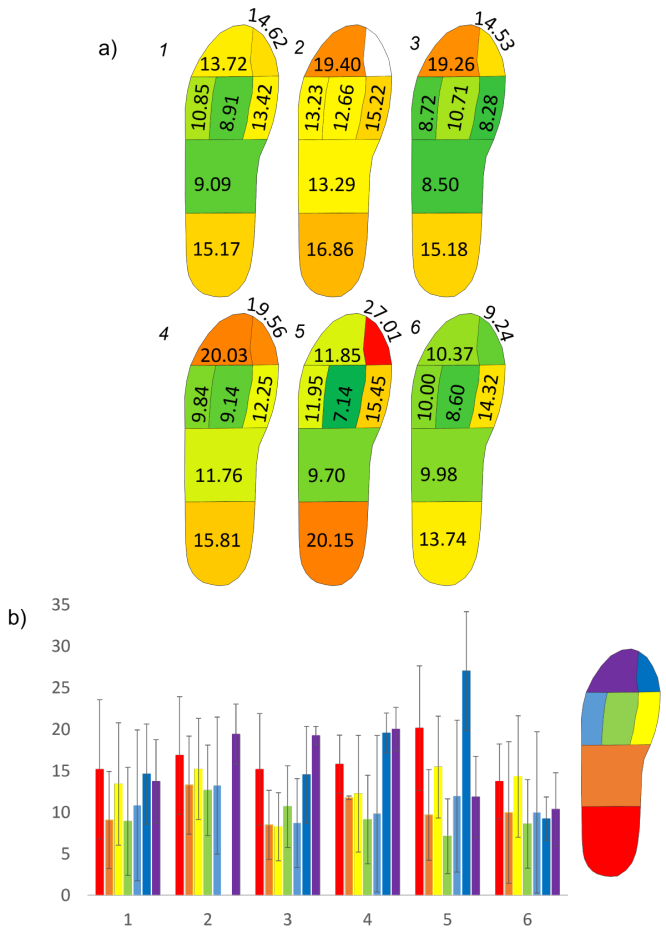

Figure 4.7: a) Peak mean values foot maps with a colour distribution overlay showing regions of highest (red) and lowest (green) strains. b) Peak mean strain per region and standard deviation throughout all frames of stance per participant.

Alongside the measurement methodology, it is equally important to consider the development of clinically relevant output measures. Whilst commercial DIC packages (e.g. GOM Correlate) provide a generalised overview of the strain, exporting the data for custom post-processing and visualisation extends the options for foot-specific clinically-focused analysis. This can help support further understanding of the properties of surface skin tribology to understand the contribution of strain to DFU formation. Applying the 3σ exclusion criteria to the data to exclude outliers brought about via out of plane motion being tracked [26], reduces the error inherent in 2D DIC processes in the data presented. Post-filtering of strain is typically used in DIC to reduce noise and outliers (e.g. due to edge effects occurring during foot shape changes) [26]. In these data, standard deviation filtering was applied (incorporated within the

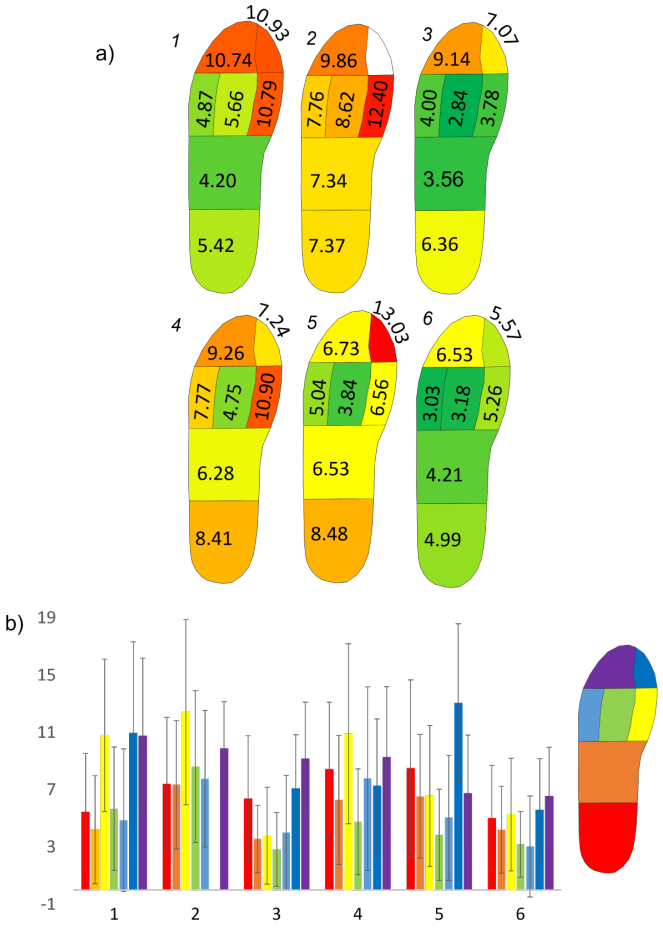

Figure 4.8: a) Averaged mean values foot maps with a colour distribution overlay showing regions of highest (red) and lowest (green) strains. b) Averaged mean strain per region and standard deviation throughout all frames of stance per participant.

GOM Correlate 2020 [v2.0.1] software) using a 3 sigma threshold. This was found by inspection to reduce edge noise without compromising the detail or magnitude of strain observed in the central plantar regions of interest.

Using segmented masking across the plantar aspect of the foot provides the ability to consolidate the wealth of temporal strain information obtained from this measurement process into specific regional plantar analyses, to work towards informing treatment approaches. This can inform both targeted analysis of anatomical locations during select phases of gait, such as during propulsion, and peak strains across the foot as a whole. Evaluating the peak mean allows us to identify the highest average strain applied to a specific region during stance phase. This will enable the researcher or clinician to assess if a participant is consistently experiencing a

high strain over a particular region, indicating potential sites at increased risk of DFU. Frame by frame temporal analysis provide the opportunity to assess if these peak means align with particular phases of stance, such as at terminal stance. Comparing this to the averaged mean can provide a baseline compared to standing of the strain experienced by the same region throughout stance. Comparatively, analysis of singular strain peaks, whilst offering indication of key areas of concern, may not see sustained high strains throughout the duration of gait or beyond a singular point on the plantar aspect. With the pressure-time integral has been highlighted as important when measuring direct pressures [42]. Both mean and peak data sets should be considered together to provide a rounded picture of the strain changes during stance. These outputs offer the potential for further tribological investigation into DFU formation in specified regions using strains derived from this DIC methodology.

The feasibility study provided valuable insight into the potential clinical relevance of this method. The segmented analysis showed moderate to high values of strain within the participant group at the midfoot. The midfoot experiences a lower DFU incidence than regions such as the 1st metatarsal head [13], and has reduced ground contact especially medially due to the longitudinal arch of the foot and likely to experience lower strains. Comparing the segmented values and the generated strain heat maps, it does not appear that high strains develop in the midfoot region. This implies that the mask, defined on the static reference image does not track as accurately on the corresponding frames during the stance phase of gait. It is likely that tissue strain and deformation of the foot can result in discrepancies with respect to the mask, for example the calcaneus may be represented in the midfoot region. This highlights a potential limitation of using a static mask during this part of the analysis process. Further development to ensure an adequate tracking mask is applied to each frame is necessary; for example adapting the masking for each frame is possible with the commercial Novel®Automask system and may provide a potential solution.

The principal limitation of this method is the inherent unshod nature of the foot meaning it cannot accurately recreate the shod environment. This aligns the method with pressure plate studies which are also conducted unshod and regularly used within clinical environments. However walking in footwear accounts for most steps taken daily and should be considered when determining how plantar tribology contributes to DFU formation. By undertaking 2D plantar DIC we can gain an understanding of the surface skin interaction with a set opposing surface, which can be used to inform further tribological study of the plantar foot during gait. However, the errors which arise from out of plane motion vary per participant and must be

adjusted by blanket data exclusion criteria, as it is impossible to account for the in errors arising from differing gait. 3D DIC is advantageous in this respect and offers the potential for dorsal strain mapping but requires assessment within footwear.

Within the six participant study a small number of frames were unable to be tracked during the mid-portion of stance phase. It was potentially due to the poor image quality of certain frames as a result of the camera lagging during operation. It was considered that sufficient information is provided on the remaining frames for this not to hinder the surface strain outputs seen in the regions analysis. An improved imaging system with a higher frame rate can readily improve this process without significant change to the technique. Considering the potential transference to clinical utility, patterning using low ink transfer stamping is suited to a time pressured and clean clinical environment. The current walkway may be unsuitable in limited space settings but could be reduced in size once clinical efficacy is determined.

Due to the scope of this study facets such as calluses were not explicitly considered. However, this is a feature that we look to address in future work, alongside other factors including skin hydration, as we work towards understanding how the skin condition affects the strain and subsequently understanding what this may mean for ulcer formation.

Following this developmental work, an extended participant study is warranted to further understand the data analyses required to effectively characterise the plantar skin strains and define normative ranges. Further research is required to understand the contribution of strain in the mechanical formation of DFU. These data will be used to inform tribological studies which replicate plantar interactions to assess skin degradation and deep tissue strain responses. Supporting this method with shod analysis techniques would also be beneficial and should be investigated further.

4.6 Conclusion

Using DIC to measure plantar surface shear strain by applying a computer-generated pattern using low ink transference stamping offers a process that is quick, relatively low mess, reliable and provides repeatable patterning, through the set nature of the stamp profile.

This technique, based on a 2D DIC method, allows for coherent tracking of strain on the plantar aspect of the foot during the frames of stance phase captured comparative to the reference image, as demonstrated in a six participants feasibility study. Temporal aspects of the stance phase were tracked from heel contact through to propulsive terminal stance. Compared to current

in shoe shear strain sensors, this technique offers high-resolution data of the plantar aspect of the foot throughout stance phase. This technique offers potential to become a clinically viable tool but further investigations are needed to support this method with more work required in understanding the role that strain plays in DFU formation.

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Chapter 5

STrain Analysis and Mapping of the Plantar Surface (STAMPS) - A Novel Technique of Plantar Load Analysis During Gait

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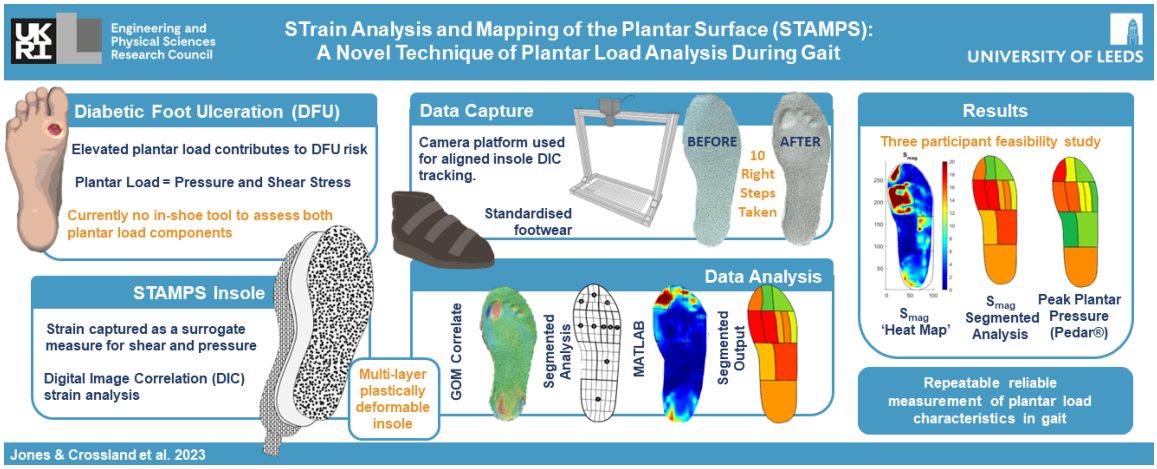

Figure 5.1: Graphical abstract for the paper STrain Analysis and Mapping of the Plantar Surface (STAMPS) - A Novel Technique of Plantar Load Analysis During Gait.

Preface

The focus of pressure as the sole metric for diabetic foot risk assessment in clinical environments is due to the availability of technology to allow for in-shoe data capture. Understanding of the contribution of shear within the shoe complex is required to work towards assessing mechanical formation of DFU. This study is designed to meet the research objective of method development of a technique to capture plantar strain within shod environments. This study embeds the DIC process used in Chapter 4 and is translated for use on a novel inlay for in shoe strain analysis. The inlay enables the capture of multiple steps to provide a cumulative strain output and was trialled on a small non-diabetic cohort, with strain analysis following the process detailed in Chapter 7. The pedar® [Novel GmbH, Munchen, Germany] pressure measurement insole was used to compare peak plantar pressures (PPP) and anatomical regional strains through applied masking.

This technique has now been expanded into a larger non-diabetic cohort trial and subsequent diabetic trial led by Alexander Jones, the joint first author of this study, in support of his medical doctorate with input provided by myself to support the studies. The non-diabetic study compares the use of the developed strain capture inlay with PPP recorded using the pedar® in-shoe pressure measurement system. The diabetic study repeats this process investigating relationships in strain and pressure seen in both low-risk and high-risk diabetic cohorts, whilst also investigating the strain response measured on the novel inlay during use with and without standardised pressure redistribution orthoses. These study whilst not directly contributing to this thesis, support the research objective of characterising plantar strain response changes under differing loading regimes and translates the technique to the diabetic population for analysis of differential strain response compared to non-diabetic populations.

5.1 Abstract

Diabetic foot ulceration is driven by peripheral neuropathy, resulting in abnormal foot biomechanics and elevated plantar load. Plantar load comprises normal pressure and tangential shear stress. Currently, there are no in-shoe devices measuring both components of plantar load. The STAMPS (STrain Analysis and Mapping of the Plantar Surface) system was developed to address this and utilises digital image correlation (DIC) to determine the strain sustained by a plastically deformable insole, providing an assessment of plantar load at the foot-surface interface during

gait.

STAMPS was developed as a multi-layered insole, comprising a deformable mid-layer, onto which a stochastic speckle pattern film is applied. A custom-built imaging platform is used to obtain high resolution pre- and post-walking images. Images are imported into commercially available DIC software [GOM Correlate, 2020] to obtain pointwise strain data. The strain and displacement data are exported and post-processed with custom analysis routines [MATLAB, Mathworks Inc.], to obtain the resultant global and regional peak strain (S_{MAG}), antero-posterior strain (S^{AP}) and medio-lateral strain (S^{ML}). To validate the core technique an experimental test process used a Universal Mechanical Tester (UMT) system [UMT TriboLab, Bruker] to apply controlled vertical and tangential load regimes to the proposed multi-layer insole. A pilot study was then conducted to assess the efficacy of using the STAMPS system to measure in-shoe plantar strain in three healthy participants. Each participant walked 10 steps on the STAMPS insole using a standardised shoe. They also walked 10 m in the same shoe using a plantar pressure measurement insole [Novel Pedar®] to record peak plantar pressure (PPP) as a gold-standard comparator.

The results of the experimental validation tests show that with increased normal force, at a constant shear distance, S_{MAG} increased in a linear fashion. Furthermore, they showed that with increased shear distance, at a constant force, S_{MAG} increased. The results of the pilot study found participant 1 demonstrated greatest S_{MAG} in the region toes 3-5 (15.31%). The highest mean S_{MAG} for participant 2 was at the hallux (29.31%). Participant 3 exhibited highest strain in the regions of the 1st and 2nd metatarsal heads (58.85% and 41.62% respectively). Increased PPP was strongly associated with increased S_{MAG} with a Spearman's correlation coefficient 0.673 ($p < 0.0001$).

This study has demonstrated the efficacy of a novel method to assess plantar load across the plantar surface of the foot. Experimental testing validated the sensitivity of the method to both normal pressure and tangential shear stress. This technique was successfully incorporated into the STAMPS insole to reliably measure and quantify the cumulative degree of strain sustained by a plastically deformable insole during a period of gait, which can be used to infer plantar loading patterns. Future work will explore how these measures relate to different pathologies, such as regions at risk of diabetic foot ulceration.

5.2 Introduction

Diabetic foot disease is a major global health concern. Over four hundred and sixty three million people live with diabetes worldwide [1], up to one quarter will develop a diabetic foot ulcer (DFU) and 5-8% will require a major amputation within one year [2]. Development of a DFU is a multifactorial process driven by diabetic peripheral neuropathy (DPN) and peripheral arterial disease. DPN causes sensory, motor and autonomic dysfunction. Motor dysfunction manifests as muscle weakness leading to structural abnormalities in the foot, including hammer toe, claw toe and hallux valgus resulting in elevated tissue stress [3]. In the presence of sensory neuropathy, this elevated tissue stress remains undetected, leading to persistent inflammation and eventual tissue breakdown [4]. Plantar load comprises vertical and tangential components [5]. The vertical component, plantar pressure, is well described in the literature. Patients with DPN exhibit elevated plantar pressure, with values commonly exceeding 600kPa, compared with 400–500 kPa in those without foot pathology [6, 7]. Utilising pressure assessment to guide offloading strategies has been shown to reduce DFU healing time and recurrence [8], and is recommended by the International Working Group for the Diabetic Foot (IWGDF) to guide offloading strategies [9]. Despite these guidelines, plantar pressure assessment is rarely performed outside of the research environment. This is in part due to the cost of the sensing devices and due to the time and expertise required to use them. Furthermore, whilst it has been demonstrated that those who develop DFUs often sustain elevated levels of plantar pressure, many do not, and there is often disparity between location of peak pressure and ulcer formation [10]. Shear stress forms the tangential component of plantar load. Friction between the foot-surface interface causes shear stress in both antero-posterior and medio-lateral axes acting perpendicular to the long axis of the foot [11]. Plantar shear stress was first described by Pollard et al. in 1983 [12], however due to the difficulty in its measurement, remains poorly understood [13].

The development of reliable technology to measure both plantar pressure and plantar shear stress has remained elusive, and no commercial platforms or wearable systems are available. Some centres have developed custom-made research platforms. The Cleveland clinic shear plate utilises an array of 80 tri-axial strain gauge sensors and has been used to measure shear and pressure in patients with diabetes [14]. However, as a sensing platform it is limited to barefoot measurements which do not reflect the typical stresses experienced in-shoe. A recent systematic review conducted by the authors investigating plantar shear stress assessment found 16 studies investigating shear stress in patients with diabetes [13], with only three studies performing

in-shoe analysis. Amemiya et al. [15], used individual tri-axial piezoelectric sensors affixed to the sole of the foot. However, the sensor's size prohibited assessment of the whole plantar surface, and as the sensors were not embedded within the insole they may act as foreign bodies. Lord et al. [16], embedded three resistive sensors within an insole, though this again lacked the capacity to measure pressure and shear throughout the plantar surface. We have previously presented evidence-based requirements for wearable systems to monitor plantar load in patients with diabetic foot disease [17]. Describing load measuring capabilities of $>$740 kPa for pressure and $>$140 kPa for shear, distribution of sensors across the plantar surface, a sensor maximum surface area of 10mm x 10mm and a sampling rate of no less than 50 Hz. In addition, sensors should be low profile and robust to maintain structural integrity in an environment subjected to significant load, changes in pH and temperature [17]. To date, no systems approaching these requirements have been developed.

In this paper we propose a novel solution to address the need for a plantar load device. The principle of our approach is to use a plastically deformable insole to capture the cumulative level of strain at the foot-surface interface and to quantify this using Digital Image Correlation (DIC) to track strain before and after a period of gait. DIC is an optical based technique utilised to measure the resultant displacement, strain and deformation of materials after exposure to different load regimes [18]. More commonly associated with material science, civil and aerospace engineering, DIC is increasingly being used with soft materials in the field of clinical biomechanics [19]. Studies have successfully demonstrated its application investigating strain of aortic tissue, cartilage and sclera [20, 21, 22]. It has recently been used to analyse strain on the plantar surface of the foot and found principle strain to be between 10-20% at the metatarsal heads during stance phase [23]. The process of DIC entails comparing an image of the object of interest prior to loading, with those after or during loading [18]. Image analysis algorithms then identify congruent blocks of pixels between the images to measure displacement or strain. If the structure lacks an inherent pattern to track, a stochastic speckle pattern is applied to the surface. DIC has several advantages over traditional sensing techniques. It is convenient and robust as it exploits conventional digital photography technology and does not require low vibration environments [24]. It also has the capability to deliver high spatial resolution defined by the size and spacing of the speckle pattern and camera resolution. In this work we present the STrain Analysis and Mapping of the Plantar Surface (STAMPS) system, an approach which harnesses DIC to measure and quantify the cumulative degree of shear strain sustained by a deformable insole during a period of gait, using this as the basis to infer plantar loading patterns. In System

Development we present development of the STAMPS approach, Experimental Evaluation of STAMPS then details experimental validation prior to a reported Pilot Study of STAMPS with healthy participants to show the efficacy of the technique. We conclude with a discussion considering relevant limitations, future development and application of STAMPS in the clinical domain.

5.3 System Development

5.3.1 Requirements and Concept

The aim of the STAMPS system is to achieve an insole that deforms plastically when subjected to representative plantar loading regimes and that this deformation can be reliably tracked using DIC. The insole is designed to be a single-use measurement device due to the nature of the permanent plastic deformation it incurs during use. Furthermore, the STAMPS insole should be capable of covering the full plantar surface across a range of shoe sizes and shapes, whilst remaining sufficiently 'low profile' that it avoids disrupting natural gait patterns and causing dorsal complications.

To meet these aims, the overall concept of STAMPS is to fabricate a custom shoe insole and combine with an imaging platform, DIC workflow and post-hoc analysis routines, to determine personalised metrics on plantar strain. The STAMPs insole forms the core of this concept and comprises a multi-layered sheet, as shown in Figure 5.2, which can be cut to a desired size and shape. The mid-layer provides the deformable element of the insole upon which is a thin speckle-patterned film, to provide a trackable surface for DIC. A base layer acts as a supporting 'scaffold' to prevent distortion of the insole during fitting and retrieval. After pre-imaging, the insole is placed into a shoe and used over a series of gait cycles after which it is removed and processed with DIC to extract a strain map across the surface. In this context, the strain is a product of both plantar pressure and plantar shear stress. Thus, the level of strain, as measured by DIC, is the cumulative effect of plantar pressure and shear stress during the period of walking. Post-hoc analysis can then segment data into anatomical regions and create summary metrics for comparative studies. The following subsections detail how each aspect of the STAMPS concept was developed to realise the implementation for practical use.

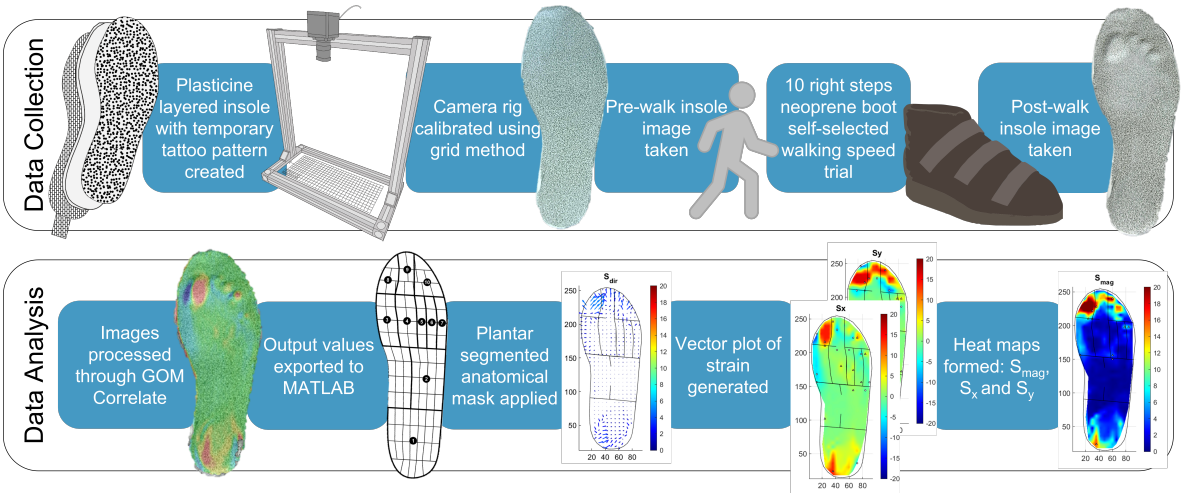

Figure 5.2: A schematic showing the process of STAMPS data collection and analysis, from initial manufacture through to generation of strain maps and associated summary metrics.

5.3.2 Insole Fabrication

The insole was developed by first identifying an appropriate material for the deformable mid-layer. Preliminary experimentation found that industrial plasticine, an oil-mixed clay composite, provides the requisite mechanical behaviour of plastically deforming under the expected plantar loads found at the foot-surface interface, exhibiting minimal creep and amenable to being formed into regulated laminar sheets which can be cut to a desired size. It has been used extensively to model plastic deformation of metals and flow behaviour during rolling and extrusion due to these properties[25]. Chijiwa et al. [26], demonstrated that temperature affects the yield stress of plasticine and that it undergoes a period of hardening during the first 24 hours after moulding. After 24 hours, time had minimal effect on the stress-strain relationship [26]. Accordingly, STAMPS insoles were made at least 24 hours prior to use, and maintained at a constant temperature of 15 degrees prior to use. A commercial clay-roller [CT-500, North Star Polaris] was used to obtain a controlled 5mm thick sheet for fabrication of the complete insole. This rolling process reshaped the bulk plasticine block into laminar form by rolling from an initial 'thick' setting (nominal 10 mm) towards a target thickness (5 mm) in five stages, progressively reducing thickness in each. A cross-patterned nylon mesh (pitch 2 mm) was selected as the insole backing to provide a low-profile strain limiting layer. This was affixed to the plasticine layer by including it in the final stage of the rolling process. The mesh extends posteriorly in a tab to prevent adherence to the footwear and allow removal without further deformation, from

footwear (see Figure 5.2).

The speckle-patterned film layer needs to provide a high contrast image while remaining stable over repeated cycles of loading. Our solution was informed by Quino et al. [27], who describe techniques for applying DIC speckle patterns for challenging scenarios. Accordingly, we printed a speckle pattern onto 'temporary tattoo' film [MEDIA-TATTOO-3T, Silhouette America, Inc.] with a thickness of 180 μm using a commercial inkjet printer. The tattoo film is then applied to the upper surface of the laminar plasticine mid-layer, achieving strong adherence through the thin water-activated adhesive backing. This approach enables repeatable use of standardised high-resolution speckle patterns while having negligible influence on the overall deformation mechanics of the insole.

As a final stage, a standardised sized template and scalpel is used to precisely cut insoles from a laminar sheet without disruption of the pattern or deformable layer. A dusting of talcum powder is applied to the patterned surface after the adhesive has dried and before storage to mitigate against unwanted adherence. A fine layer is applied that does not interfere with DIC tracking or strain analysis.

5.3.3 DIC Methodology

The basis of effective DIC is an appropriately patterned sample coupled with an imaging system which can capture sufficiently detailed information for subsequent processing.18 To meet these demands, a custom digital-camera platform was built to provide a repeatable means of imaging insoles of varying size, as shown in Figure 1. The camera-platform is based on a USB camera [Ultra HD IMX317 USB Camera, ELP Ltd.] using a high-quality charge coupled device and fixed focus lens to obtain 4K (3840x2160) images. The camera is fixed perpendicular to the imaging surface at a height to ensure the desired field of view is captured entirely. The MATLAB camera toolbox was used to calibrate the system by identifying the intrinsic camera parameters in this configuration. The same toolbox was then used in a custom script to capture and return undistorted images of insoles for subsequent DIC analysis [28].

Stochastic speckle patterns help to standardise the DIC process across multiple insoles, avoiding the variability inherent in manual 'spray patterning' techniques. Patterns are defined in terms of parameters of speckle size, speckle density and variability. The DIC process then determines strain based on tracking 'subsets' of the patterned region of interest (ROI) which must contain at least 3 speckles. Subsets are distributed across the ROI according to the DICs

'step size' which allows some overlap between subsets and effectively defines the resolution of the resultant strain data [29]. For this application these pattern and DIC parameters were selected based on recommendations for best practice in the literature [29, 30]. Thus, we used a commercial pattern generator [Correlated Solutions Inc.] to generate a speckle pattern with 65% speckle density, speckle size of 0.8 mm and pattern variation of 75%. The associated DIC parameters were a 40 pixel subset and 12 pixel step-size. With the imaging configuration described above, this provides speckles of 9 pixels (fitting for robust tracking) with an average of 15 speckles per subset. This provides high resolution and attenuates noise without a prohibitive computation time [29]. The DIC process was implemented using commercially available DIC software (GOM correlate, 2020). Pre- and post-images of each insole were imported into the software and used to generate a strain map using the above parameters. The resultant pointwise strain data were then exported into a CSV data file which defined ε_x and ε_y for each node of a 1 mm spaced grid for subsequent segmentation and post processing.

5.3.4 Segmentation and Post Processing

A custom analysis script [MATLAB, Mathworks] was developed to post-process the computed strain data, providing opportunity for clinically-specific analysis and visualisation. Firstly, the plantar strain data are pre-processed to remove outliers caused by artefacts in the physical measurement process (e.g. due to disruption of the insole edges) or in the DIC analysis.

The strain map is then segmented by dividing the plantar aspect into 10 regions according to a mask definition employed in commercial plantar analysis software [PEDAR INC]: Heel, midfoot, 1st Metatarsal Head (MTH), 2nd MTH, 3rd MTH, 4th MTH, 5th MTH, hallux, second toe, toes 3-5 [31]. The mask is scaled and rotated to fit the specific plantar data (i.e. to accommodate insole size variance) after which the strain data are allocated into each region. The segmented data are aligned with standard anatomical axes (medio-lateral in X and antero-posterior in Y), as shown in Figure 5.2. After segmentation, summary metrics are calculated for each region, and the overall plantar space, to identify peak strains in the medio-lateral axis (min S_{ML}, max S_{ML}), antero-posterior axis (min S_{AP}, max S_{AP}) and strain magnitude (max S_{MAG}). These summary data were exported for statistical analysis during each study. In conjunction, the segmented strain data were used to generate colour-mapped surface plots of S_{ML}, S_{AL}, S_{MAG} showing peak locations (see Figure 5.2).

5.4 Experimental Evaluation of STAMPS

To investigate the efficacy of using STAMPS as a measurement tool, and to characterise its operating behaviour, experimental testing was conducted. The aim of the testing was to evaluate the effects of environmental conditions (temperature), operating conditions (varying load regimes of pressure, shear stress, load cycles) and insole thickness. The outcomes from this testing were then used to inform the methods employed in the pilot study reported in Pilot Study of STAMPS.

5.4.1 Methods

An experimental test process was developed by using a Universal Mechanical Tester (UMT) system [UMT TriboLab, Bruker] to apply controlled load regimes to insole samples, as shown in Figure 5.3. The UMT comprises a load-controlled indenter (Z axis) and a reciprocating plate (X axis) driven by position-controlled micro-positioning stages. The UMT measures load in each axis at 100 Hz during movement. Insole samples were fabricated as described above and held on the reciprocating plate using a custom 3D printed fixture. The indenter was fitted with a 3D printed hemi-ellipsoidal cap (35 mm diameter) to approximate the dimensions of the 1st MTH and overlying soft tissue. Scripts were written for the UMT to define the desired load regimes. The applied load regimes were selected based on the anticipated loads at the foot-surface interface. This was informed by Brady et al. [32] who performed compressive testing of foot specimens with loads between 20 and 30 N. The test setup was maintained at room temperature (22 °C) throughout the process.

An experimental matrix, summarised in Table 5.1, was developed to investigate the various conditions' experimental parameters around a baseline configuration. Three repeats were conducted for each configuration. Normal and shear loading were defined as a displacement based on preliminary testing to produce an equivalent range of strains to those observed with in-shoe testing. Images were taken of each sample pre and post each loading regime (as defined in Table 5.1), for subsequent DIC analysis. Each sample was analysed using the DIC methodology described in System Development to obtain a strain map and associated summary metrics of the strain minima and maxima, as shown in Figure 5.3. These were then collated and processed with statistical analyses.

Table 5.1: The testing matrix of experimental conditions used to conduct UMT studies for the experimental evaluation of STAMPS.

Parameter Varied	Range	Secondary Parameter	Cycles
Normal Load	[10, 20, 30] N	Shear Load	1-10 Cycles
Shear Load	[0, 0.75, 1, 1.25] mm	Normal Load	
No. Load Cycles	[1, 2, 3, 4, 5, 10] cycles		
Insole Thickness	[4, 5, 6] mm		
Temperature	[5, 10, 20] °C		
Baseline: Normal Load = 20 N, Shear Load = 1 mm, Thickness = 5 mm, Room Temperature = 22 °C			

5.4.2 Results

All test configurations were conducted and processed using the DIC methodology successfully. The results are summarised in Table 5.2 and Figure 5.4. The results show with increased normal force, at a constant shear distance, S_{MAG} increased in a linear fashion (Figure 5.4). Furthermore, they showed that with increased shear distance, at a constant force, S_{MAG} increased (Figure 5.4). The effect was found at up to 1 mm of shear with 20 N of normal force, at 1.25 mm of shear, no further increase was noted. The mean coefficient of variation across tested applied force and strain values with sample thickness 5 mm at a constant temperature was 7.29%. S_{MAG} was also found to increase in a linear fashion with increased number of cycles.

The results were used to inform a number of parameters for the pilot study. Increased temperature increased S_{MAG} at a constant applied pressure and shear distance; furthermore, lower temperatures (<5 °C) were found to alter the adhesive properties of the temporary tattoo film. Therefore, insoles were subsequently maintained at a constant temperature of 15 °C. Sample thickness had no influence on S_{MAG}, this suggests the minimal variation in thickness of insole caused by manually rolling will not affect the results. Outcomes were consistent and pattern integrity maintained to ten steps. The results also validate the technique as a robust method to assess changes in normal force and shear stress.

5.5 Pilot Study of STAMPS

A pilot study was conducted to assess the efficacy of using the STAMPS system to measure in-shoe plantar strain in healthy participants.

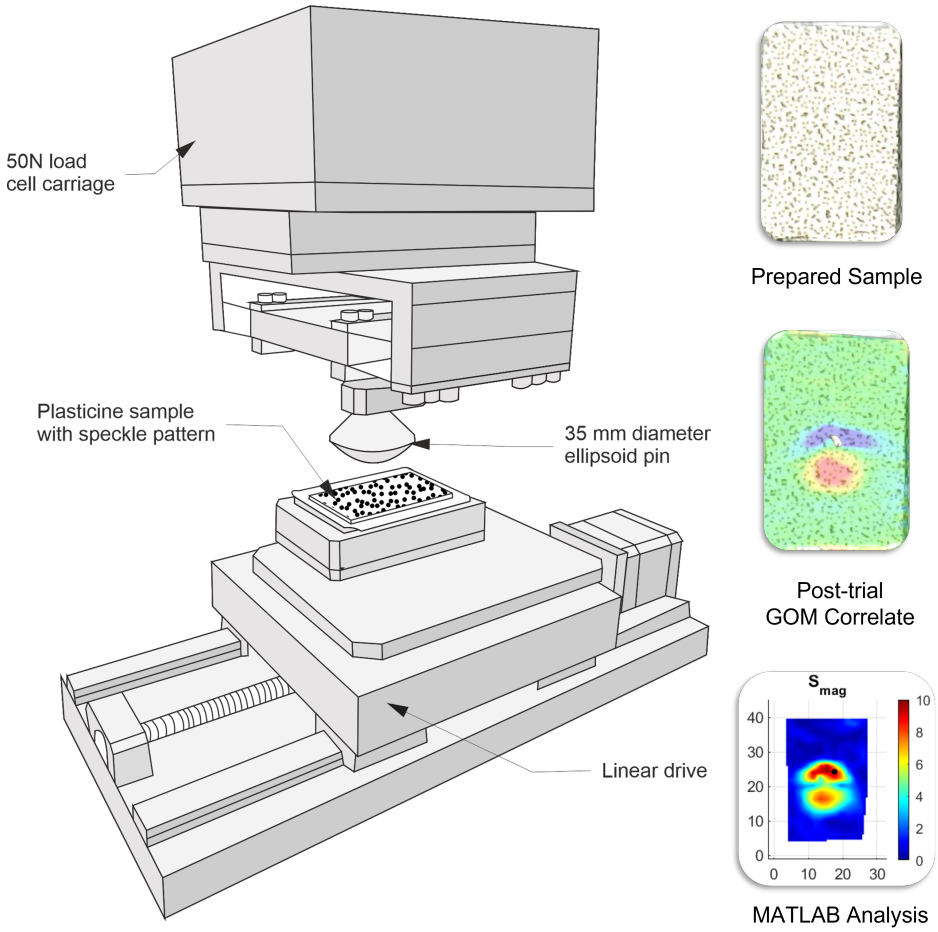

Figure 5.3: A schematic depicting the UMT [Tribolab, Bruker] configuration used in the experimental evaluation studies and showing an example of the data processing pathway of a single sample.

5.5.1 Methods

Ethical approval was obtained from the University of Leeds Ethics committee to conduct the study (LTMECH-005). Eligible participants were age >18 years and capable of walking unaided for 50 metres. Participants were excluded if they had a diagnosis of diabetes mellitus, major or minor lower limb amputation, or significant comorbidities associated with mobility or foot health. Prior to assessment, participants read the participant information sheet and provided written consent. Demographic data, including weight were recorded.

Participant shoe size was measured and the correctly sized supportive neoprene boot [Ninewells Boot, Chaneco inc.] was used. A 'before' image was taken of the appropriately sized

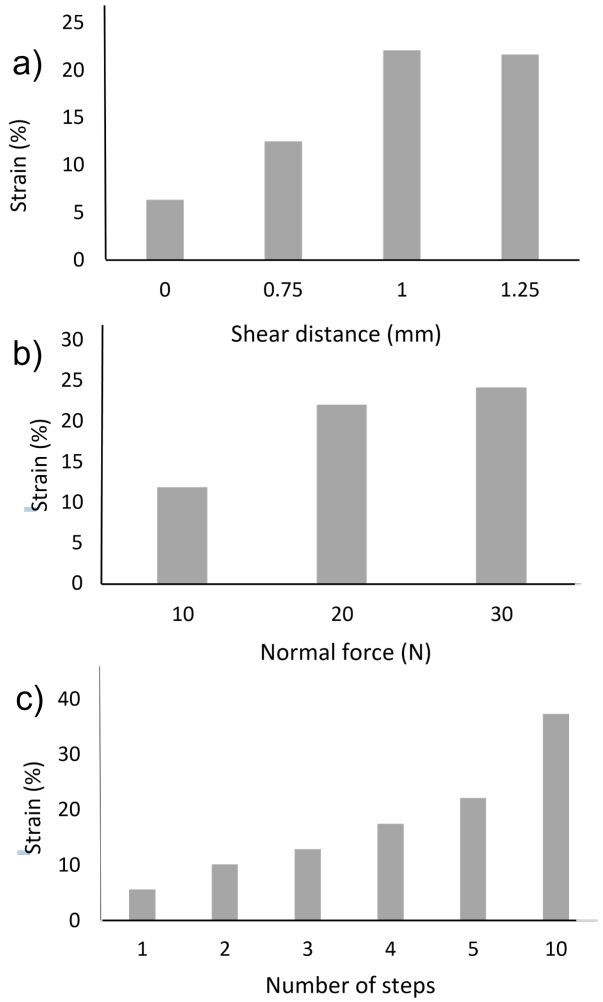

Figure 5.4: Results of the UMT evaluation studies showing the strain recorded for varying degrees of a) shear distance b) normal force and c) steps applied to the samples.

STAMP insole. This was inserted into the right shoe of the participant. A similarly sized insole was inserted into the left shoe to prevent a discrepancy in insole depth and subsequent alteration of gait. Participants were asked to walk 20 steps along a flat surface, ensuring 10 steps were taken with the right foot at a self-selected, normal walking speed. The insole was removed and an 'after' image was taken. This process was repeated three times. Following walking assessments with the STAMPS insole, walking assessments were performed using the pedar® [Novel GmbH, Munchen, Germany] in-shoe plantar pressure measurement system. Pressure data was compared with strain data, as measured by the STAMPS system to ascertain validity. No validated in-shoe shear system currently exists and therefore results are not able to be compared with validated

Table 5.2: Collated results from UMT evaluation studies showing the effect of force, shear distance, sample thickness, temperature and number of steps on S_{MAG} (%).

Force (N)	Shear Distance (mm)	Sample Thickness (mm)	Temperature (°C)	Number of Steps					
				1	2	3	4	5	10
				Effect of Shear Distance S_{MAG}					
10	1	5	22	3.10	4.89	6.98	9.67	11.94	16.24
20	0	5	22	4.95				6.35	7.03
20	0.75	5	22	4.66				12.54	23.44
20	1	5	22	5.52				22.08	37.27
20	1.25	5	22	6.00				21.66	32.61
30	1	5	22	7.36				24.21	40.41
				Effect of Sample Thickness on S_{MAG}					
20	0	4	22	5.01				6.49	7.74
20	0	5	22	4.95				6.35	7.03
20	0	6	22	6.69				8.78	10.22
20	1	4	22	5.32				18.56	31.67
20	1	5	22	5.52				22.08	37.27
20	1	6	22	5.22				19.99	28.63
				Effect of Temperature on S_{MAG}					
20	0.75	5	5	3.72				6.14	8.41
20	0.75	5	10	4.30				6.81	8.37
20	0.75	5	20	4.11				5.84	11.50
20	1.25	5	5	3.60				5.93	7.31
20	1.25	5	10	3.15				6.79	14.62
20	1.25	5	20	4.54				13.21	21.42

in-shoe shear data. Participants were required to walk a distance of 10 m along the same flat surface at their self-selected, normal walking speed [33]. This process was repeated three times. Outcomes of interest were overall plantar aspect and regional values for S_{MAG}, S_{ML}, S_{AP}, peak plantar pressure and pressure time integral.

5.5.2 Statistical Analysis

Data were analysed using SPSS statistical software [Version 26, IBM Corp, Chicago, USA]. The strain map was segmented into a mask containing ten regions: Heel, midfoot, 1st MTH, 2nd

MTH, 3rd MTH, 4th MTH, 5th MTH, hallux, second toe and toes 3-5 [31]. The peak S_{MAG}, S_{ML}, S_{AP}, for each region of interest and the total plantar surface was extracted for the STAMPS insole. Peak plantar pressure (PPP) and pressure time integral (PTI) for each region and of the total plantar surface were extracted via the multimask application [Novel, GmbH Munchen, Germany], using the previously described mask, for pedar®. The Shapiro-Wilk test was used to test for normality of continuous variables [34]. Pearson's correlation coefficient or Spearman's rho was used as appropriate to assess the relationship between S_{MAG}, PPP and PTI. A significant relationship was determined if $r > 0.4$ and $p < 0.05$. To establish repeatability, the coefficients of variation (CV) of PPP and S_{MAG} were calculated for each region, the mean value of CV was calculated for each subject [15].

5.5.3 Results

Designed as a proof concept study three participants were recruited [35], all provided informed consent, with characteristics summarised in Table 5.3. Regional S_{MAG} and PPP data for each trial are shown in Figure 5.5. The results demonstrate different strain patterns between individuals, which are consistent between trials (Figure 5.6).

Table 5.3: Key characteristics of the pilot study participants.

Participant Number	Gender	Age (Years)	Height (cm)	Weight (kg)	Shoe Size (UK)	Foot Pathology
1	M	41	175	75	10	
2	F	28	175	67.5	8	Hallux callus
3	M	31	173	74	8	1st MTH callus

Participant 1 demonstrated greatest S_{MAG} in the region toes 3-5 (15.31%). The area of greatest PPP was the hallux (308.1 kPa). The highest mean S_{MAG} for participant 2 was at the hallux (29.31%), with high areas of strain also noted at the heel (16.40%) and region of toes 3-5 (19.28%). The regions of the hallux and heel were also the regions with greatest PPP (370.9 kPa and 403.6 kPa respectively). Participant 3 showed a different strain pattern, with the highest mean S_{MAG} identified at the 1st and 2nd metatarsal heads (58.85% and 41.62% respectively). In contrast to participants 1 and 2, very little strain was found in the region of toes 3-5, and again unlike participants 1 and 2, the region of the heel demonstrated relatively low strain compared with the rest of the plantar surface. The highest PPP was found at the hallux (407.5 kPa), with relatively high pressures at the 1st and 2nd metatarsal heads (331.1 kPa and 333.7 kPa

respectively). Again, areas of high strain were found in the absence of high PPP, most notably in the region of the lateral midfoot. Strain patterns were consistent across the three walking assessments for each individual with a mean CV of 26.4%. The mean CV for PPP was 13.0%.

The relationship between S_{MAG} and PPP is shown in Figure 5.7. PPP was normally distributed; however S_{MAG} was not, and therefore Spearman's rho was used to assess the relationship between variables. Increased PPP was strongly associated with increased S_{MAG}; Spearman's correlation coefficient 0.673 ($p < 0.0001$). Increased PTI was also associated with increased S_{MAG}, Spearman's correlation coefficient 0.653 ($p < 0.0001$).

5.6 Discussion

Development of a low cost and time efficient in-shoe system to measure plantar shear stress and plantar pressure will aid risk assessment and guide treatment strategies for prevention and management of DFUs. As our recent systematic review has shown, few studies describe systems for in-shoe plantar shear stress assessment and no commercial devices have been developed [13]. Plantar pressure assessment is recommended in the IWGDF guidelines for the prevention of DFUs [9], however pressure assessment alone is a poor predictor for DFU development in prospective studies [6]. Furthermore, there is only a weak association between area of elevated plantar pressure and site of ulceration [10]. As such there is a requirement for in-shoe systems measuring both plantar pressure and plantar shear stress to determine the contribution of shear stress to DFU development and deterioration. This study reports on a novel technique developed for the measurement of plantar load at the foot-surface interface. The results of the UMT tests support the hypothesis that the strain of the plasticine insole, measured using DIC, occurs as result of normal pressure and tangential shear stress. Exposure to increased levels of normal force and increased shear distance resulted in elevated levels of strain. Strain plateaued above a shear distance of >1 mm due to the loading profile of UMT, which results in point loading and translation. This creates adverse distortion of the pattern, not seen in loading during gait. Consequently, this defined the UMT test regime. Furthermore, it is shown to be repeatable, with a coefficient of variation of 7.29%.

The method described contrasts with the trend in plantar sensing technology. Strain-gauge systems [11, 14, 36, 37, 38], piezoelectric transducers [39], magnetic resistive transducers [16], optical methods and microstrip antennas all rely upon sophisticated yet costly sensing technology to provide real-time shear stress data. The STAMPS system provides an alternative approach to

	Anatomical Region	Trial 1 Peak S_{MAG} (%)	Trial 2 Peak S_{MAG} (%)	Trial 3 Peak S_{MAG} (%)	Mean Peak S_{MAG} (%)	CV (%)	PPP (kPa)	Peak S_{MAG}	PPP
P01	Whole foot	26.28	12.52	11.69	16.83	39.8	314.1		
	Hallux	10.89	8.48	11.69	10.35	13.2	308.1		
	2nd toe	3.27	4.87	5.83	4.66	22.6	141.8		
	Toes 3-5	26.28	8.76	10.90	15.31	50.9	132.1		
	MTH1	4.33	3.70	4.41	4.15	7.6	113.4		
	MTH2	4.53	5.33	3.87	4.58	13.1	229.9		
	MTH3	5.28	6.36	3.65	5.10	21.9	198.2		
	MTH4	7.52	5.00	3.26	5.26	33.2	196.0		
	MTH5	11.15	5.28	4.80	7.08	40.8	133.4		
	Midfoot (lateral)	5.53	5.47	5.53	5.51	0.5	124.2		
	Midfoot (medial)	2.05	2.99	1.22	2.08	34.6	47.2		
	Heel	9.81	12.52	5.67	9.33	30.2	275.4		
P02	Whole foot	20.62	36.82	30.49	29.31	22.7	414.5		
	Hallux	20.62	36.82	30.49	29.31	22.7	370.9		
	2nd toe	10.93	17.57	10.66	13.05	24.5	328.4		
	Toes 3-5	19.02	28.19	10.64	19.28	37.2	188.3		
	MTH1	11.30	8.22	4.83	8.12	32.5	261.1		
	MTH2	4.12	4.33	4.72	4.39	5.6	214.2		
	MTH3	2.66	4.26	2.33	3.08	27.4	162.0		
	MTH4	9.05	7.95	2.35	6.45	45.5	162.0		
	MTH5	4.84	7.18	3.21	5.07	32.1	84.5		
	Midfoot (lateral)	2.50	1.76	2.94	2.40	20.4	57.7		
	Midfoot (medial)	3.30	4.17	2.40	3.29	22.0	31.3		
	Heel	12.66	16.36	20.18	16.40	18.7	403.6		
P03	Whole foot	49.92	64.61	62.03	58.85	10.9	407.6		
	Hallux	40.20	14.57	14.52	23.10	52.4	407.5		
	2nd toe	24.89	13.17	6.31	14.79	51.9	171.0		
	Toes 3-5	7.28	3.80	4.92	5.33	27.1	105.5		
	MTH1	49.92	64.61	62.03	58.85	10.9	331.1		
	MTH2	45.80	37.89	41.16	41.62	7.8	333.7		
	MTH3	10.10	12.57	21.86	14.84	34.1	177.5		
	MTH4	8.14	19.83	27.64	18.54	43.2	177.5		
	MTH5	4.80	8.84	7.75	7.13	23.9	72.1		
	Midfoot (lateral)	24.84	23.54	24.12	24.17	2.2	108.8		
	Midfoot (medial)	10.88	3.46	3.03	5.79	62.2	42.8		
	Heel	16.73	17.17	16.01	16.64	2.9	287.8		

Figure 5.5: A summary of the plantar loading data showing the regional peak Strain Magnitude (S_{MAG}) and Peak Plantar Pressure (PPP) data, together with corresponding graphical representation of the regional data for each pilot study participant (P01-P03).

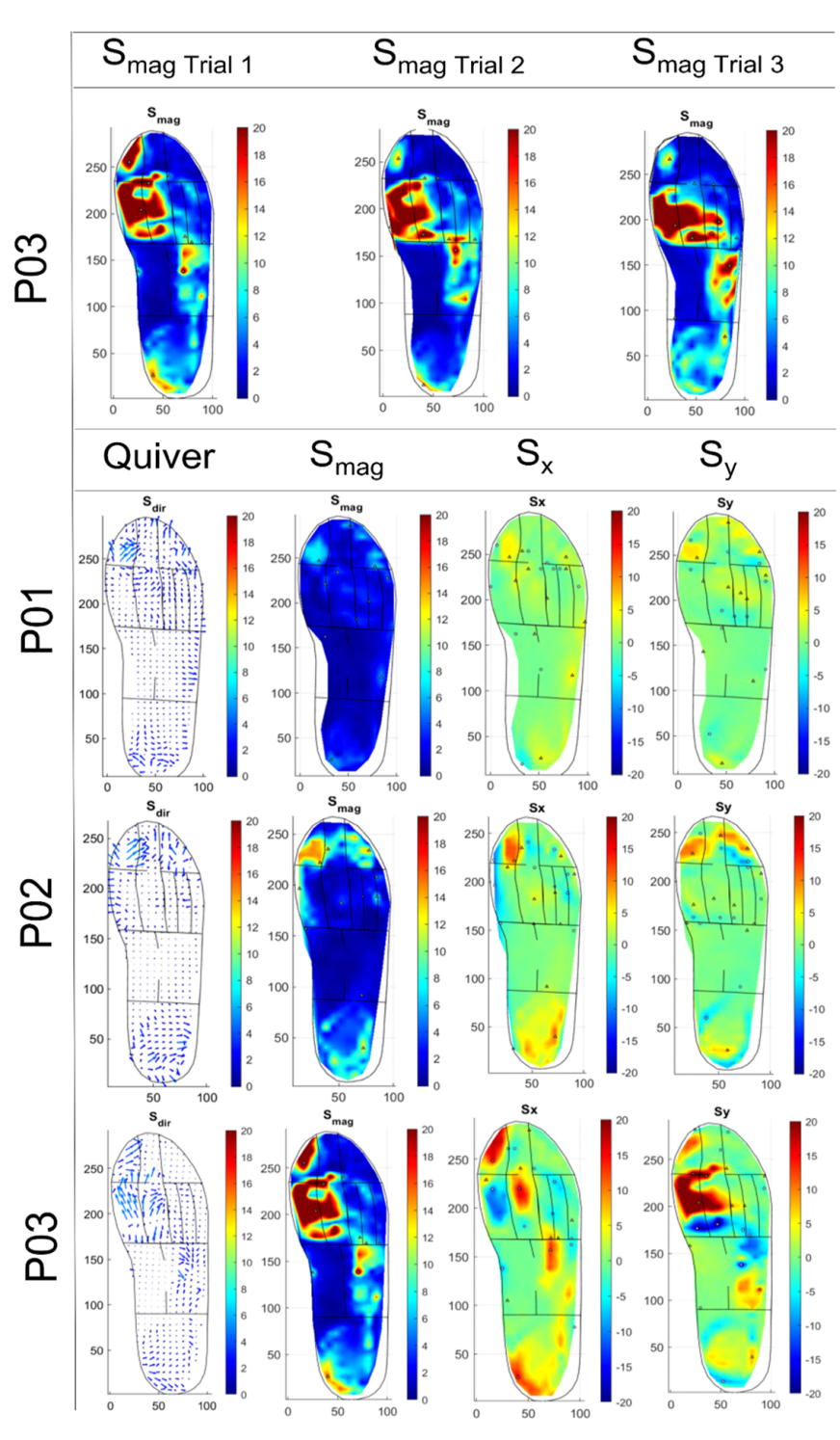

Figure 5.6: Top: heat maps showing the resultant strain magnitude S_{MAG} for P03 across three repeated trials as a representative example showing consistency of the measurement technique. Bottom: representative examples of strain data for each participant (P01-P03), shown as quiver plots for strain direction (S_x, S_y) and heat maps for strain magnitude (S_{MAG}) and strain components (S_x and S_y). The XY axes show the insole size in mm, the colour-map scale shows the measured strain values.

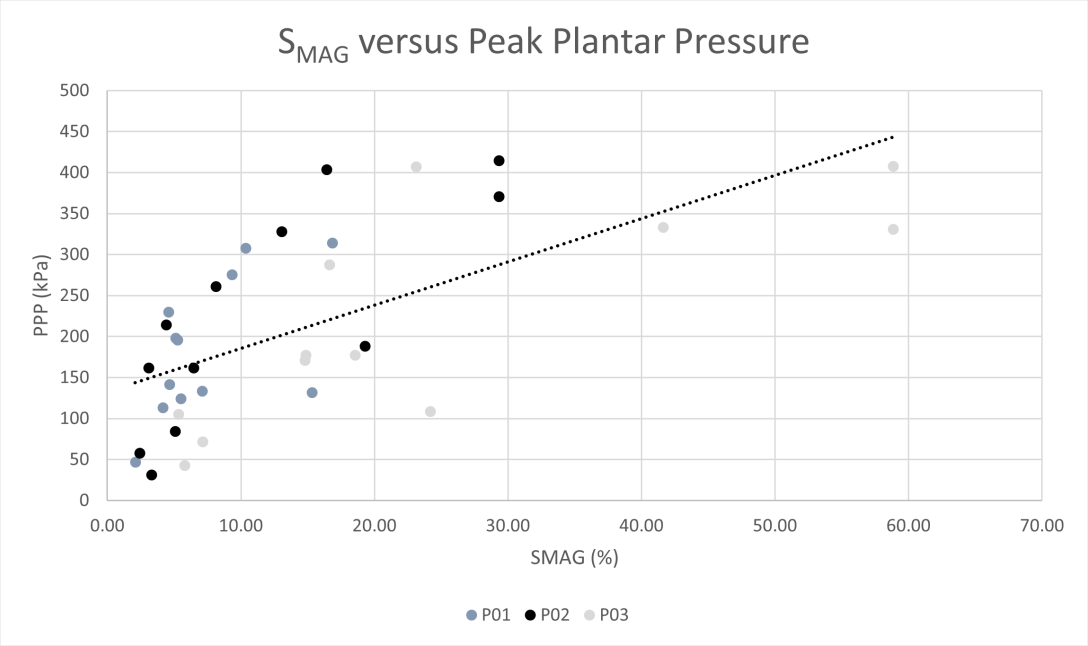

Figure 5.7: A scatter plot showing the relationship between strain magnitude (S_{MAG}) and Peak Plantar Pressure (PPP) for each participant (P01-P03) in the pilot study. The linear trend line shows the reported correlation between these variables with a Spearman's coefficient 0.673 ($p < 0.0001$).

plantar load assessment, which is low cost, simple and quick to implement. While it does not provide real-time (instantaneous) plantar pressure or shear data, it does record the cumulative strain following a period of gait, from which inferences regarding plantar load can be made. The insoles performed well under test conditions; pattern integrity was maintained throughout with no loss of DIC tracking. Insertion and removal of insoles from test shoes was achieved with minimal difficulty and facilitated by the scaffolding layer. Participants reported no disturbance to gait whilst wearing the insoles. The described method uses two programmes for data processing and analysis; DIC performed using GOM Correlate prior to export to MATLAB for segmentation and peak strain analysis. GOM is a free, easy to use software which generates a heat map that is simple to interpret. In a time-constrained clinical setting, this data may be sufficient for decision making. If regional strain data is required, secondary analysis using MATLAB can be performed. The process can be streamlined, performing both DIC and analysis using MATLAB, however the user-friendly functionality and output of GOM enables third party use with little additional expertise.

The experimental protocol was finalised following extensive preliminary testing and was

designed to ensure consistent data collection. Evidence from Chijiwa et al. [26], supported the need to manufacture insoles >24 hours prior to use. The effect of change in temperature upon resultant strain was demonstrated during UMT testing; as such, insoles were maintained at a constant controlled temperature prior to use. The strain metrics measured by STAMPS are the cumulative effect of a period of gait. Participants therefore must take the same number of steps for comparisons to be drawn. A period of mid gait steps are required, between initiation and termination of gait. Increasing the number of steps increases the proportion of deformation that represents 'normal gait', as initiation and termination steps are highly variable [40]. Preliminary work demonstrated that increasing the step count beyond this limit (i.e. 15-20 steps) degraded the pattern beyond the limit to which it could be reliably tracked, particularly in areas of high plantar strain. It is hypothesised that peak strain will be higher in patients with abnormal foot biomechanics than healthy participants. Therefore, to support future clinical use the limit of strain should not be reached within use in healthy participants. No regions of dropout occurred when healthy participants completed a total of 20 steps, with 10 steps on the ipsilateral (measured) side. Eighty percent of the steps taken during a 20 step walking assessment constitute mid-gait steps, therefore this was preferred over a 10 step walking assessment. For in-shoe plantar pressure assessment, Kernozek [41] demonstrated that eight steps were required to achieve high reliability (>0.90 reliability). Therefore 20 steps, ensuring 10 on the ipsilateral (STAMPS insole) side was selected.

Patterns of strain distribution and magnitude were consistent for each participant and demonstrated significant variation between individuals. Peak S_{MAG} varied considerably between individuals, with the level of peak S_{MAG} three times greater with participant 3 compared with participant 1. Participant 1 sustained highest peak strain at the regions of toes 3-5, hallux and heel with low levels of strain throughout the remaining regions. Participant 2 sustained highest peak strain at the hallux, with high strain also noted at the regions of toes 3-5 and the heel. In contrast, participant 3 sustained peak strain at the 1st MTH, with elevated levels of strain at the medial metatarsals, with strain reducing moving laterally. Unlike participants 1 and 2, participant 3 also sustained relatively high levels of strain in the midfoot. Direction of strain also varied. Participant 3 sustained considerable, anteriorly directed S_y in the anterior aspect of the 1st and 2 MTH regions, yet S_{MAG} was directed posteriorly at the posterior aspects across the metatarsal head regions, with low values of S_{ML}. Participant 2 sustained elevated levels of medially and laterally directed strain at the hallux, yet at the toes, the strain was largely directed anteriorly. Consideration of the patient and patient's foot pathology is required to interpret plantar load.

Further work is required to determine the relationship between the plantar load measured using STAMPS and foot pathology.

A strong correlation was noted between resultant strain and peak plantar pressure, reinforcing this technique as a valid measure of plantar load. Several regions experienced disproportionately greater strain when compared with peak plantar pressure; these included the region of toes 3-5 for participant 1 and 2 and the regions of the 1st and 2nd metatarsals and the lateral midfoot of participant 3. It is hypothesised that the increased strain within these regions is likely as a result of the effects of shear stress, however due to the lack of a valid in-shoe shear stress device, this could not be confirmed. There is also a lack of evidence within the literature to support or refute this hypothesis as no studies have performed pressure and shear stress assessment throughout the entirety of the plantar surface. A cross sectional study of healthy individuals is required to determine the 'normal values' of strain and assess the influence of confounding variables including, but not limited to gait speed and weight. Following this, the technique will be used to assess plantar load in an at-risk diabetic cohort.

5.6.1 Limitations

There are some limitations associated with the STAMPS technique. The strain metrics measured reflect the deformation of the insole following a period of gait. The strong correlation with peak plantar pressure and the results of experimental validation demonstrate that the magnitude of strain is the product of plantar pressure and shear stress at the foot-surface interface. However, direct measurements of peak plantar pressure and shear stress are not performed, and unlike traditional sensing techniques, real-time (instantaneous) data are not recorded.

Variation in strain response was identified during UMT testing with constant application of normal force and shear stress. During in-shoe tests, this variation increased to a mean of 26.4%. Variation within a simulated environment, with controlled application of load was 7.3%. This suggests the high CV is as a result of true variation, rather than error in measurement. Furthermore, the greatest variation was noted at the lower measures of load, making the variation less clinically relevant. The technique uses DIC, which can be subject to systematic errors. Several steps have been taken to ensure that the differences in strain patterns observed are a result of true variation rather than systematic errors. Patterning is consistent, with high contrast between speckle and background. The speckle size, density, variation, facet size and subset spacing has been optimised to reduce the likelihood of error. Furthermore, variables affecting

the material properties of the insole including temperature and 'cure time' were controlled. As described, further evaluation with a greater number of participants will add further insights into the repeatability of the technique.

This study was designed as a pilot study to demonstrate the principle of the insole system. It was not designed to investigate the effects of covariates that may affect resultant strain metrics. A healthy participant study, involving a larger sample size will be performed to establish normal parameters, and investigate the relationship between strain, weight and walking speed.

The experimental work found increased storage temperature resulted in increased levels of strain recorded with constant shear and normal force applied. Due to the limited period of time the insole is in contact with a participant's foot, variability in foot temperature is not expected to significantly influence strain outcomes. However, it does have implications for use within a clinical environment, as it requires maintenance of insoles at a constant temperature immediately prior to use. Future development will investigate materials which are less sensitive to temperature as well as the effect of walking speed and weight on resultant strain.

5.7 Conclusions

This study has demonstrated the efficacy of a novel method to assess plantar load across the plantar surface of the foot. Experimental testing validated the method to measure both vertical pressure and tangential shear stress. This technique was successfully incorporated into the STAMPS insole to reliably measure and quantify the cumulative degree of strain sustained by a deformable insole during a period of gait, which can be used to infer plantar loading patterns. Further work is required to establish 'normal values' within a healthy population before investigating strain patterns and parameters in patients with diabetes at risk of developing DFUs.

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Chapter 6

Evaluating a Novel Method to Characterise the Effect of Gait Speed and Inclination on Plantar Strain

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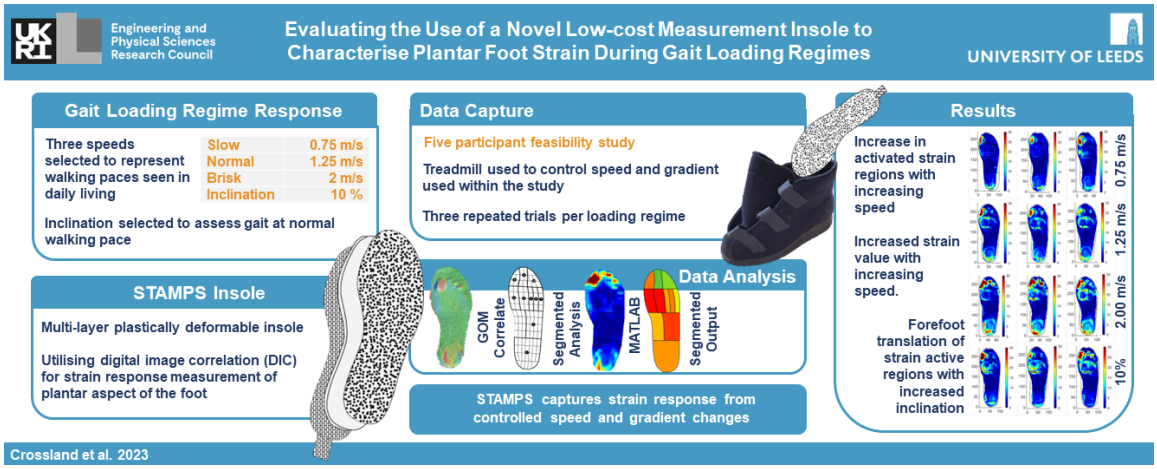

Figure 6.1: Graphical abstract for the paper Evaluating a Novel Method to Characterise the Effect of Gait Speed and Inclination on Plantar Strain.

Preface

Defining the strain response of the foot at self-selected normal walking speeds reflects a singular condition experienced by the plantar aspect, but with the foot undergoing changes in loading during activities of daily living it is important that plantar strain is characterised in these interactions also. This study reflects the research objective to investigate strain response under differing loading regimes by conducting a small cohort study into strain changes with varied speed and inclination using the novel STAMPS inlay. A treadmill was used to standardise gradient and speeds reflective of slow, normal and brisk walking paces seen in activities of daily living, with strain analysis conducted following the protocol outlined in Chapter 7.

6.1 Abstract

Under plantar loading regimes, it is accepted that both pressure and shear strain biomechanically contribute to formation and deterioration of diabetic foot ulceration (DFU). Plantar foot strain characteristics in the at-risk diabetic foot are little researched due to lack of measurement devices. Plantar pressure comparatively, is widely quantified and used in the characterisation of diabetic foot ulceration risk, with a range of clinically implemented pressure measurement devices on the market. With the development of novel strain quantification methods in its infancy, feasibility testing and validation of these measurement devices for use is required. Initial studies centre on normal walking speed, reflecting common activities of daily living, but evaluating response to differing gait loading regimes is needed to support the use of such technologies for potential clinical translation. This study evaluates the effects of speed and inclination on stance time, strain location and strain response using a low-cost novel strain measurement insole. The STrain Analysis and Mapping of the Plantar Aspect (STAMPS) insole has been developed, and feasibility tested under self-selected normal walking speeds to characterise plantar foot strain, with testing beyond this limited regime required. A treadmill was implemented to standardise speed and inclination for a range of daily plantar loading conditions. A small cohort, comprising of five non-diabetic participants, were examined at slow (0.75 m/s), normal (1.25 m/s) and brisk (2 m/s) walking speeds and normal speed at inclination (10% gradient). Plantar strain active regions were seen to increase with increasing speed across all participants. With inclination, it was seen that strain active regions reduce in the hindfoot and show a tendency to forefoot with discretionary changes to strain seen. Stance time decreases with increasing speed, as expected,

with reduced stance time with inclination. Comparison of the strain response and stance time should be considered when evaluating foot biomechanics in diabetic populations to assess strain time interval effects. This study supports the evaluation of the STAMPS insole to successfully track strain changes under differing plantar loading conditions and warrants further investigation of healthy and diabetic cohorts to assess the implications for use as a risk assessment tool for DFU.

6.2 Introduction

The global diabetic population has increased significantly in recent decades with growth predicted to continue [1]. With this comes a rise in the associated development of diabetic foot disease. From this population it is expected up to 25% will develop diabetic foot ulceration (DFU) within their lifetime [2]. The associated healing times and treatment pathway requirements for DFU lead to a labour and cost intensive process with over £900 million spent annually in the UK market alone [3], which is neither beneficial to the patient or healthcare provider. Prophylactic intervention is fundamental to reducing DFU rates, but is often unsupported in clinical practice due in part to poor evidence base and cost to implement across the at-risk diabetic population [4, 3, 5]. The current evidence base for orthotic intervention is focused on pressure as a predictor of ulceration risk to inform offloading [5]. This has centered the development of diabetic foot risk assessment tools to solely focus on pressure. While elevated and sustained plantar pressures in DFU are well researched, there is often discrepancy between ulcer location and the peak plantar pressure site [6]. Shear stress on the foot is thought in part to contribute to this deviation in expected location [7], but remains little understood and is not measured in risk assessment of the diabetic foot due to the poor availability of measurement tools. Strain, in the context of plantar assessment, can be considered as the resultant deformation from the combination of normal plantar pressure and shear stress. It is postulated that plantar tissue shear stress contributes to ulcer formation mechanics through subjecting the tissue to fatigue based failure subsurface [8, 9, 10]. In this way, strain of the plantar surface skin can be used to assess both known contributors to ulcer formation, pressure and shear stress.

The complexities seen in the feet of people with diabetes leads to a requirement of bespoke treatment approaches. This in turn drives the development of objective risk assessment tools that allow quantifiable metrics of the at-risk diabetic foot and allow for earlier prophylactic interventions to reduce DFU formation risk and work towards preventing long term escalation

of treatment costs [5]. Current approaches to quantify shear stress at the plantar surface utilise a wide range of technologies including capacitive sensors and strain gauges [11], but have not established a clinically viable tool [12, 7]. In-shoe approaches to quantifying shear strain have gained renewed interest, with a range of studies reflecting the drive for responsive technologies. Development ranges from full foot coverage arrays utilising tri-axial sensors [13, 14], to anatomically focused low coverage piezoelectric or single axis sensors. There is a current gulf in technology addressing both the pressure and shear stress components of plantar load.

Assessment of peak strain, in lieu of shear stresses is important in characterising the at-risk diabetic foot, with numerous studies highlighting the role of shear in ulcer formation [7, 10, 8]. Peak pressure was long considered the key metric in assessment, with higher peak pressures associated with increased ulcer risk [15]. More recent studies have shown that whilst pressure is important, it is not the sole predictor of ulcer formation location, with shear stresses playing a significant role [16, 10, 8]. High peak shear stress, in relation to peak strain, is associated with tissue responses that lead to callus formation, a predeterming factor for DFU, showing signs of fatigue failure to the tissues with a warming response that reduces the resistance to tissue breakdown [10]. Whilst pressure time integral is considered alongside peak plantar pressure and average pressure in assessing DFU risk [17, 18, 19], the contribution of shear strain time integral remains unclear. Currently, there are limited systems available to measure strain in lieu of shear forces and no current clinically utilised techniques for data collection.[20] employed a custom built sensor platform to measure normal and tangential forces simultaneously of the unshod foot during stance phase to derive pressure and shear time integrals for a diabetic and non-diabetic cohort. This showed by an increase in both time integrals for the diabetic population and led to calls for further investigation of temporal strain responses.

The current pressure data capture techniques are divided into two distinct focuses of shod or unshod measures. Whilst unshod measures can give an understanding of intrinsic pressures due to anatomical variances and gait deviations, they do not reflect the activities of daily living where footwear is worn. However, in clinic these pressure devices, including pressure plates [21], offer a convenient method of data capture with which to inform orthoses design. Shod pressure data allows data to be collected during these activities of daily living to provide a representative understanding of the pressure events acting upon the diabetic foot. Technologies including as pedar® [Novel GmbH, Munchen Germany] pressure measurement insoles are currently used in clinical and research settings to achieve shod pressure data collection. Recent trends include the emerging market of pressure reporting insoles offering real-time feedback to inform user

behaviour and minimise DFU risk [22]. For both of these methods, the cost, initial set-up, calibration requirements and training are prohibitive factors to their implementation in a clinical environment.

The shod environment also presents influential factors which may instigate the formation of ulceration due to pressure and shear events leading to mechanical tissue stress [23]. The interfaces between the foot, sock and shoe must be considered in this instance, alongside the pressure changes brought about by the footwear design and the influence on tissue stress [24]. To begin to understand the effect on differing loading regimes to the plantar aspect of the foot within the shod environment, controlled speed and inclination trials have been employed [25, 26, 27, 28] using the pedar® pressure measurement insole. This method allows for a benchmark to be provided, allowing reporting of patterns in pressure deviation with changing speeds that reflect activities of daily living.

Current clinical pressure measurements systems, such as pedar® [Novel GmbH, Munchen Germany], provide the functionality to monitor pressure response changes under differing loading regimes in the feet of people with diabetes. Recognition of the need to assess the plantar aspect during functional gait is seen with use of technologies such as pedar® and should form a basis for future monitoring method requirements.

The development of the STrain Analysis and Mapping of the Plantar Surface (STAMPS) insole by [29] bridges these gaps in the literature by allowing for strain assessment as a surrogate for the components of plantar load during gait. Digital image correlation (DIC), computer vision tracking of changes to an applied stochastic speckle pattern [30], is used here to quantify the cumulative effects of plantar loading in the form of strain imparted on a plastically deformable insole during gait. The aforementioned clinical need for a loading regime responsive assessment method drove the methodology to analyse the STAMPS insole response [29]. Currently STAMPS has been optimised for functionality and feasibility tested at self-selected normal walking speeds and without a gradient. This paper uses the STAMPS insole technique as a responsive tool to evaluate changes in strain characteristics aligned to changes in walking speed and inclination, including stance time, strain location and strain response. The aim of the study is to assess the response of the STAMPS insole, under these controlled gait conditions.

6.3 Materials and Methods

6.3.1 Study Protocol

To provide a consistent achieved walking speed and inclination across all studies a Nordictrack C200 Treadmill was implemented for use. Trials were selected to be conducted at 0.75 m/s, 1.25 m/s and 2 m/s speeds to reflect a slow, lower bound normal and brisk walking pace. These values align with conducted treadmill trials to monitor pressure variance with speed during gait using pedar ® [25] and also reflect the range of speeds that might be adopted in typical activities of daily living. Inclination was set to a gradient of 10% reflecting a mid value condition selected by [28]. It was decided that for the purpose of this study, the inclination trial would deviate from [28] and be conducted at the 'normal' 1.25 m/s speed, to reflect the expected general gait reported in a slower population [25], such as may be expected in the ageing diabetic population . Due to safety limitations, the treadmill belt restricts starting at the target speed and instead provides an acceleration to reach this speed. The treadmill acceleration profiles were collated using image analysis, recorded using a Nikon D5300 with AF-S Nikkor Lens (Nikon) , to track belt speed changes under the three speed conditions [31].

Insole Manufacture

The STAMPS plastically deformable insoles were prepared following the protocol described previously [29]. A commercial clay roller (CT-500, North Star Polaris) was used to provide a targeted 5 mm thickness plasticine slab from which flat insoles were cut to size requirements Fig. 6.2). Cross patterned Nylon mesh was used to reinforce the base of the insole and provide a posterior tab for ease of removal following use (Fig. 8.2). The optimised computer generated stochastic speckle (Correlated Solutions Speckle Generator, v1.0.5), consisting of a 0.8 mm speckle with a 65% pattern density and 75% pattern variation, was applied via a thin film, 180 μm, temporary tattoo (Silhoutte, USA) for the purpose of DIC. The insoles were allowed to rest for a period of 24 hours minimum prior to use after moulding to allow for any temporal hardening effects [32]. The insoles were then stored at a controlled 15 ° temperature prior to use, in line with [29] findings on storage and use optimisation for ten step gait studies.

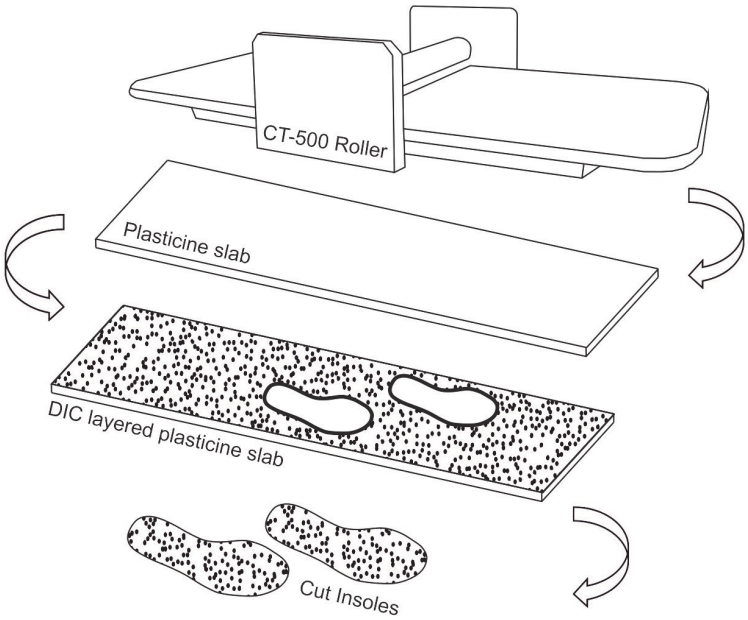

Figure 6.2: Insole manufacture process, showing schematic of stages from clay rolling slab, addition of DIC layer structure and cut out of insoles.

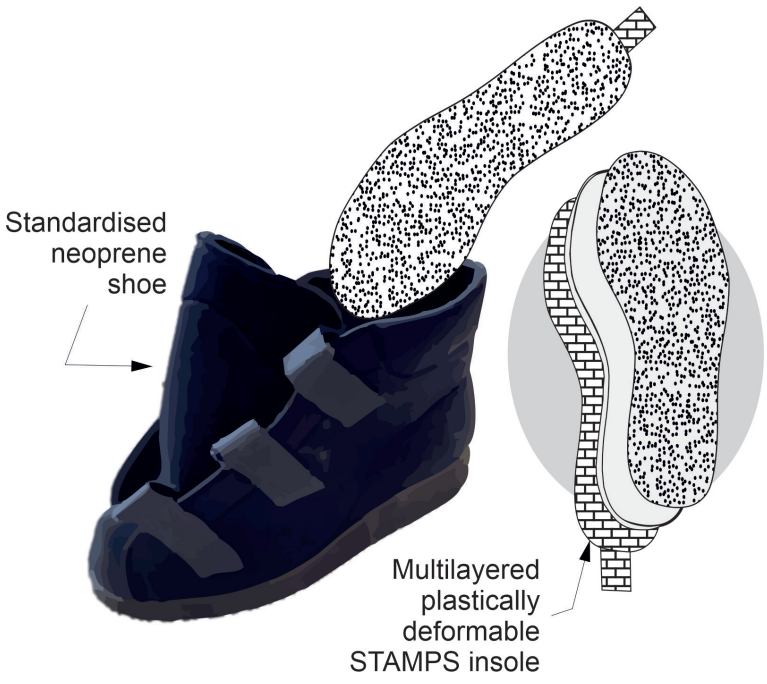

Figure 6.3: STAMPS insole layer view schematic showing standardised footwear utilised within the participant study.

Participant Study

To verify the proposed study protocol, a participant cohort was recruited. The aim of which was to assess the ability of the STAMPS insole to effectively detect strain changes under differing loading regimes through controlled speed and inclination trials. A five participant non-diabetic cohort was recruited and provided consent, see Table 6.1. The University of Leeds Engineering and Physical Sciences joint Faculty Research Ethics Committee granted ethics approval (LTMECH-005) for the study design. The study assessed right foot stance phase loading solely, with each participant provided with a STAMPS insole for the right footwear with a contra-lateral sham insole in the left footwear to reduce inconsistency in leg length. Standardised neoprene footwear (Ninewells Boot, Chaneco LTD) were used for consistency across all participants. Participants were asked to walk for ten steps on the right foot during each trial, inline with insole usability limits procured from insole optimisation [29]. Three repeats were taken at each trialled speed and at inclination, with a new insole each trial due to the plastically deformable nature of the insoles rendering them single use. The target speed was achieved following an acceleration profile. With the lowest speed it enabled for a higher number of steps to be conducted at the target speed. This is compared to the highest speed where the time to reach full speed as increased and reflected in a lower number of steps at this speed. This disparity was between eight to five steps at target speed. Images were recorded of the STAMPS insole before and after undertaking each trial and participants were recorded using an camera recording at 50 fps (Nikon D5300, Nikon) to capture stance phase contact time.

Table 6.1: Participant characterisation data collated for speed and inclination treadmill study.

Participant	Gender	Height (m)	Weight (kg)	Age (Years [Months])	Shoe Size (UK)
1	F	1.75	64.5	29 [3]	7
2	M	1.94	83.2	31 [11]	12
3	M	1.85	85.0	28 [6]	11
4	M	1.90	77.6	30 [7]	12
5	M	1.82	83.1	26 [9]	11

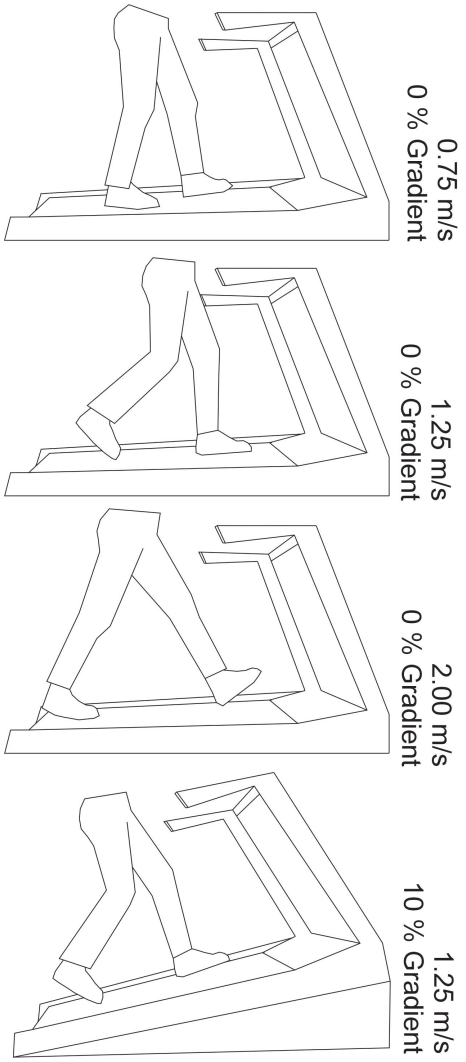

Figure 6.4: Depiction of speeds and inclination of treadmill during each phase of the study.

6.3.2 Plantar Strain Analysis

Commercially available DIC software (GOM Correlate 2019) was used for first stage post image DIC analysis to allow for the generation as insole strain maps. Strains were determined relative to the reference photo of the insole taken prior to each trial. For exportation of the data for post processing to derive positional strain values, an equidistant spread of points at 6.5 mm intervals was applied to each insole. The International Working Group on Diabetes recommends a sensor spread of $2cm^2$ for pressure assessment of the diabetic foot specifically related to fixed sensor approaches, affording the STAMPS method increased resolution comparative this guideline [33].

Post processing was conducted in MATLAB (R2021b) for implementation of custom scripts to improve visualisation and allow for anatomical regional analysis of strain data. Pedar® [Novel GmbH, Munchen Germany] used as a tool for risk assessing the diabetic foot, employs an Automask feature to divide the foot by regions of anatomically significance for segmented analysis in areas of DFU prevalence [34]. Replicative masking across key anatomical landmarks was applied to the post-processed strain maps and aligned anatomical by a qualified orthotist (SRC). A reductive masking approach was then used to combine localised regions which would be difficult to distinguish clearly through assessment of the insole imaging. A resulting eight region mask was applied to determine strain outputs (Fig. 8.3), covering: hallux, second to fifth toes, first metatarsal head, second and third metatarsal head, fourth and fifth metatarsal heads, lateral midfoot, medial midfoot and calcaneus. Average and peak strains across each segment were determined. The conducted MATLAB (R2021b) approach also allows for the recording of vector quiver plot for each trial, to provide information on the size and direction of the strain measured, though this is not presented within the scope of this study [29].

6.4 Results

All trials were successfully completed for ten stance phases on the right foot by each participant. Fig.6.6 provides representative strain visualisation outputs from a single participant, showing the three repeated trials under each loading regime. The figure shows regions identified as being strain active increase with increasing speed, strain within the active regions also increases in line with the increasing speed. Fig. 6.6 also highlights the variance between the two trials conducted at 1.25 m/s at 0% and 10% inclinations. Strain active regions are maintained in the forefoot with a reduction in activity seen in the hindfoot with increased inclination. These patterns are seen

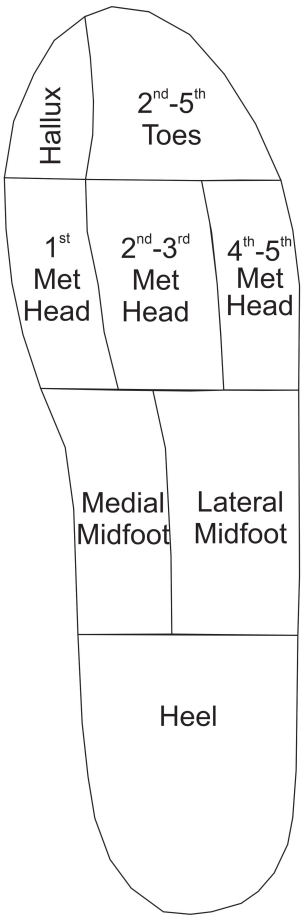

Figure 6.5: Anatomically defined regional mask which is used to catergorise strain output data for each participant trial.

generally across all participants, with supplementary corresponding figures supplied for each of the remaining participants.

Tables 6.2 and 6.3 show the averaged trial strains, standard deviations and percentage strain changes seen between speed changes (Table 6.2) and due to inclination change (Table 6.3). The trend between increasing speed and increasing average and peak strain can be seen for all participants in the majority of anatomical regions. There is some variance in the reported strain changes for inclination across differing anatomical regions and participants. All participants show a reduction in strain with increasing inclination at the rearfoot, in line with the reduction in strain active regions as seen in Fig. 6.6.

Average stance time, across all ten stance phases and over three repeated trials per loading regime (Fig8.4). decreases with increasing speed for all participants. A marginal decrease in average stance time is seen for all participants comparative between 1.25 m/s 0% to 1.25 m/s 10% inclination.

6.5 Discussion

The aim of the study was to utilise the STAMPS novel measurement insole to evaluate strain characteristic changes [29], including stance time, strain location and strain change, instigated through changes in walking speed and inclination. This was done specifically with the aim to assess the response of the STAMPS insole under controlled gait conditions [29]. Strain is measured as a surrogate of shear stress. The strain responses captured using the STAMPS insole were compared to the capabilities of current pressure measurement systems used in DFU assessment, namely the pedar® [Novel GmbH, Munchen Germany] pressure capture insole. Studies by [25] and [28] using the pedar® insole showed increased pressure with increasing speed. Strain captured by the STAMPS insole is related to plantar loading comprised of pressure and shear strain contributions, it is therefore expected that with an increasing speed and associated pressure, an increase in strain would be observed.

Strain outputs for all participants, Table 6.2, confirm this expectation by showing increased strain consistently across all trials with increasing speed [25]. Average stance time, Fig. 8.4, reduces with increasing speed which is concurrent with expectations for normal gait [35, 36, 37, 38]. Inclination strain change reductions across participants for both average and peak strains, Table 6.3, align with the reduction in rearfoot strain active locations seen, example shown in Fig. 6.6. Though there is variation in participant strain changes to the mid and forefoot

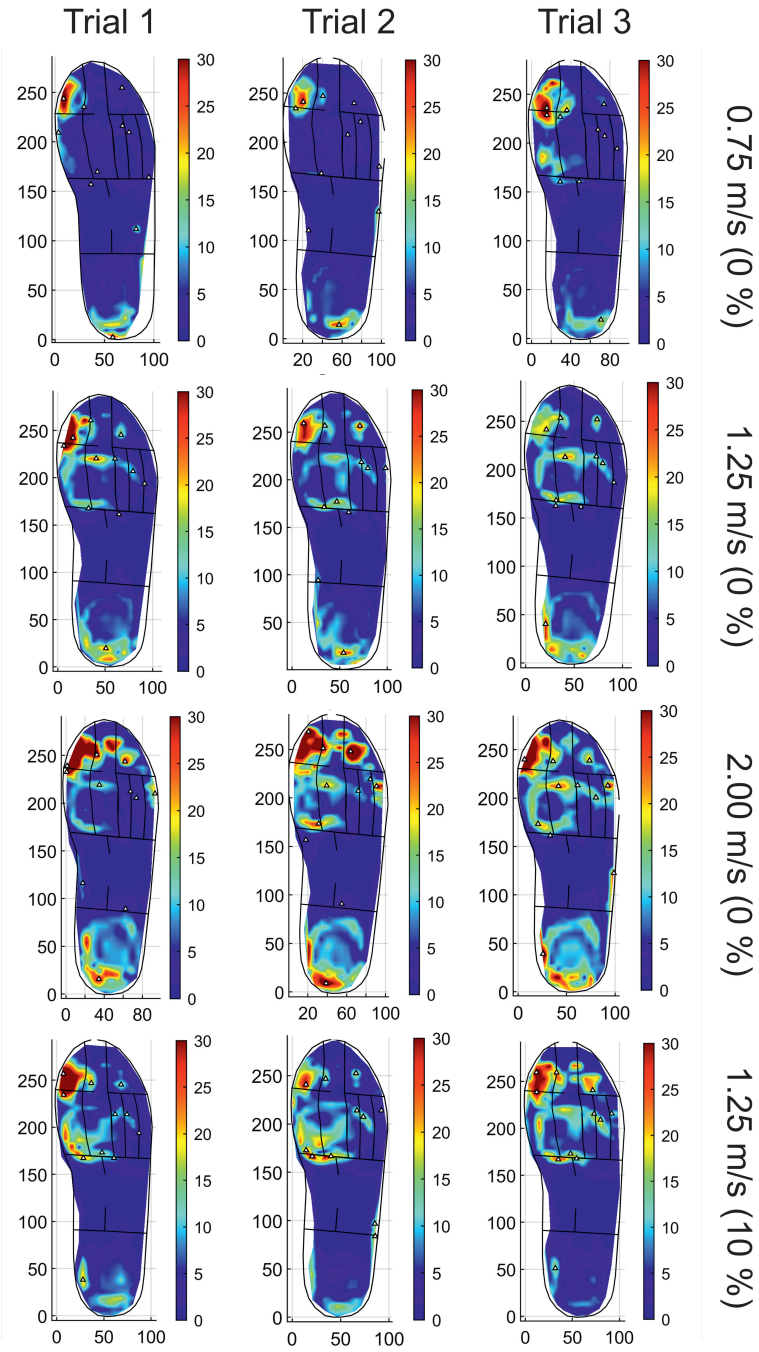

Figure 6.6: A representative example of strain profiles for repeated trialled speeds and inclinations for one participant (P03).

Table 6.2: Anatomical regional average and peak strains to 2 d.p. and standard deviations (SD) averaged across all three repeat trials, with comparative percentage strain changes for all participants (P01-P05) at walking speeds of 0.75, 1.25 and 2.00 m/s

		Average Strain						Average Strain - Strain Change (%)			Peak Strain			Peak Strain - Strain Change (%)		
		0.75 m/s	SD	1.25 m/s	SD	2.00 m/s	SD	[Slow to Normal]	[Normal to Brisk]	[Slow to Brisk]	0.75 m/s	1.25 m/s	2.00 m/s	[Slow to Normal]	[Normal to Brisk]	[Slow to Brisk]
P01	Hallux	6.13	3.65	8.79	5.17	15.46	8.60	43.35	75.78	151.99	11.57	19.73	32.11	70.57	62.72	177.55
	2nd-5th Toes	2.54	2.68	3.14	2.80	5.18	4.38	23.31	65.29	103.82	12.19	13.53	21.23	10.94	56.91	74.08
	1st Met Head	1.61	1.90	2.21	1.83	3.43	3.74	37.58	55.31	113.68	6.44	8.00	16.52	24.21	106.65	156.67
	2nd-3rd Met Heads	1.23	0.63	1.37	0.71	1.60	1.11	11.28	17.53	30.79	2.69	3.36	5.31	24.93	57.80	97.14
	4th-5th Met Heads	1.54	0.91	1.38	0.89	2.39	3.26	-10.35	73.82	55.84	4.01	3.89	14.23	-3.21	266.11	254.36
	Lateral Midfoot	0.77	0.67	0.68	1.00	0.90	0.75	-11.42	32.04	16.96	3.79	6.55	3.33	72.77	-49.12	-12.09
	Medial Midfoot	0.74	0.87	0.80	0.38	0.81	0.86	9.11	0.87	10.06	3.82	2.33	4.30	-39.09	84.78	12.55
	Heel	2.35	1.73	3.01	2.65	4.29	3.13	28.20	42.31	82.45	8.84	15.00	16.31	69.72	8.68	84.46
P02	Hallux	10.83	8.47	8.63	9.14	13.62	13.81	-20.32	57.81	25.74	35.11	51.32	51.01	18.92	46.20	73.86
	2nd-5th Toes	5.49	5.37	3.94	3.93	5.41	5.15	-28.28	37.41	-1.45	17.59	21.89	21.02	-40.85	24.48	-26.37
	1st Met Head	2.77	2.74	5.48	6.77	8.39	9.63	97.84	53.14	202.96	24.05	34.43	43.18	97.17	43.18	182.30
	2nd-3rd Met Heads	2.48	1.42	4.41	3.73	5.19	4.75	77.94	17.78	109.58	16.11	24.78	21.16	129.63	53.88	253.34
	4th-5th Met Heads	4.20	5.16	2.66	2.91	3.17	4.68	-36.58	19.06	-24.49	14.52	22.77	9.76	-37.54	56.83	-2.05
	Lateral Midfoot	1.86	1.83	1.23	1.22	0.85	1.00	-33.77	-30.76	-54.14	6.50	6.26	7.69	-19.75	-3.62	-22.66
	Medial Midfoot	0.57	0.61	0.69	0.96	0.59	0.44	21.31	-15.38	2.66	6.36	1.84	3.97	80.25	-71.09	-47.88
	Heel	3.28	2.96	4.17	4.09	5.40	4.63	27.15	29.62	64.81	24.16	24.53	14.92	63.78	1.56	66.34
P03	Hallux	12.10	11.15	14.17	10.79	24.92	18.94	17.12	75.86	105.97	38.23	31.73	63.35	-17.02	99.68	65.70
	2nd-5th Toes	2.83	3.15	4.04	4.49	8.07	9.82	42.68	99.65	184.87	15.29	25.08	42.45	64.04	69.30	177.73
	1st Met Head	6.36	5.52	8.23	6.36	10.11	6.98	29.47	22.79	58.97	25.71	30.04	32.76	16.83	9.06	27.41
	2nd-3rd Met Heads	2.63	1.78	6.47	5.38	6.17	4.88	146.27	-4.67	134.77	8.46	23.71	21.34	180.18	-10.00	152.18
	4th-5th Met Heads	1.86	1.26	3.45	3.03	5.53	6.57	85.29	60.51	197.40	5.66	15.46	29.21	173.11	88.95	416.05
	Lateral Midfoot	1.31	1.99	1.09	1.07	1.38	2.18	-16.82	27.13	5.74	15.88	4.60	12.73	-71.01	176.52	-19.84
	Medial Midfoot	1.38	1.70	1.34	1.70	1.55	1.73	-2.97	15.72	12.28	8.18	8.70	8.05	6.24	-7.37	-1.60
	Heel	5.47	4.92	7.16	5.65	10.11	7.21	30.78	41.26	84.744	27.12	28.60	37.99	5.46	32.82	40.08
P04	Hallux	12.12	17.53	23.78	22.03	19.11	22.38	96.26	-19.63	57.73	55.80	68.34	85.32	22.49	24.85	52.92
	2nd-5th Toes	7.68	11.74	9.03	10.82	14.39	13.55	17.61	59.31	87.35	59.28	51.71	62.91	-12.77	21.66	6.13
	1st Met Head	1.14	0.89	3.73	4.12	2.94	3.07	225.13	-21.17	156.28	4.32	17.10	11.94	295.99	-30.20	176.39
	2nd-3rd Met Heads	1.79	1.12	4.52	4.15	3.76	2.87	152.52	-16.77	110.16	4.64	17.55	13.83	278.20	-21.17	198.14
	4th-5th Met Heads	1.41	1.01	3.22	4.29	5.96	8.19	128.41	85.07	322.71	4.98	19.17	32.51	284.76	69.56	552.41
	Lateral Midfoot	0.41	0.27	0.52	0.78	0.41	0.68	25.41	-20.58	-0.40	1.53	4.80	4.91	214.87	2.15	221.65
	Medial Midfoot	0.76	0.92	0.47	0.56	0.41	0.28	-37.30	-13.76	-45.93	5.92	3.14	1.44	-46.89	-54.15	-75.65
	Heel	2.40	1.75	3.30	2.44	4.89	4.42	37.13	48.42	103.53	9.32	15.02	29.41	61.27	95.77	215.73
P05	Hallux	10.12	6.72	14.26	7.76	18.48	13.69	40.90	29.61	82.62	24.66	29.59	60.15	20.03	103.24	143.94
	2nd-5th Toes	2.98	3.68	3.70	4.20	11.06	11.75	24.24	198.66	271.07	20.77	19.79	58.84	-4.68	197.26	183.34
	1st Met Head	3.06	1.97	6.65	5.08	15.08	12.87	117.38	126.76	392.93	8.88	20.17	46.59	127.15	130.97	424.66
	2nd-3rd Met Heads	2.96	2.97	7.40	6.85	9.25	6.95	149.69	24.92	211.91	15.97	36.08	29.62	125.90	-17.88	85.50
	4th-5th Met Heads	4.16	6.70	7.31	9.43	5.78	8.11	75.93	-20.93	39.11	28.60	33.27	35.39	16.36	6.36	23.76
	Lateral Midfoot	1.86	1.30	1.82	1.30	1.83	1.46	-2.34	0.84	-1.52	5.31	4.91	6.44	-7.50	31.07	21.24
	Medial Midfoot	0.98	1.12	0.77	0.88	0.95	1.40	-21.25	23.22	-2.96	6.00	4.80	5.68	-20.07	18.38	-5.38
	Heel	3.67	2.99	3.93	3.34	7.73	5.91	6.83	96.87	110.33	20.18	21.31	35.45	5.61	66.37	75.70

Table 6.3: Anatomical regional average and peak strains to 2 d.p. and standard deviations (SD) averaged across all three repeat trials, with comparative percentage strain changes for all participants (P01-P05) at 1.25 m/s speed at 0 % and 10% inclination.

		Average Strain				Average Strain - Strain Change (%)			Peak Strain		Peak Strain - Strain Change (%)		
		0%	SD	10%	SD	[0% to 10%]	[0% to 10%] Regional Average	Region	0%	10%	[0% to 10%]	[0% to 10%] Regional Average	Region
P01	Hallux	8.79	5.17	7.89	4.63	-10.26	-6.12	Forefoot	19.73	17.12	-13.24	17.44	Forefoot
	2nd-5th Toes	3.14	2.80	2.73	2.19	-12.84			13.53	10.09	-25.39		
	1st Met Head	2.21	1.83	1.63	1.66	-26.09			8.00	9.05	13.22		
	2nd-3rd Met Heads	1.37	0.71	1.39	0.88	2.12			3.36	4.49	33.43		
	4th-5th Met Heads	1.38	0.89	1.60	1.36	16.48			3.89	6.96	79.17		
	Lateral Midfoot	0.68	1.00	0.54	0.34	-21.25	-6.95	Midfoot	6.55	1.62	-75.20	24.99	Midfoot
	Medial Midfoot	0.80	0.38	0.86	0.87	7.35			2.33	5.25	125.19		
	Heel	3.01	2.65	2.57	2.04	-14.74	-14.74	Rearfoot	15.00	10.44	-30.38	-30.38	Rearfoot
P02	Hallux	8.63	9.14	14.30	14.00	65.64	27.32	Forefoot	35.11	51.01	45.32	28.61	Forefoot
	2nd-5th Toes	3.94	3.93	3.97	3.66	0.88			17.59	21.02	19.55		
	1st Met Head	5.48	6.77	8.14	10.61	48.60			24.05	43.18	79.55		
	2nd-3rd Met Heads	4.41	3.73	5.68	4.31	28.80			16.11	21.16	31.38		
	4th-5th Met Heads	2.66	2.91	2.47	1.92	-7.33			14.52	9.76	-32.77		
	Lateral Midfoot	1.23	1.22	1.26	1.43	2.59	-0.52	Midfoot	6.50	7.69	18.32	-9.61	Midfoot
	Medial Midfoot	0.69	0.96	0.67	0.61	-3.63			6.36	3.97	-37.54		
	Heel	4.17	4.09	3.48	3.00	-16.42	-16.42	Rearfoot	24.16	14.92	-38.24	-38.24	Rearfoot
P03	Hallux	14.17	10.79	16.15	14.00	13.95	18.68	Forefoot	31.73	44.14	39.14	9.75	Forefoot
	2nd-5th Toes	4.04	4.49	4.88	6.21	20.76			25.08	23.94	-4.53		
	1st Met Head	8.23	6.36	10.83	7.73	31.60			30.04	32.25	7.36		
	2nd-3rd Met Heads	6.47	5.38	6.83	4.99	5.53			23.71	20.98	-11.54		
	4th-5th Met Heads	3.45	3.03	4.19	3.99	21.54			15.46	18.29	18.30		
	Lateral Midfoot	1.09	1.07	1.46	2.44	34.42	86.05	Midfoot	4.60	14.40	212.70	236.90	Midfoot
	Medial Midfoot	1.34	1.70	3.19	6.57	137.67			8.70	31.40	261.10		
	Heel	7.16	5.65	4.52	4.07	-36.81	-36.81	Rearfoot	28.60	20.16	-29.50	-29.50	Rearfoot
P04	Hallux	23.78	22.03	12.08	16.56	-49.21	-10.05	Forefoot	68.34	60.90	-10.89	-19.83	Forefoot
	2nd-5th Toes	9.03	10.82	10.35	11.00	14.59			51.71	60.21	16.44		
	1st Met Head	3.73	4.12	2.61	2.30	-29.99			17.10	9.25	-45.91		
	2nd-3rd Met Heads	4.52	4.15	4.79	3.46	5.88			17.55	14.09	-19.72		
	4th-5th Met Heads	3.22	4.29	3.49	2.65	8.46			19.17	11.69	-39.05		
	Lateral Midfoot	0.52	0.78	0.57	0.72	10.57	25.18	Midfoot	4.80	5.45	13.36	35.54	Midfoot
	Medial Midfoot	0.47	0.56	0.66	0.90	39.78			3.14	4.96	57.72		
	Heel	3.30	2.44	2.48	1.91	-24.80	-24.80	Rearfoot	15.02	10.13	-32.58	-32.58	Rearfoot
P05	Hallux	14.26	7.76	12.12	6.89	-14.99	-5.80	Forefoot	29.59	26.44	-10.67	2.86	Forefoot
	2nd-5th Toes	3.70	4.20	4.71	4.85	27.24			19.79	25.31	27.86		
	1st Met Head	6.65	5.08	8.76	7.81	31.73			20.17	29.18	44.64		
	2nd-3rd Met Heads	7.40	6.85	4.05	3.13	-45.23			36.08	14.28	-60.42		
	4th-5th Met Heads	7.31	9.43	5.29	8.36	-27.73			33.27	37.57	12.91		
	Lateral Midfoot	1.82	1.30	1.17	1.45	-35.83	-13.52	Midfoot	4.91	9.28	88.87	58.05	Midfoot
	Medial Midfoot	0.77	0.88	0.84	0.96	8.79			4.80	6.10	27.24		
	Heel	3.93	3.34	2.92	2.65	-25.70	-25.70	Rearfoot	21.31	19.08	-10.48	-10.48	Rearfoot

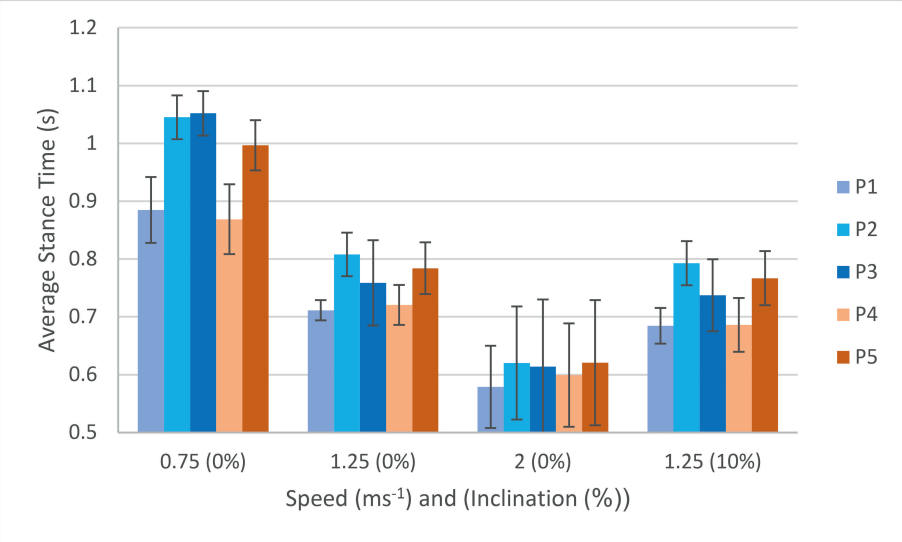

Figure 6.7: Average stance time per participant across all plantar loading regimes with associated standard deviations.

in both average and peak strain, the peak strain changes in these regions tend to show a general increase for participants at 10% gradient. Ho et al. [28] reported the effect of inclination on pressure showed reduction in peak pressures at the rearfoot at inclinations of 5%, 10% and 15% gradient, with changes to the location of strain actives regions present from the 0% gradient. This is congruent with the strain changes reported from this study. The comparative literature is limited to studies of in-shoe pressure utilising a treadmill approach and pedar insole, other approaches to pressure measurement may differ in their reported values. Whilst the use of pedar reflects the current gold standard approach for clinical assessment of in-shoe pressure, it must be noted that pressure measurement field is a wide market of existing and emerging technologies and as such, differing reported outcomes. Ankle dorsiflexion increases with increasing inclination during stance, with decreased braking forces and increased late stance phase propulsive forces also seen [39]. In turn, vertical and anteroposterior shear ground reaction forces (GRFs) increase with inclination [40]. These changes reflect the reduced strain seen at the rearfoot and increased strain at the forefoot during this study.

The gradient chosen for this study does not necessarily reflect the daily gait activities of a person at-risk of diabetic foot complications. A 10% gradient can be considered a moderate-large incline, and with high-risk diabetics skewing towards and older and less mobile population, their daily activity locations may be centred around lower gradient terrains such as the home. Further

studies at a reduced gradient and during other activities such as stair ascending and descending would be beneficial to understand strain response variations.

The regional strain percentage decreases reported for some participants across the trialled conditions for speed and gradient do not necessarily reflect the strain changes across the foot as a whole. While a tendency for the whole foot to show increasing strain with increasing speed is seen, the decreasing regional values may reflect the loading changes required of the foot to offset gait deviations undertaken in response to increasing speed as seen in [26] shod pressure study. Likewise the same can be seen in the response of the foot with inclination reported by [28].

Peak plantar pressure has been considered in DFU analysis alongside pressure time integral as metric used to determine DFU risk [19, 18, 17]. Peak pressure is a poor predictor of DFUs when considered independently, with peak shear stress contributing to ulcer risk through fatigue failure to the tissues, through localised heating and reduced resistance to breakdown, with increased callus formation [10]. Utilising peak strain, the resultant deformation from plantar pressure and shear stress, allows for the contribution of both these components to be considered in the tissue mechanics leading to DFU risk.

Whilst the STAMPS insole does not allow for the recording of strain changes during stance phase for direct calculation of strain time integral, and instead provides a reflection of cumulative strain, analysis of regional average strain in relation to longevity of stance can be considered in lieu of this metric. The small cohort in this study does not allow for statistical analysis and reporting of significance, but can be considered a benchmark study to assess this metric in a larger healthy cohort.

A limitation of this study is the use of a treadmill to standardise the walking speeds achieved, however, participants adopted all chosen pace settings comfortably. Whilst it achieves that aim, it can result in altered gait biomechanics compared to non-treadmill walking to compensate for controlled speed and belt movement [41]. Therefore the strain profiles may be altered in comparison to strain results recorded due to natural speed changes. A study analysing the strain response of self-selected slow and faster walking speeds should be run to address this.

The acceleration profile of the belt was dependent on the target outcome speed, with lower speeds having a lower initial rate of acceleration comparative to the higher target speed. The acceleration profiles were also non-liner in presentation. Speeds in all three targeted trials were reached prior to half of the steps being completed in all cases, with the plastically deformable STAMPS insole recording peak strains occurring at the target speed. The acceleration profile of the treadmill, rather than immediate target speed reached, does enable the full ten steps

undertaken in the trial to be conducted at the target speed. The increased time it takes to reach higher speeds, due to the same initial starting speed, means that a differing number of steps are completed at the target velocity in relation to which speed the trial was conducted at. The result this has on the strain outcomes should be minimal due the plastic deformation of the insole, however this cannot be measured in the remit of this study. Acceleration profiles can be present when achieving self-selected walking speeds within brisk activities of daily living. These acceleration profiles are often not seen with slower self-selected walking speeds, which can be achieved instantaneously from initiation of gait. These natural deviations from a single continuous walking speed, whilst not directly represented in the study due to the controlled acceleration profile, should be considered when assessing the feasibility of strain data capture methods to respond to change in speed during gait events.

Inclined walking on a treadmill leads to biomechanical gait deviations compared to walking on a ramp. These changes include shorter steps and shorter stance times, alongside increased hip and knee flexion angles. No significant changes are seen to ground reaction forces, leading to the assumption of consistency in plantar strain between walking on both inclined surfaces. However, the gait deviations show an unnatural gait pattern which may be reflected in differing active plantar strain regions. Whilst treadmill walking helps to maintain set speeds to compare between participants, natural ramp walking should be trialled in future to address this [42].

The participant study was conducted with a small cohort of healthy participants to assess both if there was a difference seen in strain response and stance time, and if this was measurable using the STAMPS insole technique. Due to this limited study, no statistical significance can be attributed to the strain differences reported, a larger cohort study is required with appropriate power to further this work. Therefore, at this stage no definitive conclusions can be drawn relating to shear loading during normative gait. To work towards translation of the data to reflect a range of activities of daily living in clinical decision making process, a range of inclinations should be trialled over a larger population.

A singular inclination value is studied at a relatively steep incline of 10%, to report how inclination affects strain response. Beyond this the cohort demographic only covers a young adult, non-diabetic population, meaning that it is not generalizable to other cohorts. However the opportunity to measure strain and potentially reduce the incidence of DFU requires further studies in this population. Development of 3D DIC image capture is also required to enhance the analysis of the insole deformation profiles, ensuring the recorded strains reflect a true representation of

regionalised strain response. This is particularly important in relation to potential future clinical translation to allow for strain data to support DFU risk assessment and treatment pathways.

The standard deviations presented when assessing the segmented anatomical regions are relatively large. This reflects the spread of strain within these regions and the specificity of skin response to gait. This shows that anatomical regions, whilst a helpful indicator of key regions on concerns, may overgeneralise the strain. The use of strain maps alongside regional masking of strain data can alleviate this, to allow for more specified targeting of locations of interest if required.

Prior use of the insole has been limited to normal self-selected walking speeds to reflect the average patients gait speed undergoing activities of daily living, but expanding this to reflect the altered activities of daily living experienced by diabetic cohorts due to foot structure, deformities and gait deviations is important. Assessment of the characteristics of these daily activities has been increasing in recent years and emphasises the importance of characterising gait beyond a research setting [43]. Focus should also be given in future research to assess anatomical region displacement within the segmented mask under speed variation, to reflect movement of the foot in relation to the insole. A larger scale participant study is required to support this approach. Understanding strain response to speed and inclination offers the opportunity to provide informed treatment approaches, such as footwear design, to optimise plantar loading for reduced DFU risk. With the increase in biomechanical assessments of activities of daily living, the clinical translation potential of the STAMPS insole could also be optimised to explore pathology and disease progression through plantar loading.

6.6 Supplementary Figures

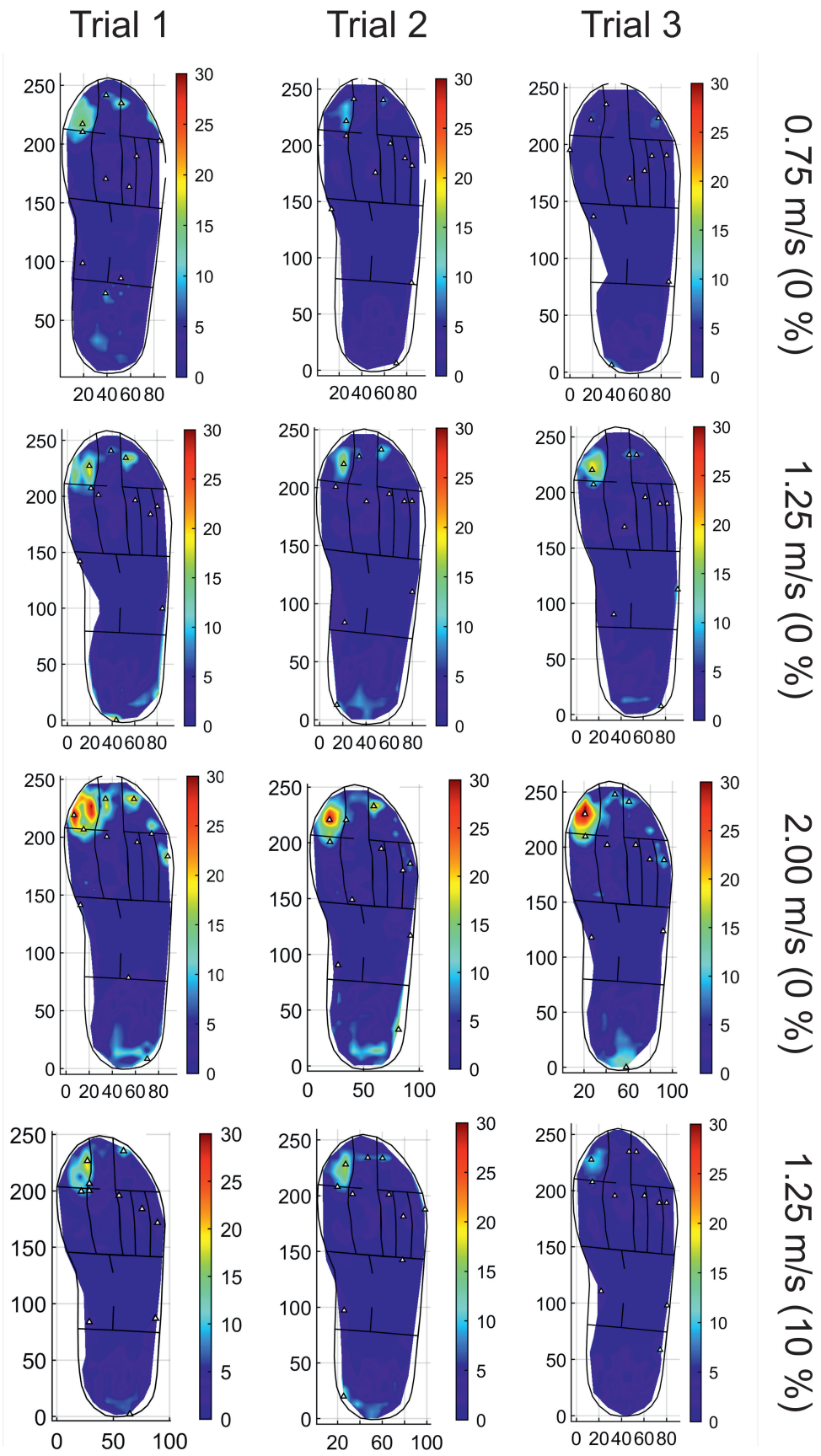

Figure 6.8: Strain profiles for repeated trialled speeds and inclinations for P01.

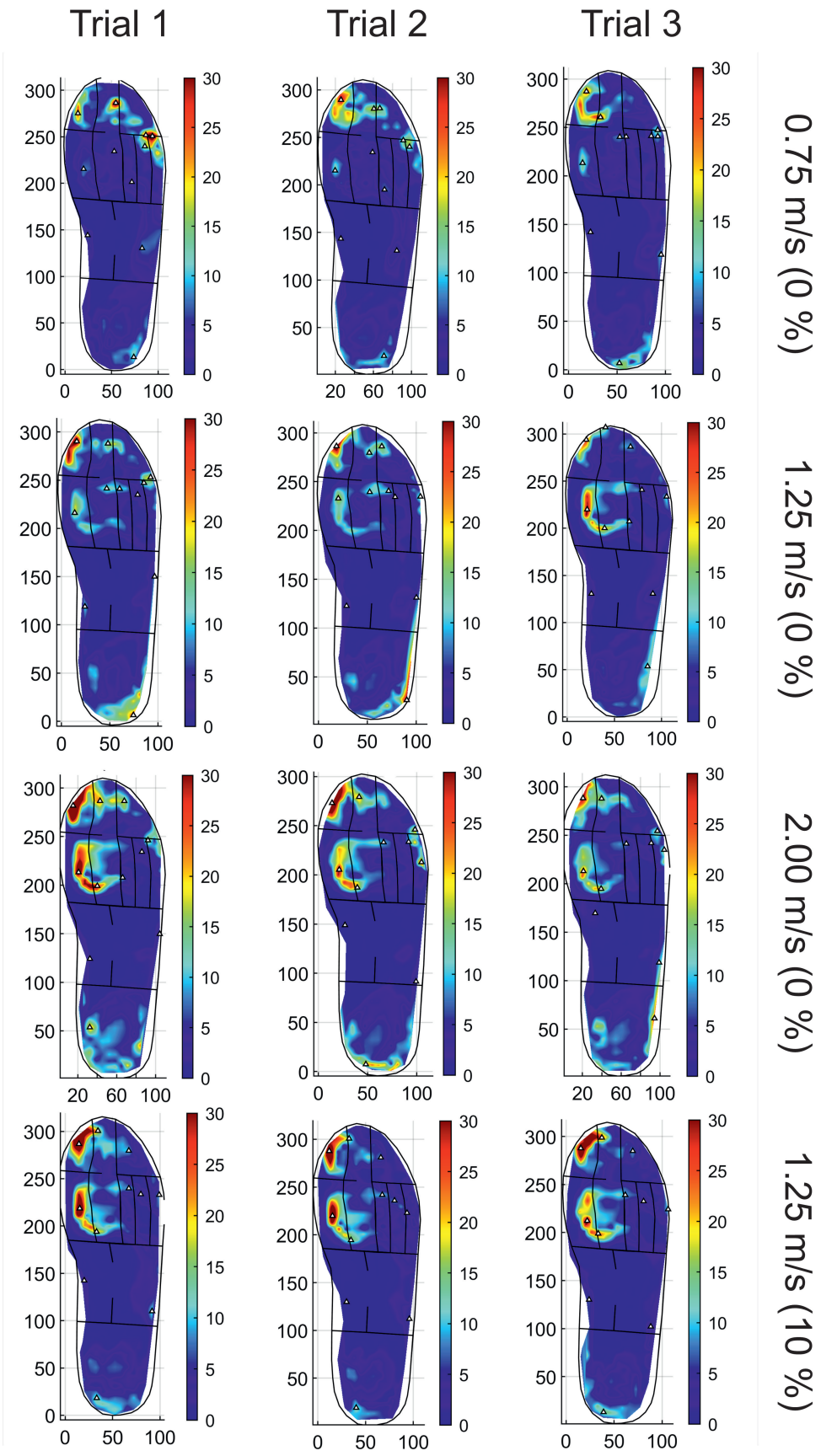

Figure 6.9: Strain profiles for repeated trialled speeds and inclinations for P02.

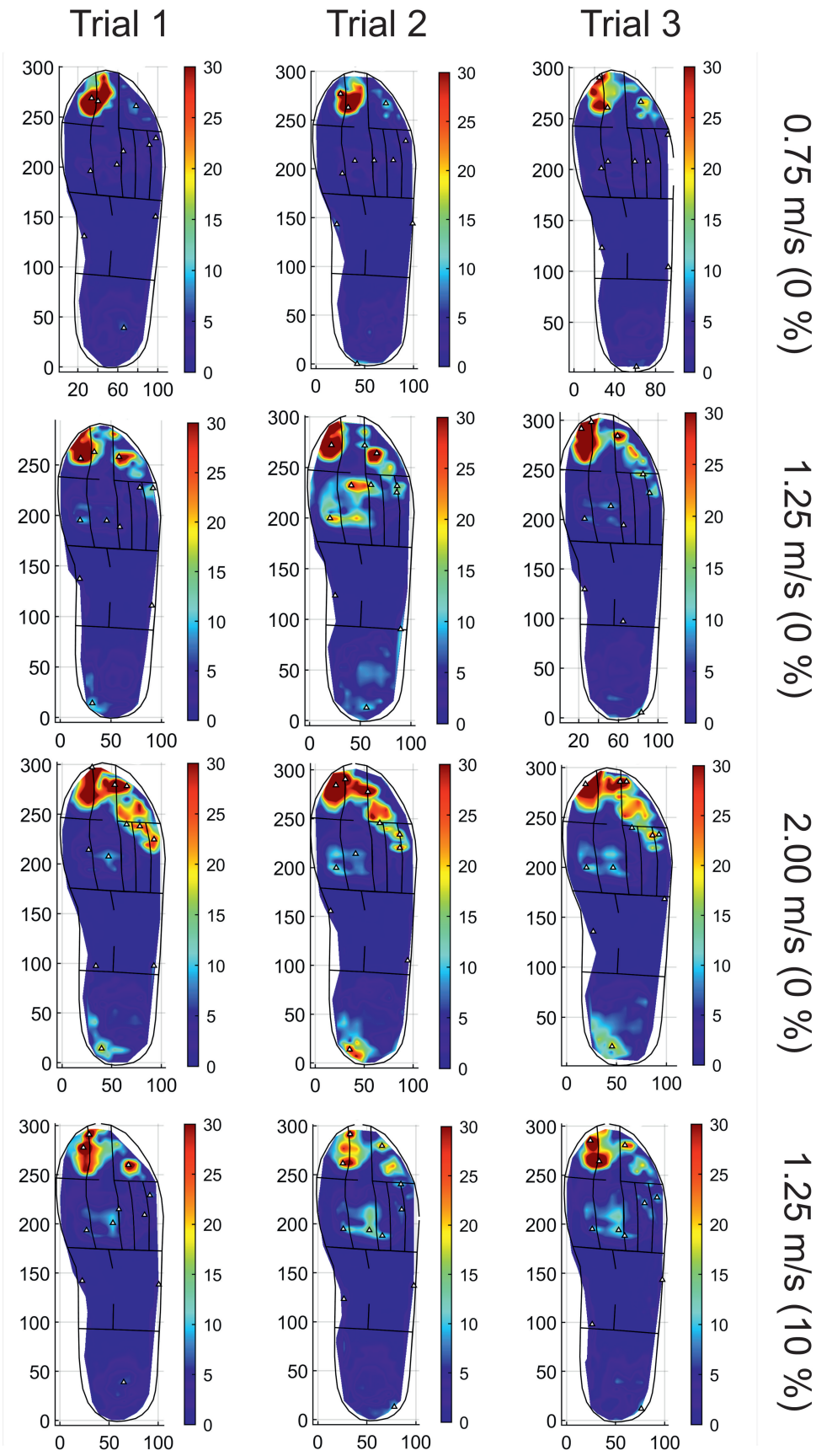

Figure 6.10: Strain profiles for repeated trialled speeds and inclinations for P04.

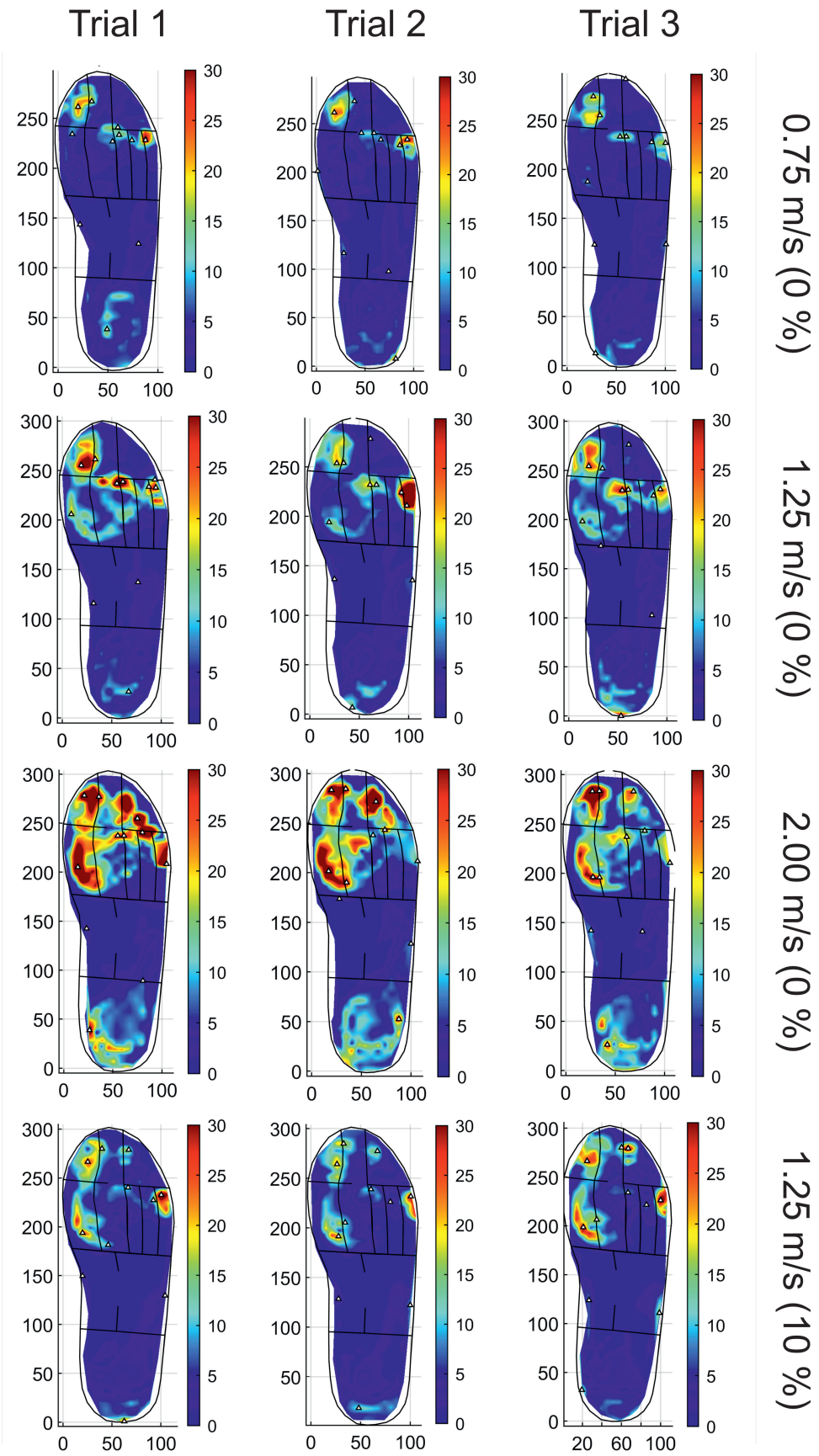

Figure 6.11: Strain profiles for repeated trialled speeds and inclinations for P05.

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Chapter 7

Digital Image Correlation Data Processing

Both the Plantar Loaded Observation DIC (PLOD) method and the STrain Analysis and Mapping of the Plantar Surface (STAMPS) method employ DIC techniques to provide the strain outputs generated. The data processing workflow undertaken for both methods is discussed in the sections below highlighting the key phases including camera calibration, processing via commercially available software [GOM Correlate 2020 [v2.0.1]] and a custom script approach (MATLAB [R2021a]).

7.1 Camera Calibration

The intrinsic lens properties of a camera impose an inherent distortion during image capture. To counter this all captured frames or images must undergo processing to account for this. Single camera calibration of a standard lens can be completed via the MATLAB Camera Calibrator Application. This method is centred on a chequerboard of known grid dimensions, which are reported within the process to allow for determination of real world image size of captured images. Between 10 to 20 images of the chequerboard are taken to allow for sufficient reference point tracking across focal space, with images captured at varying angles and rotations no more than 45° in relation to the lens position (Fig. 7.1). The calibration app processes the images, detecting the known real-world chequerboard dimensions, to determine the intrinsic lens distortion present while allowing for detection and removal of unsuitable calibration reference images to improve the output. This allows for the generation of a matrix of intrinsic camera parameters, which can be used applied to correct for lens distortion in any chosen image taken by the calibrated camera. MATLAB Image Batch Processor was used to allow for a streamlined approach to processing all collected study images prior to analysis.

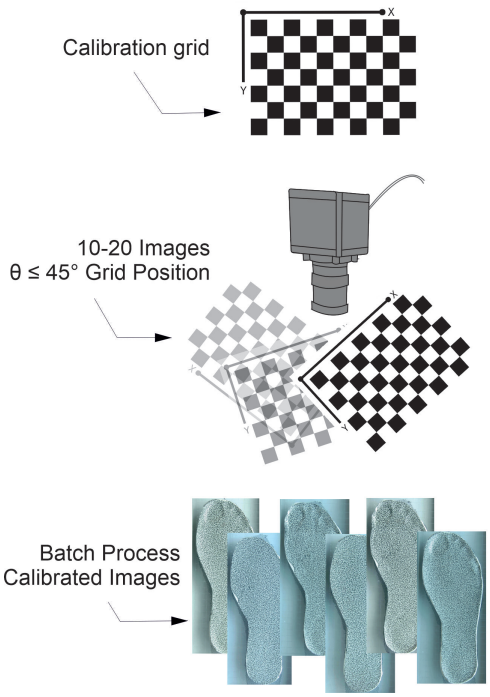


Figure 7.1: Overview of camera calibration process undertaken for all employed DIC techniques.

7.2 GOM Correlate Process

Initial image processing is conducted via GOM Correlate [2020 [v2.0.1]] commercially available software. Use of the software allows for an immediate generation of a relative strain plot to produced allowing for assessment of any potential tracking failures to the DIC patterning between frames and an overview of strain features present in the data. Insufficient interface design for data analysis requires that the data is exported from the software for further analysis. To achieve this an equidistant pointwise data plot spread is applied to the DIC surface component with spread dictated by maximum data point limits relative to the surface component size, shown in Fig. 7.2. From each data point, the location, relative displacements of the DIC and subsequent strain values are tracked in both x and y directions due to the 2D nature of the data capture. This data is then exported to MATLAB [R2021a] for further analysis.

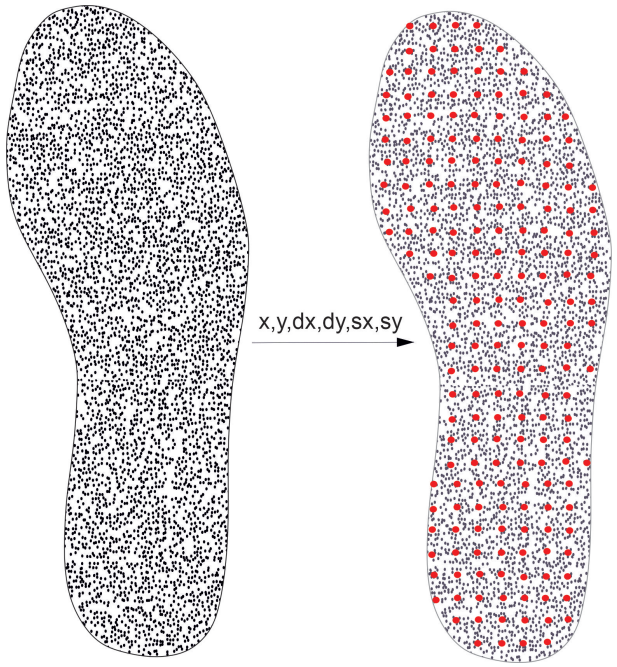


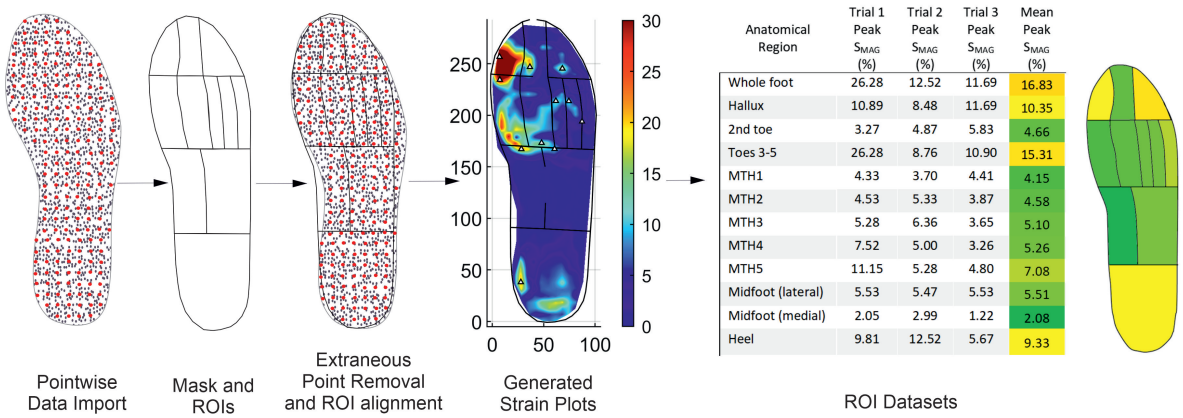
Figure 7.2: Depiction of equidistant pointwise data point spread applied to DIC surface component to provide location specific strain data.

7.3 MATLAB Process

Further processing of the data through MATLAB [R2021a] allows for the application of anatomical masking approaches to assign desired regions of interest (ROIs). Pedar® [Novel GmbH, Munchen, Germany] employs an ROI masking approach to segment the plantar aspect into anatomical regions aligned with key areas of ulceration prevalence to the foot and in respect to the sensor arrangement within the insole. Comparative masking approaches can be applied by utilising a custom script approach to assessing the exported GOM data.

The process used to generate output data according to the desired ROIs for both DIC methods can be seen in Fig. 7.3. The script initially imports the data extracted from the equidistant pointwise data spread applied in GOM Correlate. Due to the location specific data imported here, a mapped point view of the respective surface component is generated to use in the alignment of masking and ROI application. A representative mask reflective of the Pedar® masking regions is loaded alongside an overall mask. The ROIs initially are split into 11 predefined regions, three ROIs for the toe region, five for the metatarsal heads, two midfoot regions and the heel. The application of the masking can reduced to reflect combined regions and provide

fewer ROIs for analysis to account for difficulty in determining anatomical positioning and sufficient tracking approaches. Masking is applied to remove extraneous points and at this stage a sigma filter can be applied to the PLOD method as discussed in Chapeter 4. The outline mask and ROIs are then adjusted to determine foot positioning and anatomical alignment. The data is then processed according to the applied ROIs to generate quiver plots, axial and combined strain output plots alongside regional data valuations to provide peak and mean strains with relevant standard deviations.



Anatomical Region	Trial 1 Peak S_{MAG} (%)	Trial 2 Peak S_{MAG} (%)	Trial 3 Peak S_{MAG} (%)	Mean Peak S_{MAG} (%)
Whole foot	26.28	12.52	11.69	16.83
Hallux	10.89	8.48	11.69	10.35
2nd toe	3.27	4.87	5.83	4.66
Toes 3-5	26.28	8.76	10.90	15.31
MTH1	4.33	3.70	4.41	4.15
MTH2	4.53	5.33	3.87	4.58
MTH3	5.28	6.36	3.65	5.10
MTH4	7.52	5.00	3.26	5.26
MTH5	11.15	5.28	4.80	7.08
Midfoot (lateral)	5.53	5.47	5.53	5.51
Midfoot (medial)	2.05	2.99	1.22	2.08
Heel	9.81	12.52	5.67	9.33

Figure 7.3: MATLAB [R2021a] process to generate ROI specific output data.

7.4 Discussion

The application of a custom script to process the data provides study relevant output data comparative to achievable pressure data metric outputs utilised in research and clinical settings. Whilst the outcome is appropriate the process has limitations which require addressing to optimise the workflow for future applications of the DIC approach for plantar strain assessment.

Passing the data through GOM Correlate is a quick and commercially validated method of DIC assessment and provides immediate outputs to ensure data tracking is successful. However, this provides an additional stage in the process that requires taking the data out and back into the MATLAB framework between calibration and ROI application. Ncorr has been identified as an open source software to utilise MATLAB throughout the entire DIC analysis process. It also offers a solution as opposed to applying the equidistant pointwise spread for data exportation, which reduces information collected and provides a lower resolution strain output. By optimising Ncorr and the subsets utilised for analysis a high resolution low-smoothing strain data spread

can be generated across the entire DIC surface component, although this is beyond the scope of this project. DIC tracking is also a source for data limitation, which is smoothed by the use of the pointwise equidistant data spread and subsequent analysis. Improved tracking during the PLOD method is difficult to achieve due to the static reference image in relation to the dynamic data capture, however optimising Ncorr subset parameters poses a potential method to improve speckle detection of distorted post-data capture patterns during for STAMPS DIC applications. The subjective nature of the applied outline masking and ROIs is difficult to overcome. Whilst the masking applied is based on the proportionally ascribed pedar ® masking regions and is enlarged and rotated collectively to the varied insole sizes used, it does not necessarily relate to anatomical landmarks on the plantar aspect. Due to this incongruence between anatomical masking locations and person specific deviations, using a self-selecting approach to aligning the imprints on the insole with the masking regions is required. A further limitation of this process is a product of the data capture techniques used. Using a single camera method limits the data collection to 2D strain analysis. Implementing a stereo camera set-up, will allow for 3D DIC and can be incorporated in the MATLAB process using Ncorr.

Chapter 8

Mechanical Characteristics of Diabetic and Non-Diabetic Plantar Skin

This work is under review in:

Sarah R. Crossland, Francesca Sairally, Jen Edwards, Peter R. Culmer, Claire L. Brockett

Journal of the Mechanical Behavior of Biomedical Materials

Journal Article: Under Review

Dataset: https://doi.org/10.5518/1331

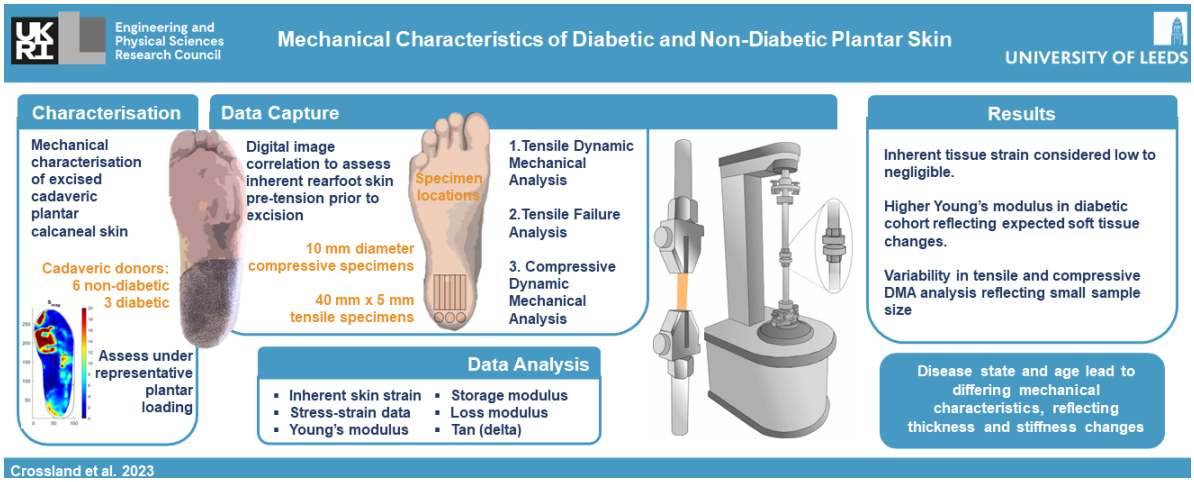


Figure 8.1: Graphical abstract for the paper Mechanical Characteristics of Diabetic and Non-Diabetic Plantar Skin.

Preface

Translation of in-vivo strain responses into understanding the skin and subcutaneous tissue mechanical behaviour is an important step towards building a greater picture of shear in the formation of diabetic ulceration. Characterising the mechanical response of plantar skin under representative tensile and compressive properties supports this step and allows for development of biofidelic surrogates and test beds to further plantar tribological analysis. This study assesses the mechanical characteristics of cadaveric plantar skin for both diabetic and non-diabetic donors under compressive and tensile dynamic mechanical analysis and tensile failure analysis. The plantar heel skin has been chosen as the anatomical focus of this study due to availability of tissue for multiple specimens to be cut for repeat measures. It has also been chosen due to the reduced complexity of the underlying bony mechanics compared to other ulcer prevalent sites such as the metatarsal heads, for ease of anatomical replication in potential translation to future biofidelic test bed approaches.

8.1 Abstract

Diabetic foot ulceration is linked to high amputation and mortality rates, with the substantial associated annual spend on the at-risk diabetic foot reflecting the intensive time and labour involved in treatment. Assessing plantar interactions and developing improved understanding of the formation pathways of diabetic ulceration is important to orthotic interventions and patient outcomes. Plantar skin surrogates which emulate the mechanical and tribological characteristics can help improve physical models of ulceration, reduce reliance on cadaveric use and inform more complex computational modelling approaches. The information available from existing studies to characterise plantar skin is limited, typically featuring ex-vivo representations of skin and subcutaneous tissue combined and given focus to shear studies with time dependency. The aim of this study is to improve understanding of plantar tissue mechanics by assessing the mechanical characteristics of plantar skin in two groups; 1) non-diabetic and 2) diabetic donors without the subcutaneous tissue attachment of previous work in this field. Digital image correlation was used to assess inherent skin pre-tension of the plantar rearfoot prior to dissection. Young's modulus, storage and loss moduli were tested for using tensile stress-strain failure analysis and tensile and compressive dynamic mechanical analysis, which was conducted on excised plantar rearfoot donor specimens for both disease state cohorts at frequencies reflecting

those achieved in activities of daily living. Plantar skin thickness for donor specimens were comparable to values obtained using ultrasound acquired in vivo values. Median tensile storage and loss moduli, along with Young's modulus, was higher in the diabetic cohort. With a mean Young's modulus of 0.83 ± 0.49 MPa and 1.33 ± 0.43 MPa for non-diabetic and diabetic specimens respectively. Compressive studies showed consistency between cohorts for median storage and loss moduli. The outcomes from this study show mechanical characteristics of plantar skin without the involvement of subcuteanous tissues under reflective daily achieved loading regimes, showing differences in the non-diabetic and diabetic specimens trialled to support improved understanding of plantar tissue response under tribological interactions.

8.2 Background

Diabetic foot health is an ever growing research area, mirroring the growth of the global diabetic population [1]. The diabetic population is more at risk of amputation than the general global population [2], with the number of diabetes related major lower limb amputations reaching nearly 8000 in England alone between 2017 and 2020 [3]. This correlates with data that shows the risk of mortality within five year of a diabetic foot ulcer (DFU) is 40% [4], rising following a major lower limb amputation to around 79% [5, 6]. In the UK alone, the annual spend on diabetic foot intervention and treatment totals to over £900 million [7], making the care of this diabetic patient subset both costly financially and in terms of labour resources also.

Prediction of DFU formation, through assessment techniques to allow for the use of prophylactic interventions, is a focus of much of the research surrounding the diabetic foot. Although the contribution of shear in the mechanical formation of DFU is considered, it has often been overlooked in assessment methods in favour of pressure solely due to the availability of technology to capture the relevant metrics [8, 9, 10, 11]. Research to investigate the contribution of shear in the interaction of the plantar surface has emerged in recent years due to the improved technology capabilities [12, 13, 11] and supports the vast body of pressure data already accumulated. Whilst the understanding of plantar skin in vivo surface response to shear and pressure is progressing, the need for translation and comprehension of the effect of these normal and tangential forces on the subcutaneous tissues is required to underpin DFU formation mechanics and is an emerging focus for researchers [14]. Current studies of plantar tissue mechanical characteristics are often centred on compressive shear studies mimicking direct plantar interactions [15, 16, 17, 18, 19, 20, 21, 22], using bulk property approaches to characterising the

soft plantar tissues during mechanical testing approaches [23, 24, 25, 26]. The need to isolate the interacting layers to define specific properties will support the development of more complex surrogate and finite element model methods and provide a basis for the development of treatment approaches for the at-risk diabetic foot.

Assessment of plantar skin thickness and stiffness between non-diabetic and diabetic cohorts has been studied using a range of in vivo and ex vivo approaches to begin to characterise the soft tissue response. Ultrasonography measurements have long been used to assess skin thickness in research and have been used to reveal the presence of increased skin thickness in the diabetic population [27], with improvements to ultrasound diagnostic tools it has developed into a key in vivo assessment approach. Outcomes from using these techniques with diabetic populations show thickening to the stratum corneum, increases in total thickness of plantar soft tissues, alongside epidermal thickness reduction in ulcerative and neuropathic groups [28, 29]. The plantar heel pad has been investigated to assess biomechanical properties at this subcutaneous layer utilising ultrasound. The heel pad superficial layer microchambers were seen to show decreased stiffness in diabetic populations compared to increased stiffness in the deep macrochamber layer, compared to healthy controls, which may lead to the decreased cushioning capacity seen in the diabetic foot [17]. The same methods have shown plantar skin thickness of the heel to range from 2.34 ± 0.33 mm to 2.86 ± 0.40 mm (2.s.f) dependent on disease state and study [29, 30]. In contrast, ex vivo histomorphological measurements have estimated plantar skin thickness to be closer to 2.06 ± 0.66 mm, but showing a 0.2 mm approximate increase in thickness than non-diabetic samples [31], and shown lower elastin content in diabetic calcaneal tissue in comparison [32]. Other studies using the same techniques found an a 1.70 mm (2.d.p) calcaneal skin thickness averaged across both disease states [33].

Whilst in vivo studies enable an understanding of the in-situ tissue response to mechanical loading, they are limited by the ability to recreate realistic loading patterns in both normal and tangential applied forces. The benefit of in vivo approaches are that functional tissue data can be obtained and used as a reference for ex vivo and in vitro studies. Existing ex vivo studies enable replicative pressures and strains to be applied to the tissue as seen at the plantar interface, but lack any representation of the foot's underlying anatomy provided to the tissue in vivo. Alternatively, in vitro assessments enable the replication of some in vivo characteristics, such as temperature or humidity, but has the structural tissue limitations of ex vivo assessment and is often chosen to support histological characterisation [14, 33]. Alongside a focus on compressive and shear responses, research is limited in reflection of the frequency of loading, instead opting to assess

characteristics over a set time period due to the soft tissue non-linear behaviour.

Understanding the tribological interface and mechanical characteristics of plantar skin is fundamental in developing improved skin surrogates. Current skin surrogates are often developed for use with a singular or limited range of use in mind [34, 35], such as to test the skin care industry, or for use in surgical simulations and thus often neglect the plantar aspect of the foot or provide simplified mechanical properties [36]. Chanda [37] recognised this need and have begun to develop elastomer surrogates alongside the development of calcaneal fat pad surrogates [38] but plantar skin surrogate development is still under-served. The development of surrogates to recreate mechanical characteristics of skin and underlying tissue of the plantar foot allows for biofidelic test bed creation. Utilising biofidelic test beds as a testing protocol enables the reduction in use of cadaveric tissue and allows for recreation of in vivo loading regimes without the difficulty in measurement brought about by direct measurements whilst also reducing ethical requirements and participant recruitment [39]. Further understanding of the plantar soft tissue responses during activities of daily living through simulated interactions, may lead to improved understanding of DFU formation pathways and allow for testing of existing and new treatment modalities.

Diabetic foot ulcers have complex etiology involving with both skin and subcutaenous tissue involvement in their mechanical formation. With the plantar skin interface being the focus of the interaction of the diabetic foot with its external surroundings, the skin has been selected as the primary focus for the scope of this study to better understand the mechanical characteristics for both diabetic and non-diabetic skin and address the research gap in this area. The need to characterise plantar skin mechanical characteristics under tensile and compressive loading independently of subcutaneous tissues is clear. Plantar skin undergoes both normal pressure and shear forces during daily interactions, this paper assesses the mechanical characteristics of ex vivo cadaveric plantar skin under tensile and compressive dynamic mechanical analysis (DMA), alongside tensile stress-strain failure analysis to reflect these forces and to characterise the role each makes to the skin response. Testing was conducted at representative walking and running frequencies for both diabetic and non-diabetic specimens to inform future physical models for biofidelic testing.

8.3 Methods

The study used a range of non-diabetic and diabetic cadaveric foot specimens from donors through a certified human tissue service [MedCure Inc., Orlando, USA]. Ethics were obtained via the University of Leeds MaPS and Engineering joint Faculty Research Ethics Committee (MEEC FREC) under ethics reference MEEC 18-040. Either left or right foot were taken without specificity from the individual donors based on the availability of donor tissue for use. Five non-diabetic donors and two diabetic donors being used to create six and three individual test specimens respectively. The sample size was determined by the availability of cadaveric donor tissue. The plantar surface was assessed prior to selection of the tissue to ensure that the presence of any skin defect, such as significant bruising or callousing, was not present across all specimens. Due to tissues being obtained post-mortem, no data was available on the duration of diabetes in the diabetic donors used within the study. A two-sample t-test was used to compare the relevant metrics between the non-diabetic and diabetic groups.

8.3.1 DIC Skin Pre-Tension Analysis

To support tensile mechanical testing, an understanding of initial tension to apply to the sample prior to data collection is required. Digital image correlation (DIC) was employed as a technique to assess the inherent pre-tension of the skin prior to excision from the cadaveric foot. Digital image correlation uses computer vision techniques to track positional changes of an applied stochastic speckle pattern during strain events [40]. A computer generated pattern, previously optimised for use in plantar strain tracking [41], was created with 0.8 mm speckles, 65% density and 75% variance [Speckle Generator, Correlated Solutions Inc.] and applied to an adhesive thin film of 0.18 mm thickness [Temporary Tattoo Paper Clear, Silhouette America Inc.].

The thin film speckle pattern sheet was adhered with a water application to the plantar rearfoot of each cadaveric donor prior to dissection of the specimen samples for mechanical testing (Fig. 8.2). The plantar aspect was positioned on a suspended glass plate using a 12 MP camera capturing a 2208 x 944 pixel image. Single camera calibration via a multi-image checkerboard process was undertaken to determine corrected image size and remove lens distortion [MATLAB, R2021a] [42]. An initial reference image was taken of the intact defrosted cadaveric foot and attached speckle distribution. Following dissection of the rearfoot plantar skin a second image was captured in the same orientation to track pattern changes caused from

dissection, as seen in Fig. 8.2. GOM Correlate [2019] software was used to apply an equidistant 1 mm data point spread across the DIC component to extract positional and strain values for exportation to MATLAB [R2012a] for further analysis. Masking was applied to select the outer boundary of the excised plantar region and a corresponding inner boundary of non-determinant values, sized proportionally with growth of the outer boundary. The inner boundary reflects a central region of the tissue less likely to show edge effects formed from shape changes due to the tissue dissection process.

Figure 8.2: Placement of the thin film DIC layer as applied to the plantar rearfoot of the cadaveric feet used within the study. The call-out shows the excised portion of the skin used for post analysis of strain changes using DIC.

8.3.2 Specimen Sample Preparation

Cadaveric feet were stored at -80 °C before being defrosted within storage bags in a waterbath until the plantar aspect was thawed, prior to the application of the speckle pattern for DIC

analysis. Dissection of the rearfoot plantar skin was conducted to remove the skin from the underlying subcutaneous tissue and extract an area covering the calcaneal region. Post DIC analysis, the excised plantar skin samples were bagged and frozen at -40 °C.

Prior to mechanical characterisation testing the skin was thawed for 20 minutes at room temperature. Dissection of the calcaneal sample was then completed to create tensile and compressive testing specimens (Fig. 8.3). Compressive specimens consisted of three cored 10 mm diameter samples taken from the posterior calcaneal region. Six samples were obtained for tensile testing in the form of 5 mm x 40 mm strips, aligned contiguously in the anterior-posterior direction of the foot (Fig. 8.3), in line with the direction of progression during gait and perpendicular to the langer lines of the foot. Strips were taken in lieu of 'dog-bone' samples due to limited availability of tissue from which to excise all samples. Samples were then stored in PBS solution prior to immediate mechanical testing to preserve tissue hydration. Testing of the tissue specimens was conducted immediately following sample preparation to reduce time of exposure to room temperature conditions and reduce potential for drying, from initial to final test, this time was approximately 1 hour 30 minutes. Sample thicknesses were measured using a digital thickness gauge [J-40 Series, Schmidt control instruments] to 2 d.p. for all excised specimens and reported in Table 8.1.

8.3.3 Cadaveric Tensile Testing

A universal load tester [ElectroForce® BioDynamic® 5110, TA Instruments®] was used in tensile testing, equipped with serrated tissue clamps (Fig. 8.4) Spacing was configured to allow 20 mm of visible sample length between the clamps. Tensile studies were conducted for both DMA and stress-strain testing to mechanical failure. Three excised samples were used for conducting DMA studies and three utilised for stress-strain testing. Specimen thickness was measured with a digital thickness gauge [J-40 Series, Schmidt control instruments] and reported in Table 8.1.

Specimen measurements were input in the software prior to running each test as required [WinTest®, TA Instruments®]. For DMA an initial pre-load tension of 0.1 N was applied in line with Chanda [37] to reduce any sample slack and reflective of the pre-tension of the skin prior to dissection. Tests were conducted to apply 4% strain to the sample inline with averaged strain values obtained from in-vivo plantar strain DIC testing at a normal walking pace of 1.25 m/s [43, 44]. Each sample was initially pre-conditioned at a frequency of loading at 1 Hz and recorded from 1.2 Hz to 3 Hz in 0.2 Hz increments. The initial frequency steps align well with

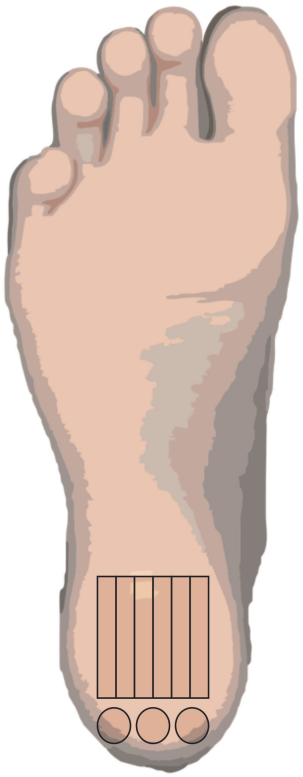


Figure 8.3: Location and orientation of the excised samples for tensile and compression testing. Tensile samples shown in the anterior-posterior direction. Compression samples shown taken from the posterior heel.

stance phases at slow walking speeds, building to brisk walking and running frequencies of stance phase loading during gait [43, 44]. The storage (E') and loss modulus (E") were recorded alongside tan δ (E"/E') for each frequency increment.

Stress-strain response was conducted at a rate of 0.24 mm/s, reflecting a strain rate of 0.012 s^{-1} for the visible specimen length as used by Ni Annaidh et al. [45], and continued until failure of the sample. Software, developed specifically for soft tissue analysis, was used to determine the mechanical characteristics of the plantar skin specimens from the output stress-strain curve data [Dots-on-plots™, Boise State University, USA]. The Young's Modulus of each specimen was reported alongside the transition, yield and ultimate stress and strain value, where default settings were used with the transition point considered to be 2% below the inflection point of the stress deviation from the linear fit and the yield point 0% above the inflection point.

8.3.4 Cadaveric Compression Testing

The universal load tester with 220 N load cell with compression plate adaptions attached [ElectroForce® BioDynamic® 5110, TA Instruments®], see Fig. 8.4, was employed alongside software for dynamic mechanical analysis (DMA) compressive testing [WinTest®, TA Instruments®]. Compliance compensation stiffness testing of the set-up was conducted. Samples were loaded centrally between the compressive plates and an initial compression of 0.1 N loaded onto each sample following the protocol of Pai and Ledoux [46] and to reflect the pre-tension of the skin prior to dissection. Specimen measurements were recorded on the DMA software prior to running each test. Three cored 10 mm diameter samples were taken from each donor for repeat testing.

Non-diabetic donor specimen samples were loaded to 20 N and diabetic samples were loaded to 30 N for DMA analysis in line with approximate cross-sectional area average peak pressure loading for plantar tissue determined by Brady et al. [33]. Each sample was initially pre-conditioned at a frequency of loading at 1 Hz and recorded from 1.2 Hz to 3 Hz in 0.2 Hz increments in replication of tensile DMA stages. The storage (E') and loss modulus (E") were recorded alongside tan δ (E"/E') for each frequency increment.

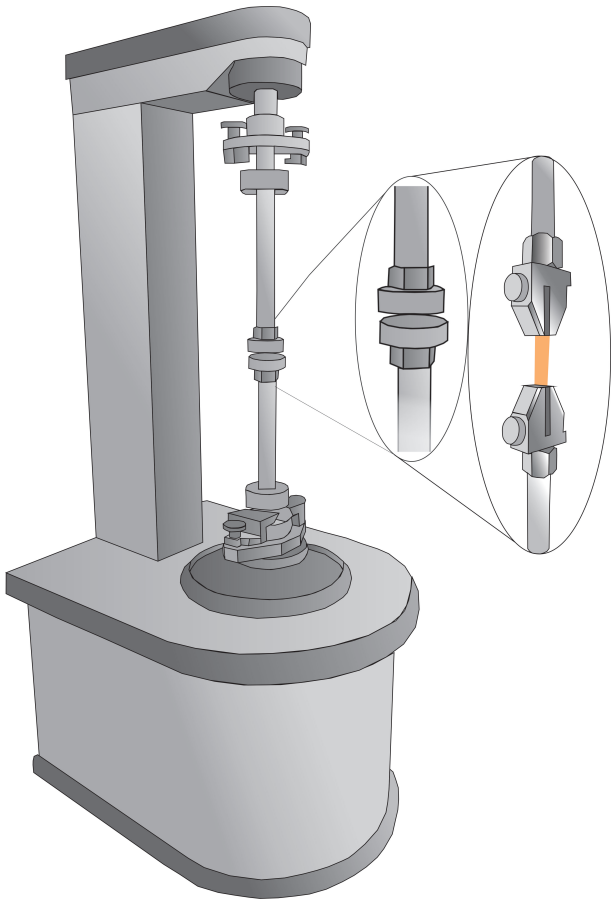


Figure 8.4: Configuration of the universal load testing equipment used in both tensile and compression testing with call-out showing the compression plate arrangement and tensile clamp positioning alternative [ElectroForce® BioDynamic® 5110, TA Instruments®].

8.4 Results

Table 8.1 shows the characteristics of the donors and the test specimens generated. Both the non-diabetic and diabetic group feature a donor with both left and right feet used as individual specimens, with this reflected in the number of donors, gender ratio, donor age and weight categories.

Table 8.1: Characteristics of the cadaveric donors and sample specimens showing Mean [SE] values.

	Non-Diabetic	Diabetic	p
Number of Donors (n)	5	2	-
Donor Age (years)	75 [3]	64 [4]	0.12
Donor Weight (kg)	67 [3]	114 [4]	0.00*
Gender ratio (M:F)	3:2	1:0	-
Number of Specimens (n)	6	3	-
Left and right ratio (L:R)	1:5	1:2	-
Tensile Sample Thickness (mm)	2.90 [0.10]	3.13 [0.13]	0.17
Compressive Sample Thickness (mm)	2.79 [0.13]	3.30 [0.25]	0.06

* $p < 0.05$ two-sample t-test

8.4.1 DIC Skin Pre-Tension Analysis

Successful DIC tracking was achieved for 4/6 non-diabetic and 2/3 diabetic plantar specimens. In the remaining 2 non-diabetic and 1 diabetic cases, DIC analysis could not be performed due to misaligned sample positioning between pre and post dissection images. Table 8.2 shows the mean strain values and standard deviations determined from DIC analysis for both the non-diabetic and diabetic cohort and combined as a singular group. The applied central and outer boundaries referred to in Table 8.2 can be seen in Fig.8.5, which shows an example of the strain 'heatmap' outputs generated for an individual plantar specimen. Central boundary values are chosen to reflect consistent equivalent positions of reference between specimens for assessment. The low values strain values seen for S_{mag} for both cohorts with relatively high standard deviations show a low strain that can be considered negligible in relation to any inherent pre-tension in the skin prior to dissection.

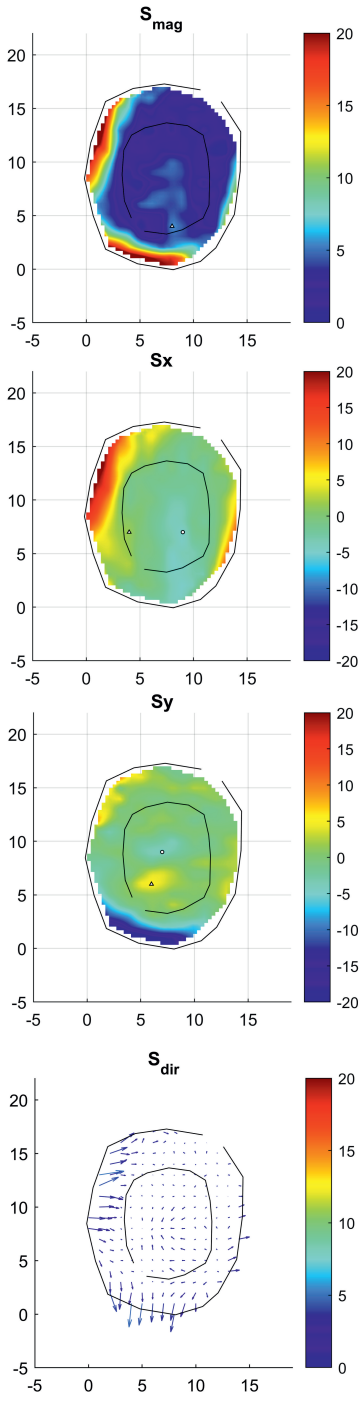


Figure 8.5: Example of a typical strain profile for one excised plantar skin specimen displayed as a heat map showing applied outer and central boundaries for S_{mag}, S_x, S_y and S_{dir} (quiver plot).

Table 8.2: DIC output data showing Mean [SD] strain values (S_{mag},S_x,S_y) for four non-diabetic and two diabetic rearfoot plantar skin samples tracked upon excision.

		Non-Diabetic	Diabetic	p	Combined
Outer Boundary	S_{mag} Mean	6.77 [8.03]	4.80 [5.00]	0.31	5.99 [7.05]
	S_x Mean	1.56 [8.98]	0.65 [5.91]	0.36	1.20 [7.92]
	S_y Mean	-1.36 [5.06]	-1.63 [3.18]	0.76	-1.47 [4.41]
Central Boundary	S_{mag} Mean	2.73 [1.72]	1.67 [1.96]	0.87	2.31 [1.76]
	S_x Mean	-1.55 [2.12]	-0.20 [2.17]	0.48	-1.01 [2.06]
	S_y Mean	-0.42 [1.85]	0.36 [2.35]	0.35	-0.11 [1.98]

* $p < 0.05$ two-sample t-test

8.4.2 Tensile Mechanical Properties

Results from tensile testing were plotted to show the individual specimen figures showing the mean storage modulus, loss modulus and tan δ alongside shaded errors depicting standard deviation for the three repeat trials. Fig. 8.6 shows the combined means and associated standard deviations for the two cohorts. Fig.8.7 shows the distribution of the storage and loss moduli and tan δ for both disease states with a greater number of data outliers in the non-diabetic cohort than the diabetic cohort, with a similar distribution of values around the median. For non-diabetic data plateauing of the storage and loss moduli median is seen to occur at around 2 to 3 Hz. In comparison to the non-diabetic group, the diabetic results show a tempered plateauing of the median occurring later at approximately 2.6 - 3 Hz for both the storage and loss moduli, with relatively higher achieved final values. The difference in sample size should be considered in reflection to these outcomes.

Table 8.3 presents the tensile characteristics from stress-strain failure testing. A two-sample paired t-test shows significance in the larger Young's modulus for the diabetic cohort, albeit with a small sample size limiting the implication of this.

8.4.3 Compressive Mechanical Properties

Compressive DMA output figures were generated in line with the tensile testing approach. Fig.8.8 shows the per specimen and combined cohort means and associated standard deviations for the storage modulus, loss modulus and tan δ values in relation to the increasing frequency.

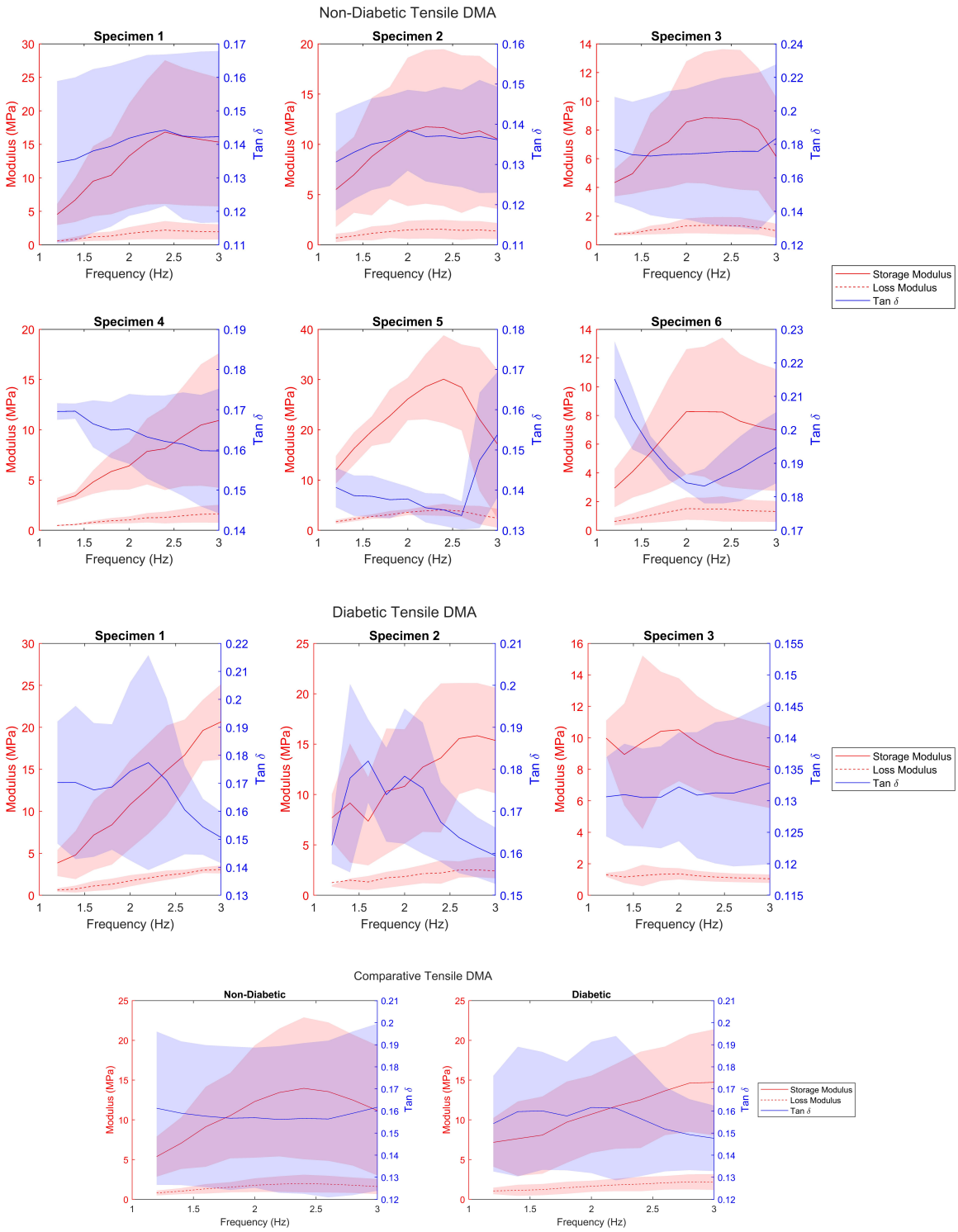


Figure 8.6: Tensile DMA analysis outputs showing storage modulus, loss modulus and tan δ mean and standard deviation for each non-diabetic and diabetic plantar skin specimen.

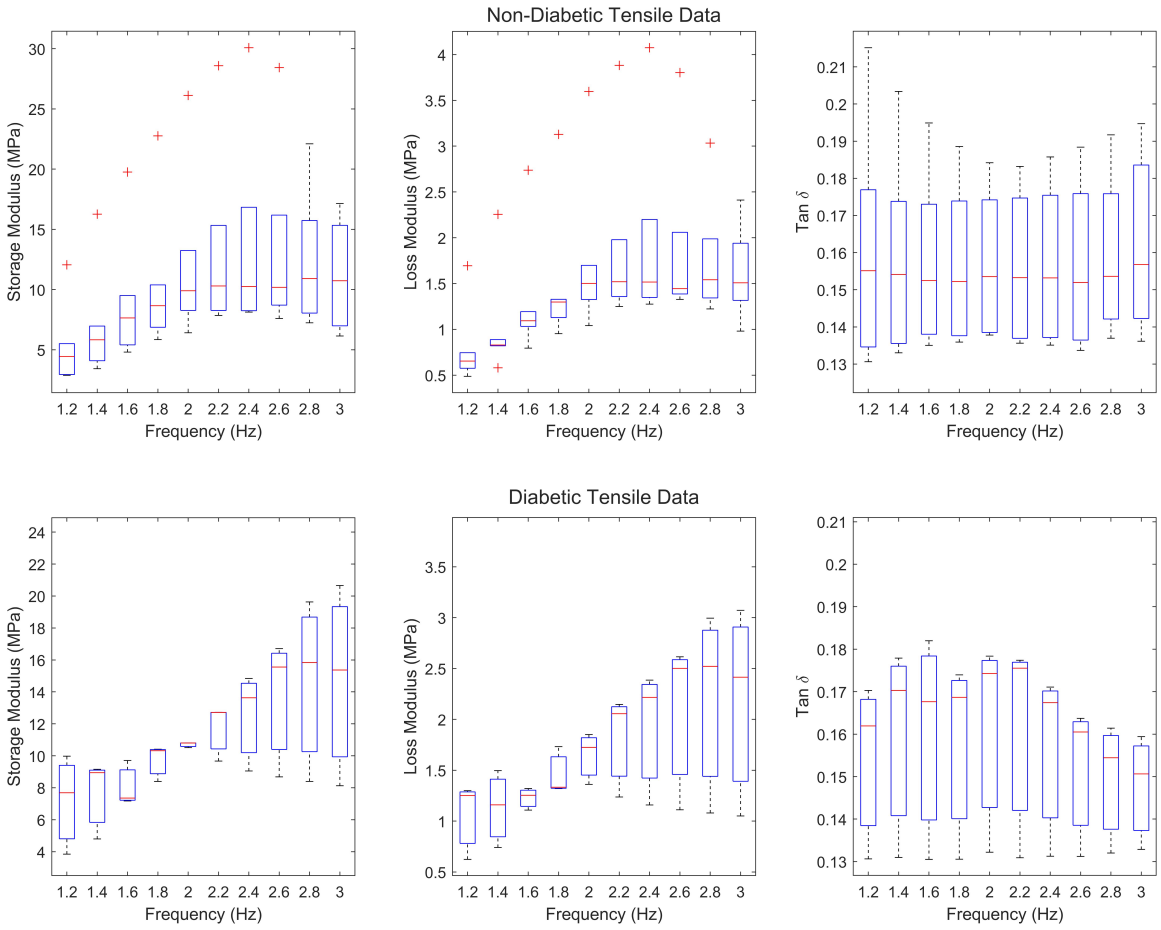


Figure 8.7: Tensile DMA comparative outputs for the combined cohorts of non-diabetic and diabetic plantar skin specimens.

Table 8.3: Stress-strain failure testing data of non-diabetic and diabetic plantar skin showing the mean and [SD] per specimen, combined means and p values, as determined using Dots-on-Plots™software.

		Non-Diabetic							Diabetic				
		Specimen 1	Specimen 2	Specimen 3	Specimen 4	Specimen 5	Specimen 6	**Non-Diabetic Mean**	Specimen 1	Specimen 2	Specimen 3	**Diabetic Mean**	p (1 s.f)
Strain (mm/mm)	Transition	0.02 [0.01]	-0.11 [0.02]	-0.07 [0.06]	0.01 [0.05]	-0.04 [0.03]	0.03	**-0.03 [0.02]**	-0.05 [0.01]	0.02 [0.06]	-0.04 [0.06]	**-0.02 [0.02]**	0.9
	Yield	0.06 [0.01]	-0.07 [0.03]	-0.04 [0.05]	0.08 [0.06]	0.01 [0.03]	0.07 [0.06]	**0.02 [0.07]**	-0.01 [0.01]	0.06 [0.07]	0.00 [0.06]	**0.02 [0.06]**	1
	Ultimate	0.18 [0.01]	0.24 [0.10]	0.06 [0.04]	0.28 [0.05]	0.23 [0.07]	0.21 [0.09]	**0.20 [0.09]**	0.13 [0.03]	0.25 [0.07]	0.15 [0.05]	**0.18 [0.07]**	0.5
Stress (MPa)	Transition	0.05 [0.01]	0.03 [0.01]	0.05 [0.01]	0.04 [0.01]	0.07 [0.01]	0.02 [0.01]	**0.04 [0.02]**	0.05 [0.00]	0.07 [0.02]	0.07 [0.02]	**0.06 [0.02]**	0.02*
	Yield	0.08 [0.02]	0.06 [0.03]	0.09 [0.02]	0.07 [0.02]	0.12 [0.02]	0.03 [0.02]	**0.08 [0.03]**	0.09 [0.01]	0.11 [0.03]	0.29 [0.12]	**0.24 [0.09]**	0.03*
	Ultimate	0.17 [0.05]	0.17 [0.07]	0.17 [0.04]	0.15 [0.04]	0.27 [0.04]	0.07 [0.03]	**0.17 [0.07]**	0.19 [0.05]	0.24 [0.03]	0.29 [0.12]	**0.24 [0.09]**	0.04*
	Young's Modulus (MPa)	0.96 [0.21]	0.86 [0.24]	1.13 [0.22]	0.50 [0.09]	1.13 [0.16]	0.41 [0.10]	**0.83 [0.49]**	1.11 [0.21]	1.25 [0.17]	1.64 [0.58]	**1.33 [0.43]**	0.004*

* $p < 0.05$ two-sample t-test

Fig.8.9 presents boxplots of the combined cohort characteristics for compressive storage and loss moduli and tan δ, showing greater variability in non-diabetic cohort, but increased consistency in median value growth with frequency comparative to the tensile outcomes for both cohorts. Plateauing of the storage and loss moduli are not seen in the compressive analysis, as with the tensile DMA, with miminally increased values achieved for the diabetic cohort in relation to the non-diabetic cohort.

8.5 Discussion

Donor weight was higher in the diabetic cohort reflecting group dynamics in the study of Brady et al. [33], with a non significant increase in tensile and compressive sample thickness seen also. Specimen sample thickness measured in this study is comparable to in vivo non-compressive plantar skin thickness determined by Morrison et al. [30], but thicker than seen in ex vivo techniques employed by Wang et al. [31], Wang et al. [32] and Brady et al. [33]. Alternative measurements of stained tissue using an optical measurement approach have been applied previously to find values of calcaneal and plantar skin thickness of between 1.70 and 2.06 mm (2.d.p), not congruent with the physical measurements determined by this study [31, 32, 33]. Whilst this technique was outside the scope of this study, the variance between values achieved utilising different measurement techniques and states should be investigated further.

Employing DIC to determine the surface strain response of skin is an effective technique to generate high resolution tissue characteristics. Reference images for DIC analysis are traditionally obtained from the initial frame of the video prior to collection of the remaining frames. In this instance the reference image is obtained from the whole foot with the comparative image collected once dissection has occurred. This is a source of potential tracking issues due to misalignment of the specimen with the original positioning of the reference image. This is the most likely cause of failure in this applied DIC process, leading to only 4/6 and 2/3 non-diabetic and diabetic specimens tracking. To reduce the likelihood of this a marked position on the glass was determined to place the excised sample, but slight rotational changes can lead to complete loss of tracking as seen in some specimen tracking in this study.

The region between the outer and central boundary, depicted in the example Fig.8.5, shows higher values of strain than within the central boundary consistently (Table 8.2). Factors which influence this value include the positioning of the sample on the glass post-dissection. It is postulated that some adhesion of the tissue to the glass surface occurs, creating a faux

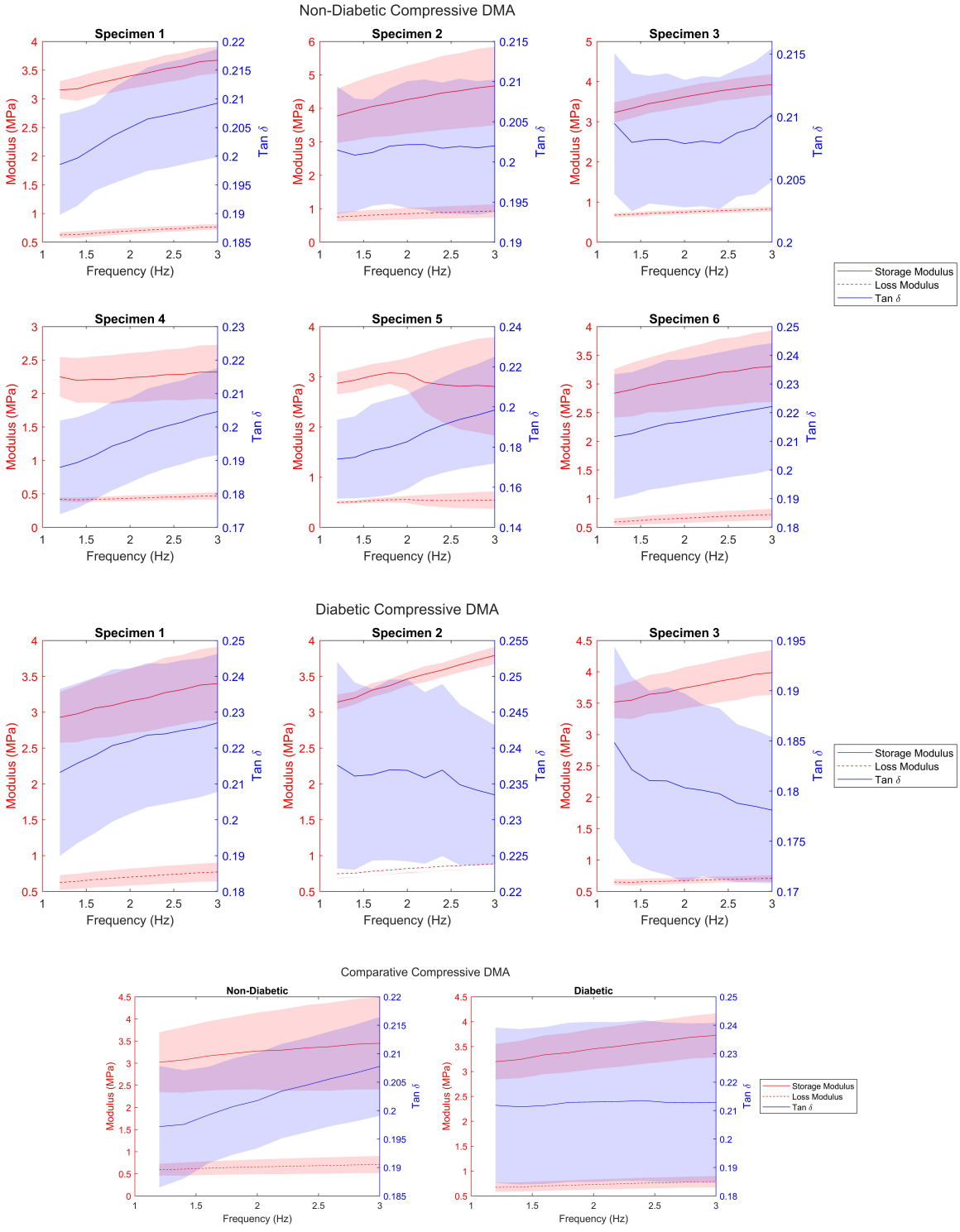


Figure 8.8: Compressive DMA analysis outputs showing storage modulus, loss modulus and tan δ mean and standard deviation for each non-diabetic and diabetic plantar skin specimen.

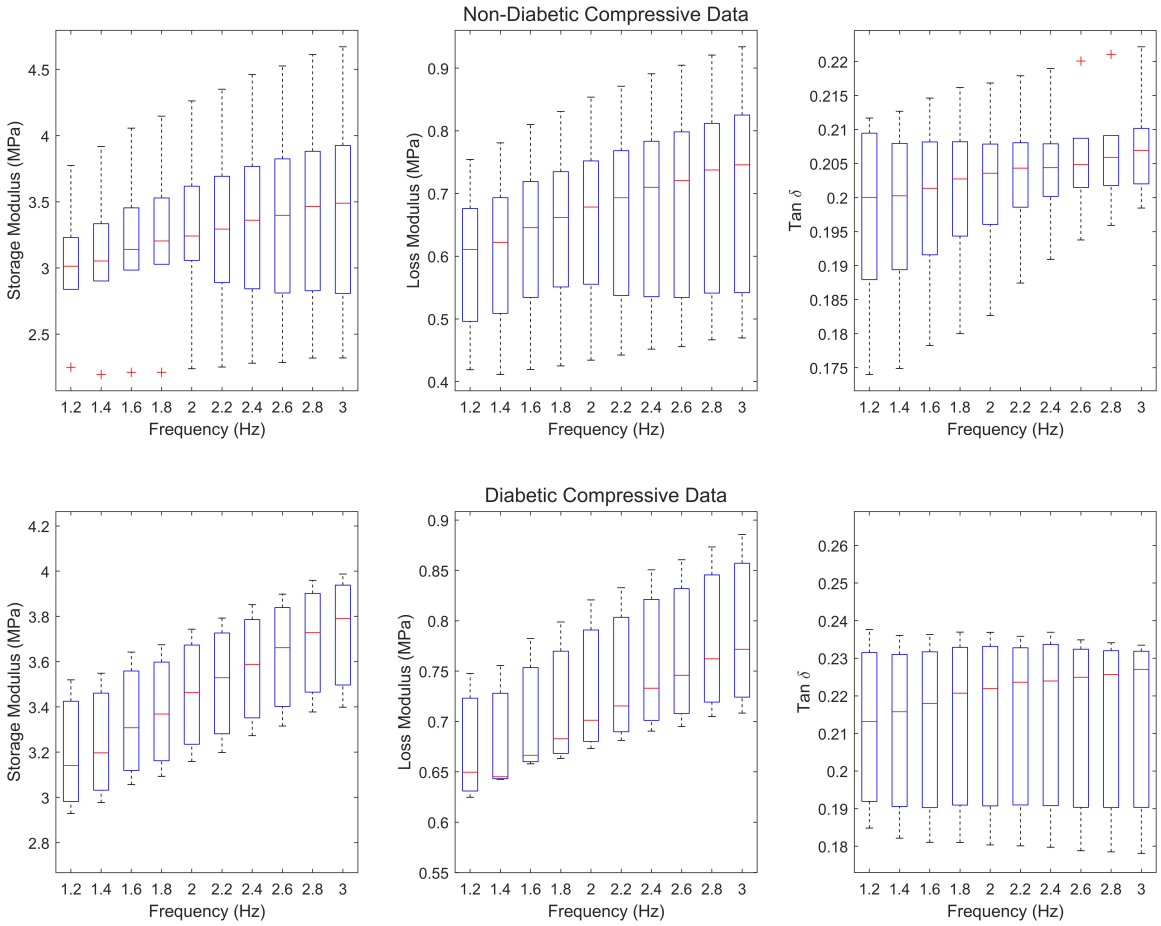


Figure 8.9: Compressive DMA comparative outputs for the combined cohorts of non-diabetic and diabetic plantar skin specimens.

strain region at the tissue edges in particular during alignment [47]. Strain at the outer boundary is also thought to be higher than the central region due to shape changes to the tissue upon dissection. The central region was established to account for these edge effects and focuses on a comparative sample across the specimens. Whilst glass refraction is present, it is accounted for due to the pre and post dissection images being taken under the same conditions in contact with the glass. The combined mean S_{mag} value, 2.31 ± 1.767, for central boundary can be considered to be the closest representation to pre-tension of plantar calcaneal skin. This low value of strain and discussed method errors, support an outcome of negligible strain and implied minimal skin pre-tension prior to dissection. This supports the standard applied pre-tensions used in the tensile and compressive testing dervived from literature [37, 46].

Tensile stress-strain failure testing provided a relatively low Young's modulus in comparison to other in vitro derived values for the skin across a range of sites and testing modalities, but not disproportional to in vivo response results [45]. Ni Annaidh et al. [45] study of the effect of orientation on mechanical characteristics of excised back skin shows that at 90°orientation to the langer lines exhibits lower Young's modulus, which is congruent with the specimens excised in this study in the anterior-posterior direction on the plantar aspect. Differences in plantar skin to other skin sites, including increased skin thickness [27, 28, 29], lead to differing mechanical characteristics and Young's moduli. The higher Young's modulus of the diabetic cohort reflects the expected soft tissue changes of increased thickness and stiffness of the tissue comparative to non-diabetic specimens [27, 28, 29]. Pawlaczyk et al. [48] report the linear increase of Young's modulus of the skin with age, but with a higher value seen in the younger donor diabetic population it, it can be postulated that diabetic skin changes influence stress-strain plantar skin response.

Storage modulus reflects stiffness changes with load applied to the tissue, Wang et al. [32] reports of reduced elastin content in diabetic plantar tissue and combined with expected comparative stiffness increases to the tissue [17], meant that the higher storage modulus achieved in the diabetic tensile DMA testing was unexpected (Fig. 8.7). The disparity in sample size within the disease population may contribute to this, but the population age should also be considered. As in Table 8.1, the non-diabetic donor age is higher than the diabetic population, and with age being a function of increasing skin stiffness this may effect the data [48]. Diabetic disease state is also known to contribute to plantar soft tissue changes [29], and with disease longevity, neuropathic and pre-ulcerative history unknown for the donor group it is uncertain the contribution this plays in the study outcomes. Fig. 8.7 shows the tan δ median decreasing with

increasing frequency in the diabetic population compared to relative stability in the non-diabetic cohort, suggesting that disease state may impact dampening effects of the skin undergoing tensile evaluation. DMA analysis was conducted at frequencies representative of a range of gait speeds undertaken during activities of daily living [44].

Compressive DMA subjected the disease groups to different loading conditions of 20 and 30 N, reflective of expected loading in the respective non-diabetic and diabetic populations [33]. Fig. 8.9 showed minimal difference in median values for storage and loss modulus and tan δ between the populations. With these characteristics being a function of load, it would be expected that the value may differ due to exposing the diabetic specimens to 10 N increased loading. Further studies with an increased sample size and under consistent and varied loading conditions should be considered to investigate population variance.

Due to the limited availability of tissue, in particular diabetic donors, the sample sizes used in this study are small and lead to reduced power in any statistical evaluations considered, as reflected in similar studies [33]. Limited availability also meant that in both cohorts, one donor provides specimens from both feet for assessment whereas all other donors provided only one foot for specimen collection. Limitations also exist in the methods of tissue excision and measurement, leading to variability in the values obtained for skin thickness. The difficulty in separating the subcutaneous fat from the skin and the inability to distinguish between any remaining fatty tissues still attached using a thickness gauge supports this limitation. The protocol employed for tensile testing also provides a potential source of result variability. Gripping tissue using serrated clamps, whilst maintaining tissue hold, may lead to some loosening of the tissue position alongside elongation of the tissue during the study. Improved tissue grip designs alongside torque controlled clamping may improve consistency in grip and subsequent soft tissue testing results and should be considered for future studies [49].

Application of the mechanical properties of plantar skin characterised in this study offer the potential for use in developing an improved plantar surrogate, deviating from the oversimplified models often currently employed in tissue surrogates [37]. When translating mechanical characteristics into surrogate development it is important to consider the response of shear due to the role it plays in plantar interactions leading to DFU formation [11]. Though this is outside the scope of this study it has been considered previously in other studies of skin mechanical characterisation [33, 50]. Holt et al. [50] found that skin exhibits strain hardening under shear step-stress conditions, but when analysing independent skin layers, the dermis alone demonstrates stress softening. This individual layer response showed the epidermis providing

elastic rigidity to the skin, with the dermis responsible for viscoelasticity [50]. Due to this differing response of the skin layers, future studies should investigate the dermis and epidermis separately to ensure that any subsequent surrogate development aligns with the mechanical characteristics of the complete skin structure. Further studies should also focus on the role of subcutaneous tissues acting under the loads transmitted from the plantar skin surface during interaction with the external environment, to characterise their behaviour and contribution in the development of ulcerations.

The mechanical characterisation of the skin in this study offers potential for translation of findings to surrogate development of both diabetic and non-diabetic tissues for use within biofidelic test bed approaches. Biofidelic test beds offer the opportunity to reduce reliance on cadaveric tissue when assessing plantar interactions, but the lack of appropriate mechanical surrogates limits their employment at present. Future studies should consider surrogate manufacture utilising the defined tissue characteristics for biofidelic testing approaches.

8.6 Conclusions

Measuring plantar tissue mechanical characteristic differences between disease states is fundamental in working towards improved understanding of diabetic foot ulceration formation pathways. DIC offers a useful method to assess inherent surface straining of the skin both in and ex vivo. Assessing tissue response under frequencies representative of activities of daily living to determine dependant characteristics, provides a method that ensures development of physical models to be tested under the same loading regimes can be met. Whilst the sample size in this study is low, due to availability of donor tissue, differences can be seen in the mechanical characteristics of the non-diabetic and diabetic population plantar specimens undergoing DMA and stress-strain analysis. Utilising these response characteristics will inform the creation of non-linear response surrogates, moving away from the current simplified property models and allow for more realistic physical models for tribological assessment. A successful surrogate will reduce the reliance on donor procurement for testing and allow for increased testing demand of plantar tribological studies to work towards improved interventions and patient health outcomes for the at-risk diabetic foot.

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Chapter 9

Discussion and Conclusions

9.1 Publication Review and Impact

The findings of the four publications which contribute to this thesis can be found summarised below along with a following statement on the contribution of the body of work to the research field.

Plantar Surface Shear Strain Methodology Utilising Digital Image Correlation
Refinement of a computer generated speckle pattern and application process via a rubber stamping approach enabled consistent 2D DIC tracking of plantar skin surface shear strain during stance across all participants of a small cohort feasiblity study. DIC offers a low cost method of gaining valuable in-vivo skin strain data at the plantar interface.

STAMPS
Development of the STAMPS plastically deformable insole with application of an optimised computer generated DIC speckle pattern, enables it to be used as a novel low-cost strain measurement tool to capture the cumulative level of strain under plantar loading at the foot-shoe interface in shod stance. This novel system provides a repeatable method of DIC implementation, successful across a small cohort study, with good agreement with pedar® recorded plantar pressure data, and potential for future translation to clinical environments.

STAMPS Speed and Inclination Analysis
Under controlled variable plantar loading regimes, the STAMPS plastically deformable insole shows increase in activated strain regions with increasing speed and increasing strain value. Increasing inclination shows forefoot translation of strain active regions, in line with expected response. This study supports that the STAMPS insole successfully tracks strain changes under differing plantar loading conditions representative of activities of daily living in the population and warrants further investigation in larger healthy and diabetic cohorts.

Mechanical Characteristics of Diabetic and Non-Diabetic Plantar Skin
Mechanical characterisation of cadaveric diabetic and non-diabetic plantar skin was undertaken to enhance the limited literature in this area of study, focusing on the skin alone without subcutaneous tissues. This study showed that inherent skin pre-tension prior to dissection from the cadaver can be considered to be negligible. Whilst the power of the study is too low to draw firm conclusions, higher Young's modulus was seen within the diabetic cohort reflecting the expected changes seen in soft tissues within this population. The variability in the tensile and compressive DMA analysis reflected the small sample size and warrants further investigation. This work establishes mechancial skin characterisation values which would support the future development of improved skin surrogates for biofidelic test bed analysis approaches.

This body of work contributed novel methods of strain capture to analyse the 'difficult to measure' in-vivo plantar interface. Previous developments in this area have focused solely on sensor technology, with no current commercially available products on the market. Through this work, the STAMPS strain capture system has been implemented within a parallel NHS trial on patients at low and high risk of DFU occurrence, providing a first step towards a translational tool for clinical use which also operates at a lower cost than sensor technology. Beyond this it has provided foundational results for the strain response changes under a range of loading regimes. This research has also contributed to the fundamental mechanical characterisation of plantar skin at frequencies seen within representative activities of daily living for both diabetic and non-diabetic population to inform future research into plantar skin tribological interactions. This work provides a key fundamental stage for development of modelling analysis approaches by providing both tools with which to capture input data and mechanical characterisation data of plantar skin.

9.2 Research Objective Review

The research aim and objectives were presented in Section 1.2 to outline the direction of the project. This section addresses where these objectives have been met within the respective studies.

Objective 1 *To identify and develop a method to capture plantar skin shear strain response during gait events.*

Chapter 4 outlines the application of an optimised DIC approach for direct application to the

plantar aspect to track strain changes. This method was trialled with a small cohort feasibility study during a single stance phase assessment of gait.

Objective 2 *To develop and optimise plantar strain capture methods for use in shod environments.*

The translation of a DIC approach to an in-shoe novel plastically deformable strain measurement insole was outlined in Chapter 5. This method enabled the capture of strain data within the shoe complex over cumulative steps for a small cohort trial to validate the method approach.

Objective 3 *To characterise plantar strain response deviations under differing loading regimes reflecting activities of daily living.*

Changes in speed and inclination often characterise fundamental changes in movement undertaken during activities of daily living. Chapter 6 assess the response of strain and anatomical strain activity of the plantar aspect during shod interactions at controlled gradient and speeds using the novel STAMPS strain measurement insole developed in Chapter 5. The speeds reflect a slow, normal and brisk walking pace to reflect daily changes to gait.

Objective 4 *To evaluate the mechanical characteristics of plantar skin under representative tensile and compressive loading.*

Translation to understanding mechanical behaviour of the skin and underlying tissues to known surface strains was identified as a key component to improving understanding of ulcer formation pathways. Chapter 8 evaluates the response of cadaveric plantar skin under representative tensile and compressive loading patterns to assess mechanical characteristics of both non-diabetic and diabetic tissue.

9.3 Discussion

With the global diabetic population continued increase [1] and associated ulceration affecting around 34% of this cohort [2], the burden of DFU is an ever present problem. Whilst the at-risk population grows, improving assessment approaches and treatment pathways is essential to reduce the burden on healthcare services and the associated high cost and labour requirements [3], and reducing amputation and mortality risk for the patient. To work towards this goal, greater understanding of the routes of ulcer formation are required.

The mechanical contribution to DFU formation is determined by the data that can be measured to assess the surface interactions occurring at the foot during daily life of the diabetic population. Measurement techniques that assess the foot are focused to the plantar aspect, which accounts for 48% of all ulceration prevalence in the diabetic population [4]. Whilst this neglects dorsal ulcer formation pathways and the contribution of footwear fit and material, it focuses on characterising the loading regime changes through varied activities of daily living. To develop a wider understanding of the interaction of the plantar aspect, assessment is centred on pressure measurement. This is due in part to the availability of pressure measurement technologies both in and out of the shoe complex that enable a wide variety of trials [5]. Pressure alone is not a good predictor of the ulcer formation [6], with shear understood to play a contributing factor in ulcer development mechanics [7]. Interest in understanding the role of shear in skin tribology and DFU is growing, but with data collection methods for shear in their infancy and commercially viable options unavailable [8, 9, 10, 7], there is a reduced capacity for exploring plantar tribology in this way. The complexities of tribological interactions of the foot cannot be trivialised and any approach undertaken must consider the multiple factors at play. Characterising the interaction may be conducted utilising an overarching technique, but person-specific constituent elements play a significant role in plantar soft tissue responses, including but not limited to, foot deformities, soft tissue changes, moisture at the interface, socks use and footwear selection.

Chapter 4 establishes a DIC strain measurement method to characterise interactions of the plantar surface. Focusing on strain as a surrogate measure for the involvement of shear in the plantar complex allows for the implementation of DIC. DIC approaches offer a low-cost, high resolution outcome, in antithesis to clinically used pressure sensing technology which is often associated with high initial costs and resolutions reliant on the sensor spread used. Soft tissue responses during plantar interactions reflect the changes in loading regime across the gait cycle, such as for the calcaneus when high impact phases such as heel strike reduce towards midstance. In-shoe pressure sensing insole have the capability to monitor loading response changes throughout the gait cycle. Reflecting this approach in the employed DIC technique provides a wealth of information about skin strain changes in ulcer prevalent plantar locations. In this way, once a greater understanding of the translation of strain events into ulcer risk is established, identification of areas within gait where the foot requires accommodation for strain can inform orthosis design. The limitations of this DIC approach are that whilst phase specific direct plantar surface skin strain information is generated, it is limited to assess a single phase. This lack of reflection of the 'real world' response of the foot during activities of daily living is

problematic in some instances in gaining a full picture of plantar tribology, but similar to existing pressure plates, it can capture detailed information of a point in time that is a reflective snapshot of that foot profile [11].

Translation of this DIC technique approach into the in-shoe complex is a necessity to provide a true reflection of plantar tribology during activities of daily living. The DIC method established in Chapter 5, was responsive of the optimised computer generated stochastic speckle pattern developed within Chapter 4. Using a repeatable DIC pattern means that reliability of tracking is improved across repeat measures. Alongside a non-electronic method of shod data capture, a reduction in failure modes of the method comparative to other DIC implemented approaches [11] and pressure sensing technology is seen. Strain was also seen to be strongly associated with increasing peak plantar pressure reflecting the combined pressure and shear assessment. The limitations of the shod STAMPS DIC approach are that it is limited to only capturing ten steps of gait. This improves upon the unshod DIC method, by providing an increased number of steps conducted during mid-gait rather than solely during phases of increasing and decreasing momentum at the tail ends of gait. Though this limited step number is suited to a clinical environment for gait assessment, it lacks the translation potential as a commercially viable toolkit due to inability to continue use during everyday tasks. Understanding the varied loading regimes experienced by the patient in everyday life is important in understanding ulcer formation and providing prophylactic treatment approaches tailored to their requirements. Future studies should consider investigating alternative plastically deformable mediums which allow for a high step count of test to be conducted, as this is an area of research that is currently not investigated.

The STAMPS pilot study was reflective of the expected normal walking pace undertaken by the majority of patients during daily ambulation. Scoping the use of the STAMPS measurement insole beyond a self-selected normal walking pace ensures the viability of the tool for use under differing loading regimes. Chapter 6 investigation of controlling of speed and inclination for a five participant study using STAMPS showed that the insole was able to reflect increasing strain values and strain active locations with increasing speed. It also showed forefoot transition of strain activity from the rearfoot during inclination, reflecting speed and inclination controlled studies using the gold standard pedar® pressure sensing insole [12, 13].

The development and evaluation of the STAMPS insole under differing loading regimes of gait has enabled congruent studies to be run to explore strain valuations. Studies have been conducted beyond the scope of this PhD, to support the work of the joint first author of the

journal article associated with Chapter 5. This work focuses on implementation of STAMPS in larger non-diabetic and diabetic cohorts, via NHS ethics, to assess strain variance in the populations. The diabetic study focuses on both low risk and previously ulcerated groups, assessing strain at normal self-selected walking speeds with and without pressure offloading intervention. Associated study publications are in development to discuss the results of the trials.

Establishing strain data collection methods and developing benchmark population data provides a step towards improved understanding of diabetic plantar tribological changes. Translating this information into understanding the mechanical tissue response of skin and the subcutaneous soft tissues is required to work towards the development of biofidelic test beds for tribological evaluation of varied plantar interaction regimes to underpin tissue mechanical response under DFU forming loads. Surrogate development for use in biofidelic modelling of the plantar aspect is limited. Surrogates are often developed for specific applications, such as surgical practice, and as such have simplified or bulk mechanical properties that do not reflect soft tissue response under pressure and shear interactions [14]. This need has been identified by other studies, with the focus given to assessing skin and subcutaneous tissue together under shear conditions for time dependant properties [15]. Chapter 8 characterises the mechanical properties of plantar skin solely, tested under expected strain and loading and at replicative frequencies of a range of daily achieved gait speeds [12]. Though a small sample size was tested, due to tissue availability, giving reduced power, differences in the diabetic and non-diabetic donor specimen values for Young's modulus, storage and loss modulus and Tan δ were seen. To support the surrogate development phase using the devolved tissue characteristics, increased specimen testing would be beneficial along with characterisation of the epidermis and dermis separately, due to the known mechanical differences to the layers [16].

9.4 Future Work

This research project establishes the early stages of characterising the tribological interface of the plantar aspect of the foot including the contribution of shear. It assesses the ability to measure changes in strain occurring through altered loading regimes and builds to translate this characterisation of the interaction into measurement of mechanical plantar skin responses through cadaveric studies. This development works towards building an understanding of the loading and response of the foot during activities of daily living, providing a foundation for working towards a deeper understanding of DFU formation pathways. To continue this development the following

studies are proposed.

9.4.1 Plantar Skin Surrogate Development

Development of biofidelic surrogates is an important component towards biofidelic test bed approaches, allowing for reduced reliance on cadaveric studies and removing complexities brought about by in-vivo data collection.

Skin surrogate development as a field of research is often focused on the cosmetics or surgical industries, to assess new formulations and provide training materials respectively. Due to this, little attention has been provided to the plantar aspect in terms of surrogate development and due to differences in plantar skin characteristics, as expanded upon in Chapter 2, other skin surrogates bear reduced resemblance and cannot be used in lieu [14]. It is therefore suggested that mechanically representative surrgate development is a future area of research.

9.4.2 Plantar Aspect Biofidelic Test Bed Development

The development of strain responsive biofidelic surrogates can be considered the initial step to work towards a biofidelic test bed. Biofidelic test beds allow for variable controlled, repeatable studies of tribological interactions reflecting loading patterns seen in activities of daily living. This also reduces reliance on cadaveric tissue use and can be used to inform further participant cohort studies. Characterising the interaction between the plantar aspect and opposing surface provides a wealth of data relating to plantar skin response, but does not explain the response of the subcutaneous tissues. Development of a plantar strain biofidelic test bed would allow for the use of strain responsive plantar surrogates to be embedded for bench top assessment of subsurface motion of controlled input loading on the created plantar surface.

9.4.3 Evaluation of Alternative Plastically Deformable Mediums

STAMPS is limited in its reflection of gait undertaken during activities of daily living due to limited number of steps it is optimised to collect data over. Providing prophylactic interventions is reliant on capturing the tribological interactions during patient's activities of daily living. Evaluation of other plastically deformable mediums for use alongside the STAMPS optimised DIC approach could support the development of an enhanced insole with increased step limit thresholds. By allowing for an increased number of steps to be taken, clinicians could utilise the

insole beyond the clinic and into 'real world' settings to capture patient strain data over increased periods and during realistic daily use.

9.5 Concluding Remarks

The research project was developed based on the aim to measure and characterise the strain response in lieu of shear at the tribological interface of the plantar aspect during gait. The function of this was to work towards understanding the implications of loading patterns upon mechanical response of the skin to develop a pathway towards an improved understanding of the mechanical contributions in the formation of DFU. Methods to capture plantar strain changes both within and out of the shoe-complex and under differing loading regimes have been established and feasibility tested under small cohort studies. The shod STAMPS approach has now continued into ongoing parallel studies of larger cohort non-diabetic and diabetic populations, including strain capture within commercial pressure relieving orthoses. The output strain data collected in the initial studies has informed input experimental conditions for tensile and compressive testing of cadaveric plantar skin to build on the pathway to understanding mechanical formation of DFU. This work has translated into four paper publications and been presented at numerous conferences, winning both national and international awards in the fields of tribology and biomedical engineering.

This work sets a foundation into understanding of the contribution that shear makes at the plantar aspect, an area previously under researched due to limited technological capacity for measurement. It provides the opportunity to utilise the determined strain characteristic of individual plantar interactions to inform future testing approaches into biofidelic test bed studies to progress varied loading assessments of the plantar tissue complex. Together these approaches will help to develop a greater picture of the mechanical pathways involved in ulcer formation within the diabetic population and provide opportunity to develop effective treatment pathways.

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