TESTING THE EFFICACY OF THERAPEUTIC FOOTWEAR WITH ROCKER-SOLES TO PROTECT ULCERATION IN DIABETIC AND NEUROPATHIC PATIENTS

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Statement of authorship

Except where explicit reference is made in the text of the thesis, this thesis contains no material published elsewhere or extracted in whole or in part from a thesis by which I have qualified for or been awarded another degree or diploma. No other person's work has been relied upon or used without due acknowledgement in the main text and bibliography of the thesis.

Susan Joy Stacpoole Shea Date

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Publications and conference proceedings that have resulted from the thesis studies

Paper

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Abstracts

Stacpoole-Shea, S., Shea, G., Armstrong, D. & Lavery, L. (1999). Do rocker soles reduce plantar pressure in persons at risk for diabetic neuropathic ulcerations? (Abstract) *Proceedings of the XVIIth International Society of Biomechanics Congress,* Calgary, Canada, 224.

Stacpoole-Shea, S., Walden, G., Villarreal, E., Gitter, A., Lavery, L & Armstrong, D. (1999). Could seamed socks impart unduly high pressure to the diabetic foot? (Abstract) *Diabetes, 48(S1) A179.*

Stacpoole-Shea, S., Shea, G., Miles, TP. & Lavery, L. (1999). Using plantar pressure measurement to identify location of forefoot ulceration. (Abstract) *Proceedings of the American Geriatrics Society & American Federation for Aging Research Annual Scientific Meeting*, Philadelphia, Pennsylvania, USA, 237.

Posters

Stacpoole-Shea, S., Walden, G., Villarreal, E., Harkless, L. & Shea, G., (2000, March). What are the effects of incremental pressures on the pressure exerted from sock seams? *Poster session presented at The Diabetic Foot, Conference of the Australian Podiatry Council*, Sydney, Australia.

Stacpoole-Shea, S., Walden, G., Villarreal, E., Armstrong, D. & Lavery, L., (1999, June). Could seamed socks impart unduly high pressure to the diabetic foot? *Poster session presented at the American Diabetes Association Annual Scientific Meeting,* San Diego, California, USA.

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Abstract

Walking for people with diabetes related foot neuropathy and ulceration incurs risk. This risk may lead to amputation of the affected limb as the ulceration becomes infected and ultimately life threatening. It is in reducing this risk that this thesis contributes new knowledge.

Footwear with rocker-sole modification is routinely prescribed as a means to protect ulceration from walking impact pressures. However, the current experimental evidence is of limited value and may actually be leading clinicians to prescribe treatment detrimental to their patients. This is because rocker-sole efficacy to protect ulceration has not been determined for populations with diabetes and foot ulceration. A compounding difficulty is studies are not readily comparable as methodologies are not standardised and interpretation limits have yet to be defined.

This research aimed to determine which rocker-sole shoe design was the most effective at protecting diabetes related foot ulceration from further injury. As a precursor, the research methodology was developed from an analysis of the literature, interpretation limits were defined by archival data analyses and it was safety tested prior to application to people with diabetes related ulceration. Innovative analyses were developed and showed a relationship between shoes, impact pressures and time.

Statistically significant differences between in-shoe peak pressures measured on the first metatarsal phalangeal joint ($p=0.01$: 95% CI 2.83 – 25.95kPa) but not on the hallux were identified between sub-populations with and without diabetes related neuropathy and ulceration when walking in an athletic shoe. However, the plotting of the pressure-time results proved most clinically useful and showed that there was a different relationship with peak pressure when ulceration is present on the hallux compared to the first metatarsal phalangeal joint.

Statistically significant differences were not found between in-shoe peak pressures measured on either first metatarsal phalangeal joint or hallux ulceration when therapeutic shoes with rocker sole modifications were worn. These results disagree with studies that have found peak pressure differences in healthy subjects when walking in these footwear styles. The results of this research do not support the claims from healthy subject research that beneficial reductions in peak pressures from walking in rocker sole shoes may also be achieved in diabetic subjects with neuropathy and ulceration.

This research developed methods to plot in-shoe plantar peak pressures with time. The patterns formed by peak pressures in different sub-populations with and without ulceration and neuropathy

showed that functional differences were present. These differences provide insight for future research and potentially clinical diagnostic outcomes. Specifically, the methods developed by this research provide clinicians with evidence to inform on prescribing, and a method to evaluate shoe therapies for maximum protective benefit for people with diabetes related neuropathy and ulceration.

CHAPTER ONE

INTRODUCTION

Background to the problem

> "I marvel that society would pay a surgeon a large sum of money to remove a patient's leg…but nothing to save it"(p 55).
>
> George Bernard Shaw (1856-1950) (Shaw, 1911).

The amputation of a leg is a horrific possibility that people with Type 2 diabetes mellitus[1] are at risk to endure (Payne, 2000b). Amputation is a life saving procedure performed when the limb is no longer viable, often due to infiltration of infection into the body via foot ulceration (Reiber, 2001). Ulceration is a chronic wound that affects 15 percent of people with diabetes at some time during their life (Reiber, 1996) and commonly occurs on the plantar forefoot due to inadequate protection from the normal repetitive physical microtrauma experienced during walking gait (American Diabetes Association, 1999). Physical microtrauma to the plantar tissues of the foot arises due to pressures from impact with the ground during walking. Injury from impact pressures is avoided in the normal foot by constant conscious and unconscious minor adjustments to the walking style that redistributes the stress across the foot (Sanders, Goldstein, & Leotta, 1995). Even though people with diabetes and a history of ulceration are nearly 50 percent less active than their ulceration-free and healthy counterparts (Maluf & Mueller, 2003), without sensory input from the injured foot, these people continue to walk without gait deviation and therefore, fail to protect fragile or injured tissues until skin and tissue integrity deteriorates to ulceration (Brand & Yancey, 1993). Eventually either the person or a carer notices the ulceration and seeks therapy and healing occurs, or infection infiltrates the body necessitating urgent limb and life saving intervention (Bild et al., 1989).

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[1]Type II diabetes mellitus is abbreviated to 'diabetes' from this point on.

Regular daily walking is essential to people with diabetes not only for general mobility, but also as a self-management practice to assist in glycemic regulation. Regulation of glycemic levels to within the non-diabetic range is the goal for people with diabetes, as this limits the severity of secondary systemic complications of diabetes, especially cardiovascular disease (Ousman & Sharma, 2001). Cardiovascular disease is a leading cause of mortality in people with diabetes and walking is the main form of prescribed exercise to limit and treat its effects on the body (American Diabetes Association, 1997b). Walking for mobility and exercise poses both the people with diabetes and their carers with a dilemma; walk to manage glycemic levels, limit cardiovascular disease and potentially prolong life but at the same time also increase the risk for the morbidity/mortality associated with pressure-induced foot injury. Clearly, this dilemma would diminish if the feet were protected from the stress of impact pressures during walking.

There are many and varied forms of therapeutic footwear prescribed to people with diabetes to provide external foot protection and for ulceration management strategies (Coleman, 1987). Therapeutic footwear covers a wide range of shoes and devices that includes socks, different shoe styles, insoles and outsole modifications (Payne, 2000a). Socks, shoes and insoles are prescribed specific to the patient's foot needs (Albert & Rhinoie, 1994), whereas there are several outsole modifications that are prescribed to modify walking to protect ulceration independently of individual foot differences (White, 1994). Even though therapeutic shoe therapy has been funded for diabetic patients in the USA via the Medicare Therapeutic Shoe Bill since 1989 (White, 1994), no conclusions on their efficacy to protect the foot could be drawn from the Health Care Finance Adminstrations' Therapeutic Shoe Demonstration (Reiber, 1994). Additionally, two randomized controlled studies of 352 and 400 diabetic patients, respectively, did not find evidence to support the perceived benefit of foot protection from using therapeutic footwear with individually prescribed insoles (Litzelman, Marriott, & Vinicor, 1997; Reiber et al., 2002). Therefore, either, therapeutic footwear is not effective for non-individualised widespread use unless based on individual patient-efficacy evaluation (Cavanagh, Ulbrecht, Caputo, & Lemmon, 1996), or that the assumption that therapeutic shoes and their modifications provide protection to ulceration through pressure reduction, is unfounded.

When ulceration is present on the plantar forefoot, a *rocker-sole* modification to the outsole of the shoe is often prescribed with the understanding that the pattern of pressures and resultant stresses on the ulceration will be minimised, therefore, allowing healing to occur (Brown, Wertsch, Harris, Klein, & Janisse, 2004; Chantelau, Kushner, & Spraul, 1990; Coleman, 1987; Praet & Louwerens, 2003). The pattern of pressures is assumed to be diverted from the forefoot and ulceration by changing the shape and location of the rocker-sole; specifically the pivot position and toe off angle. These outsole changes negate the need for the forefoot to be actively involved in 'pushing

off' for the propulsion of the limb, and instead the limb passively 'rocks' forward following the shape of the out-sole (Nawoczenski, Birke, & Coleman, 1988). However, it remains an assumption and without experimental basis, that these modifications are effective at protecting ulceration from walking pressures in people with diabetes, neuropathy and plantar forefoot ulceration. If this assumption is incorrect, then this may explain why ulceration healing remains unpredictable even when these shoe modifications are used.

Technological developments of the past three decades and large epidemiological studies have yielded experimental evidence that has seen great improvement in the management of the glycemic component of diabetes management (American Diabetes Association, 2002). However, even with the advent of sophisticated computerised instrumentation that measures in-shoe plantar (impact) pressures, clinically applicable evidence to the efficacy of shoe interventions, specifically rocker sole modifications, prescribed to protect forefoot plantar ulceration from walking impact pressures is scant. This lack of evidence leaves clinical shoe selection to be somewhat *ad hoc*, leaving clinicians to rely on their deductive reasoning and clinical experience, and ulceration healing is unpredictable and amputation common. Evidence is lacking for two main reasons. First, there is a lack of standardised protocol for dynamic in-shoe plantar pressure measurement, which prevents valid comparisons between studies, leaves the uncertainties of walking impact pressure measures undefined and prevents intervention evaluation because reference databases are not developed (Barnett, 1998). Second, rocker-sole shoe efficacy research on clinically relevant diabetic and neuropathic with ulceration patient sample populations are also lacking.

General aim of the thesis

This thesis aimed to test rocker-sole shoe modification designs to select the most effective design for protecting plantar hallux and plantar first metatarsophalangeal joint ulcerations from plantar pressures during walking in adults with diabetes and peripheral neuropathy. To achieve this, the following work was undertaken:

Chapter Two

This chapter reports on a review of the literature pertaining to the underlying mechanisms that lead to ulceration on the plantar forefoot in the presence of diabetes and the measurement of the effect that footwear and footwear modification designs have on these mechanisms.

Chapter Three

This chapter reports on the development of a standard protocol for the thesis study using analysis of literature and reanalyses of archival in-shoe plantar pressure measurement data. The protocol was developed in the chapter over two parts.

Part I

This part reports on a protocol analysis that was undertaken of the literature to standardise aspects of procedural theory for use in the thesis studies, that were incompletely addressed in the International Protocol Guidelines for Plantar Pressure Measurement. .

Part II

This part reports on analyses conducted to define the result interpretation limits for the thesis studies. The analyses were conducted using an archival database constructed from in-shoe plantar pressure measurement results of adults with diabetes, peripheral neuropathy and forefoot ulceration. Part II contained four sections:

a) A report on a method for checking mid-gait step data validity.
b) A report on the number of steps that was required for calculation of a reliable average step and its associated precision.
c) A report on the number of steps that was required for calculation of an average step with maximum practical accuracy.
d) A report on the selection of pressure variables for use in analyses for predicting the site of ulceration in the thesis studies.

Chapter Four.

This chapter describes the methods that are common to all thesis studies.

Chapter Five.

This chapter reports on one study and two bench-based experiments conducted to select the standard sock to be worn by the subjects in the thesis studies.

Chapter Six.

This chapter reports on a study using the protocol and procedures developed and described in chapters three and four. In this study, adults with diabetes and normal protective sensation (neuropathy-free) were studied while they walked in a standard athletic shoe. The results of this

chapter became the non-neuropathy reference results for the following thesis chapter. Specifically this chapter reports on study conducted with the aim to:

1. Ensure that subjects were not put at risk of foot injury due to the procedures in the thesis protocol for in-shoe plantar pressure measurement;

2. Verify that spatial and temporal gait variables are consistent during in-shoe plantar pressure measurement study when subjects self-select their natural comfortable walking pace, and;

3. Explore peak pressures beyond the absolute measured value, and construct and cross-validate plots of force, mean pressure and peak pressure with 95% confidence bands normalised in the time-domain from 0-100% of stance.

Chapter Seven.

This chapter reports on a study using the protocol and procedures developed in chapters three and four, and tested in Chapter Six. In this study, adults with diabetes and peripheral neuropathy who were diagnosed with forefoot ulceration on either their plantar hallux or plantar first metatarsophalangeal joint were studied while they walked in a standard athletic shoe.

Specifically, this chapter reports on peak pressure absolute values and peak pressure-stance time plot comparisons made to explore first, the effect of neuropathy, and secondly the difference between hallux and first metatarsophalangeal joint ulcerations to each other, and to the non-neuropathic population (Chapter Six reference results).

Chapter Eight.

This chapter reports on a study using the protocol and procedures of Chapter Seven with additional subjects and different footwear designs. In this study, the subjects walked in a standard athletic shoe, an unmodified therapeutic shoe and therapeutic shoes with five different rocker-sole modifications.

Specifically, this chapter reports on peak pressure absolute values and peak pressure-stance time plot comparisons made between hallux and first metatarsophalangeal joint ulcerations when walking in the different shoes to determine the shoe or shoe modification that was most effective in protecting ulceration from walking pressures.

Research questions

1. Are in-shoe plantar pressure measures of walking in the adult diagnosed with diabetes, peripheral neuropathy and ulceration:

   a) reliable,
   b) precise,
   c) accurate, and
   d) can they identify the location of forefoot ulceration?

2. Are in-shoe plantar pressure measurements of walking in adults with diabetes:

   a) affected by differing sock fabric, and
   b) do they impose foot injury risk?

3. Are in-shoe plantar pressure measures of walking in the adult with diabetes, peripheral neuropathy and ulceration significantly different between:

   a) ulceration site,
   b) shoe type, and
   c) rocker-sole shoe modifications?

4. Is there a particular rocker-sole shoe modification design (angle and pivot position) that affords the best protection from plantar impact pressures to ulcerations on the:

   a) plantar hallux and
   b) plantar first metatarsophalangeal joint?

5. Do examinations of plots of peak pressures, as they relate to percent-normalised stance time, provide more clinically useful insight into walking pressures than the absolute peak values?

To provide order to the overall complexity of the thesis, a specific format for directing the flow of inquiry was mapped with clear ties through to the desired outcome and is presented in *Figure 1*.

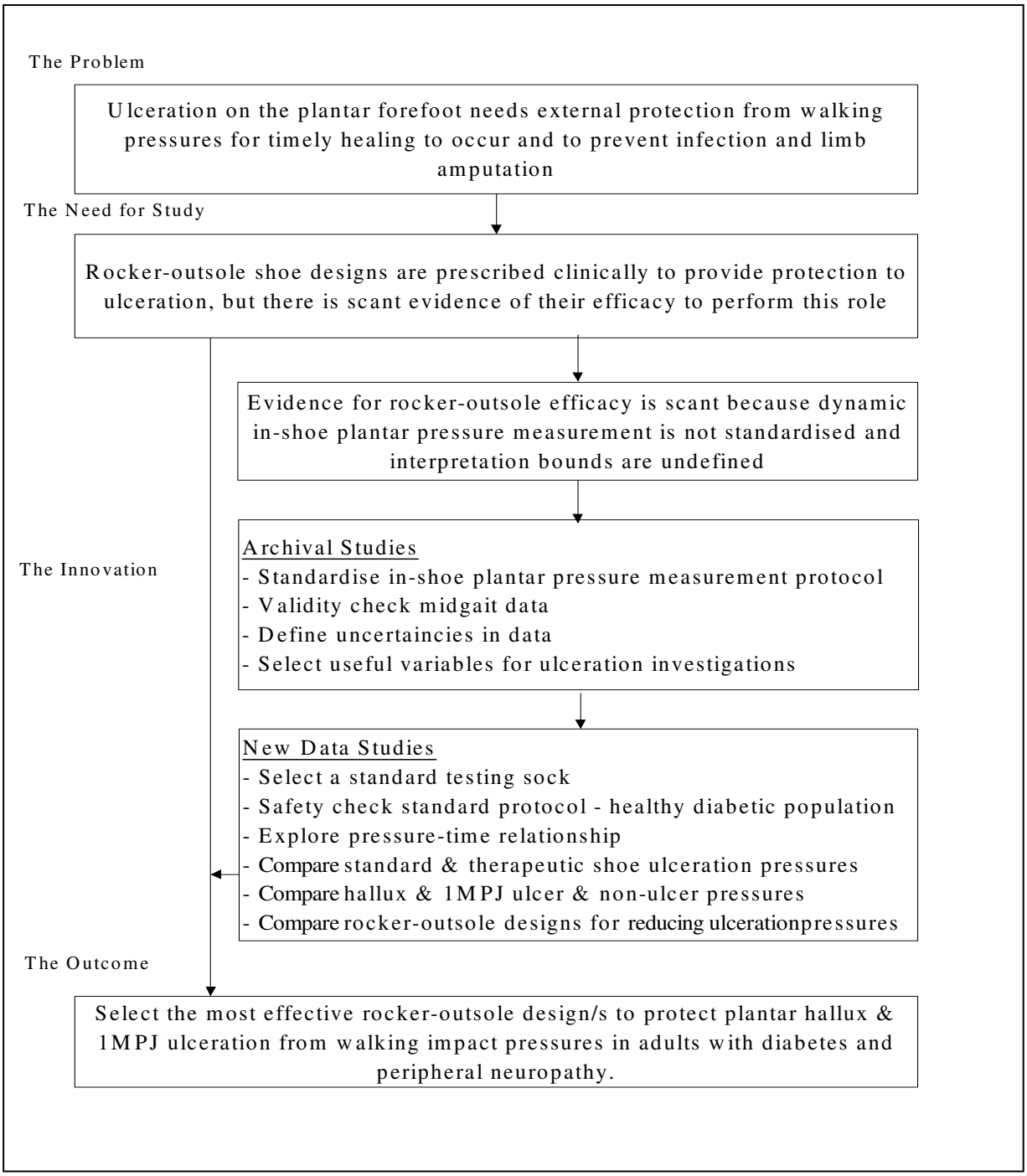

Figure 1. Concept map that shows the flow of the thesis studies towards the required outcome (1MPJ = first metatarsal phalangeal joint).

Assumptions

The measurement of walking impact pressures using the Pedar™ system in the laboratory is a valid representation of impact pressures transferred to the plantar foot from the ground/shoe interface during general walking.

Steps measured in the middle section of walking, that exclude any starting, stopping or turn around steps, are a valid representation of steps taken during general level ground walking.

Lack of statistically significant difference from a one way paired *t*-test with unequal variances confirms the validity for pooling limbs as independent measures.

Delimitations

Texas Diabetes Institute (San Antonio, Texas, USA) patients were studied.

Ulceration located on the plantar hallux or plantar first metatarsophalangeal joint anatomical regions were studied.

Pedar™[2] pressure insole analysis system was used for in-shoe dynamic study.
F-scan™[3] pressure insole analysis system was used for bench-based study.
EMED™[4] pressure plate system was used for un-shod dynamic sock study.
GaitMat II™[5] gait measurement system was used for *subject-as-control* verification study.

Limitations

Measures of the subjects with diabetes, neuropathy and forefoot ulceration and their walking that may contribute to explanation of impact pressures (velocity, step length, limb length, muscle flexibility and strength, joint ranges of motion) were not obtained.

Left and right limbs were not statistically significantly different at $p<0.05$ and were therefore, treated as being independent for all analyses.

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[2] Novel Electronics Incorporated, St. Paul, Minneapolis, USA.

[3] Tekscan, Boston, New York, USA.

[4] Novel Electronics Incorporated, St. Paul, Minneapolis, USA.

[5] GaitMat II, Chalfont, Philadelphia, USA.

CHAPTER TWO

REVIEW OF THE LITERATURE

Background

The literature reviewed for this thesis was obtained initially by reading the key textbooks and peer-reviewed journals related to the topic of inquiry. The books included: *Pain: The Gift That Nobody Wants, Levin and O'Neal's: The Diabetic Foot, Diabetic Neuropathy, Diabetes Mellitus and the Foot* and *Medical and Surgical Management of the Diabetic Foot.* The peer reviewed journals included: *Diabetes Care, Diabetic Medicine, Journal of Bone and Joint Surgery, The Foot, Journal of the American Podiatric Medical Association, Foot and Ankle, Journal of Foot and Ankle Surgery, Archives of Physical Medicine and Rehabilitation, Gait and Posture, Journal of Prosthetics and Orthotics* and *Clinical Biomechanics*.

Specific research reports were located using computerised databases by imputing key words that were identified from the initial reading. The databases included: Pub Med, CINAHL, The Cochrane Library, and Academic Search Premier. The key words included: *diabetes, foot ulceration, neuropathy, plantar pressure, footwear, therapeutic shoe, rocker-sole, diabetes and exercise, amputation* and *foot-care.*

This review of the literature will be formatted under five main headings, these being:

- Diabetes and its complications that lead to ulceration of the foot
- Diabetic complications and foot ulceration
- Diabetic foot ulceration classification and prevalence
- Footwear and ulceration
- Footwear and foot protection from walking pressures

Diabetes and its complications that lead to ulceration of the foot

The epidemiology and monetary cost of diabetes mellitus (diabetes)

Diabetes mellitus (diabetes) is a disease that may have devastating consequences that may be preventable and one of these is diabetes related foot and leg amputation. Epidemiology statistics show that the disease of diabetes is of epidemic and expanding proportions, that shows no sign of stabilising or abating. More than 150 million adults worldwide suffer from diabetes, a figure that is expected to double over the next 25 years (American Diabetes Association, 2002). The prevalence of diabetes varies widely between populations. Prevalence is reflected in environmental influences and genetic susceptibility and is a consequence of the advancing age of populations and the effects of modernisation of lifestyle (Dunstan et al., 2002). There are many reports about diabetes from the United States of America (USA). This country is estimated to have the largest number of people with diabetes of all the developed countries, with more than 16 million people currently diagnosed with the disease (American Diabetes Association, 2002). The Asia and Pacific region (Australia) has also been found to have very high rates of diabetes. There are two Australian reports that show that diabetes prevalence more than doubled between the years of 1981 and 2002 (Dunstan et al., 2002; Glatthaar, Welborn, Stenhouse, & Garcia-Webb, 1985). There was a prevalence of the disease of 8.0% in men and 6.8% in women in total in the Australian population in 2002 and an additional 17.4% of men and 15.4% of women had impaired glucose tolerance, which is an indicator of diabetes risk (Dunstan et al., 2002). These statistics suggest that approximately 2.5 million Australians have diabetes and a further 5.5 million are at risk of diabetes, confirming that diabetes is a disease of epidemic proportions in Australia as well as worldwide.

Diabetes is an expensive disease to treat and in the USA, one in every seven dollars spent on medical care is related to diabetes, with an annual cost of over $US100 billion (Black, 2002). Modelling of the cost of treating diabetes and its complications has facilitated a monitory estimate based on blood glucose level over time. It suggests that a person who has been diagnosed with diabetes for five years without ideal glucose control will cost the health system, an average of $US47, 240 over a period of 30 years (Caro, Ward, & O'Brien, 2002). A major limitation of this model is that it optimistically assumes that many complications such as foot ulcerations are reversible and are “episodes” that will resolve, an assumption that is questionable such that the realistic per-person cost could be much higher. Part of the cost of diabetes can be clearly demonstrated from hospital utilisation statistics. Diabetes has been shown to account for 3 million hospital stays in the USA (Black, 2002), and 0.12% of all admissions and 0.41% of total bed/days

in New Zealand (Payne, 1997). The costs related to keeping a person with diabetes out of hospital would be difficult to tally, but at least 15 million physician visits are attributed to diabetes in the USA annually (Black, 2002). There is no doubt that diabetes poses a significant health cost burden with recognition as being the fifth National Health Priority Area in Australia (DHAC & AIHW, 1999).

The disease of diabetes

To more fully elucidate the problem of diabetes, it is useful at this point to outline the disease. Diabetes is a group of metabolic diseases that are characterised by hyperglycaemia, commonly referred to as high blood sugar. Hyperglycaemia is caused by the body's inability to produce or effectively utilise enough insulin, a hormone that the body uses to convert food into energy (glucose) (Black, 2002). The main concern with diabetes is the range of acute and chronic complications that can be experienced in isolation and combination. The range of complications means that diabetes cannot be managed paternally with medical supervision and therapy alone. The treatment must be in partnership, with the patient taking full control of living with the disease, assisted by education under medical supervision. The complexity of diabetes means that there is interest from multiple persons in addition to the patient and the medical personnel. These include researchers, educators, clinicians, carers and third party payers. The American Diabetes Association (ADA) supports interested parties in many forms and funds committees and research reports and commissions position statements that focus on particular needs, not only useful to Americans, but also worldwide, and these readily apply to the Australian context.

In 1997, the ADA issued a position statement that determined new diagnostic classification criteria for diabetes (American Diabetes Association, 1997c). The classification includes four clinical classes: Type 1 diabetes, Type 2 diabetes, other types (that includes; genetic defects, diseases of the exocrine pancreas, drug or chemical induced) and Gestational diabetes mellitus. Type 1 and 2 are the most common forms of the disease, with Type 1 generally being identified in younger people due to the severity of onset with absolute dependency on insulin injection to survive, and Type 2 with a more insidious onset, typified in the overweight, unfit and older aged person. This thesis focuses on Type 2 diabetes characterised by insulin resistance and inadequate beta cell insulin secretion, because these people represent more than 90% of the population diagnosed with diabetes (Beckman, Creager, & Libby, 2002).

All sub-diagnoses of diabetes are determined by criteria that include the presence of classic symptoms of diabetes in conjunction with measurement of blood sugar level administered via a blood test. The classic symptoms of diabetes include excessive urination (polyuria), excessive

thirst (polydipsia), unexplained weight loss and raised blood glucose level (hyperglycaemia). The aim of diagnosis, treatment and management of diabetes is to maintain the blood glucose (glycaemic control) levels, measured via the glycosylated haemoglobin (HbA_{1C}) at a three-month average, at less than 7% (HbA_{1C} has a normal range of 4.2 to 7.4%). Glycaemic control success has been associated with reduced rates of the serious complications of diabetes. The complications of diabetes that are most prominent are blindness (retinopathy), kidney failure (nephropathy), and loss of nerve function resulting in foot injury, ulceration and amputation (neuropathy) (Boulton, 1996). People with diabetes are also at a greater risk of cardiovascular disease and this risk can be reduced with intensive glycaemic control and regular exercise (Ousman & Sharma, 2001).

Management of diabetes and the risk to the foot

Walking is the main form of exercise prescribed to people with diabetes to maintain homeostasis and therefore, reduce cardiovascular disease risk (American Diabetes Association, 1997a). Cardiovascular risk reduction via glycaemic control is achieved when the blood glucose level is maintained within the non-diabetic limits. Glycaemia control is managed with diet and exercise, which equates to limiting the glucose put into the body (diet control), and eliminating any excess from their body (exercise). When sufficient control is not achieved by diet and exercise alone, then drug therapy is initiated. The initiation of drug therapy can assist to regulate glycaemic fluctuations, but unlike many diseases, drug therapy is insufficient without continued and carefully managed diet and exercise.

Minor foot injuries are possible for all people who walk, especially to the plantar forefoot and the toes due to irritations from ill-fitting footwear and normal walking pressures. However, sensory and nutritional compromises limit both prevention of injury and limit protection of existing injury during walking. Therefore, leaving potentially minor injuries likely to progress to ulceration (American Diabetes Association, 1999). Foot injuries resulting in ulceration, which are cutaneous erosions characterised by a loss of epithelium that extends into or through the dermis to deeper tissue, are a ready portal for infection. If the ulceration is unresolved, infection may lead to the surgical removal or amputation of part of the limb (Reiber, 2001).

An average of 2629 diabetes-related foot or leg amputations occur in Australia each year with a prevalence of 11.34 per 100 000 of total population (Payne, 2000b). Unfortunately, amputation is a likely event from poor healing or infection of the foot ulceration in patients in the 65 – 79 age group (Payne, 2000b), and stems in a large part from *ad hoc* prescription of, and inadequate design of injury protection footwear (Litzelman et al., 1997; Ross, 1962; Ulbrecht, Perry, Hewitt, & Cavanagh, 1994). Currently, clinicians and diabetes patients are in a dilemma. There is growing

evidence that walking daily as exercise assists in maintaining homestasis and therefore, reducing diabetes and cardiovascular disease severity, but at the same time, carries increased risk to injure the insensitive foot. Clearly, this dilemma may diminish if appropriate shoes could be prescribed to the diabetic patient that protected ulceration and areas of high risk of injury on the insensitive foot from adverse walking pressures while not limiting the benefits gained from a normal walking exercise regime.

Understanding the mechanism of injury is essential before prevention and protection can be instigated. A foot injury is an uncommon event when the feet can detect normal sensory input such as temperature, pressure and pain. If injury does occur, then the source of injury is not only obvious, but either highly preventable or accidental and its extent is minimised by the person's reaction. The person will react to both remove themselves away from the injury risk and if injury occurs initiate care to protect the injury and encourage healing. Injury can be denoted either as being specific, where the skin has been broken, or insidious where there has been sufficient disruption of the skin and tissue layers or cells that results in tissue ischaemia. For the skin to be broken, the trauma can occur if a small force is applied to a small area, such as a pin prick. However, for a large injury to occur a much higher force is necessary (Sanders et al., 1995). Hence, the area over which a force is applied is critical to the type and occurrence of the injury and this is quantified as pressure (Pressure = Force divided by Area). In the person with diabetes whose feet are insensitive to pain, they do not receive the sensory input to alert them to react to move away from the risk and limit further injury, or initiate care to protect the injury that has occurred. This places them at risk of specific and insidious injury to their feet from everyday events. Specifically, localised regions of high pressure have been recorded under the foot both at sites where ulceration commonly occur (Veves, Murray, Young, & Boulton, 1992). The presence of localised regions of high pressures under the foot is confirmed as a prerequisite for and aetiological factor in the development of ulceration in people with diabetes whose feet are insensate (Cavanagh, Ulbrecht, & Caputo, 2001).

The physiological complications of diabetes and the risk to the foot

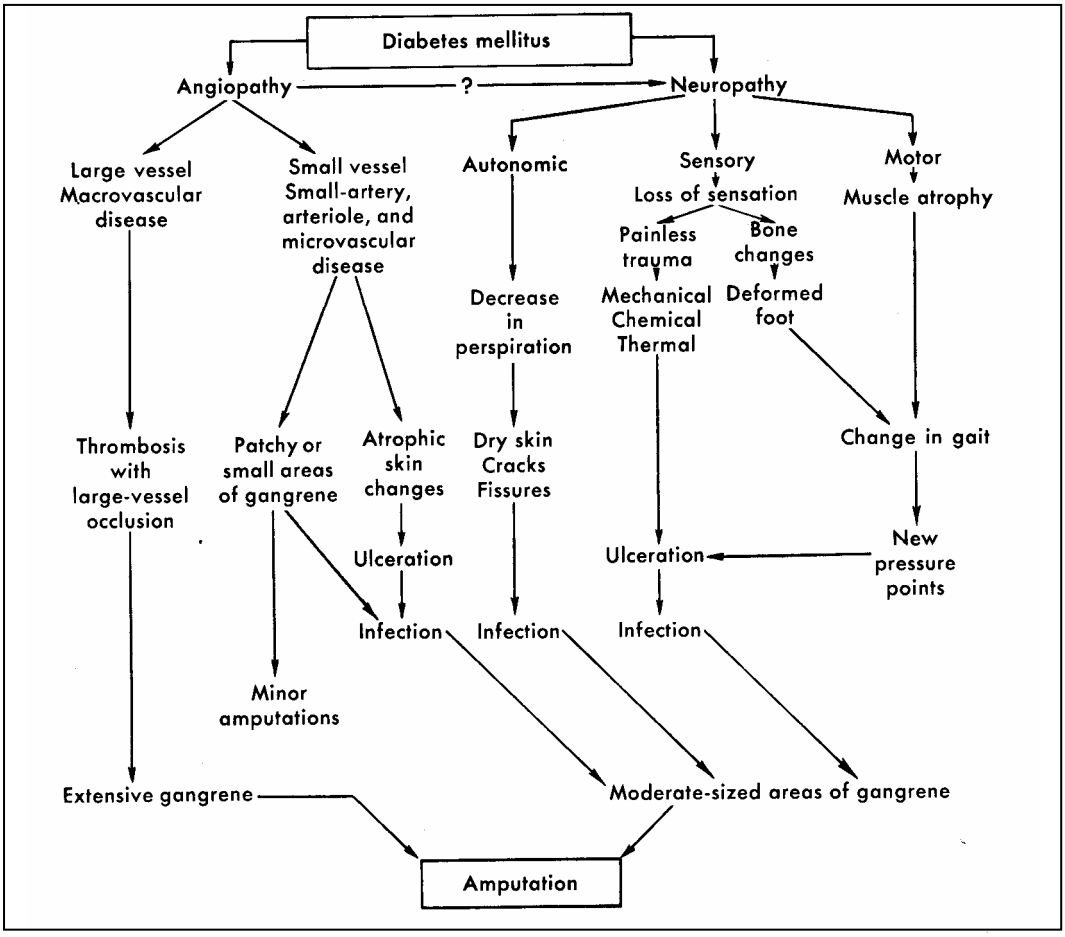
In diabetes, two main complications have been shown to be of constant concern due to two main diabetic complications, angiopathy and neuropathy, and this is due to their role in potential ulceration occurrence and poor healing, which potentially leads to foot or leg amputation (Adler, Boyko, Ahroni, & Smith, 1999; Tooke & Brash, 1996). The model developed by Levin (1983) shows the pathways through which these complications can lead to ulceration or amputation and is presented in *Figure 2*. The model shows five main pathways, two that stem from angiopathy and three from neuropathy. Cardiovascular (large vessel), and peripheral vascular (small vessel)

disease follow the angiopathy pathways. This thesis is concerned with injury risk during walking, and walking is prescribed as therapeutic exercise for vascular disease and will be discussed later. The neuropathy pathway that describes motor neuropathy is limited in its applicability to this thesis. Motor neuropathy may present as foot deformities and abnormal walking or gait patterns that would limit therapeutic shoe interventions. The peripheral neuropathy[6] pathway that exhibits as loss of protective sensation in the foot forms the basis for selecting the population for the thesis inquiry. This pathway suggests how the person with diabetes cannot identify an irritation to the foot or potential injury until it has occurred, nor protect an existing injury or ulceration to allow healing to occur. Even though Levin's model clearly defines pathways through which the disease of diabetes can lead to amputation, its prevention is not readily achievable. This makes clinical management of this problem particularly difficult as some or all complications may be present in a greater or lesser degree, especially in the environment of poor blood glucose control in an ageing adult.

Diabetic complications and foot ulceration

The diagnoses of diabetes and neuropathy were first linked in the 19th century. Leval-Picquechef in 1855, as cited by Taylor and Dyck (1999), described the complication of neuropathy as causing serious symptoms and impairments, but not death. The link between insensitivity of the foot due to peripheral neuropathy and the need for external and artificial foot protection was then confirmed by Paul Brand in his work with people suffering from Leprosy (Brand & Yancey, 1993). In his book, aptly titled: *Pain the gift that nobody wants*, Dr. Brand eloquently described his revelation into the link between insensitivity of the feet and injury, poor healing and ulceration (Brand & Yancey, 1993).

[6] Peripheral neuropathy is shortened to neuropathy from this point on.



From: Levin, M. E. (1983). Medical Evaluation and Treatment. In M. E. Levin & L. W. O'Neal (Eds.), *The Diabetic Foot.* St Louis: C. V. Mosby Company, Figure 1.1, Page 2.

Figure 2. Pathogenesis of diabetic foot lesions.

In summary, Dr. Brand wrote that after carefully cleaning and bandaging a significant plantar foot ulceration for his friend who was diagnosed with both Leprosy and peripheral neuropathy:

> Instead of returning to my examining room, I stood and watched Sadan walk down the steps, cross a sidewalk,…Then for the first time I noticed something. He had no limp!…he was putting his full weight on the exact spot we had so carefully treated. No wonder the wound never healed (pp. 119-120).

This observation directed Dr. Brand towards designing therapies for leprosy affected feet to provide artificial protection during walking. In the early 1970's, Dr. Brand was invited to present his findings on the clinical management of leprosy to specialists in diabetes, and from this point on these patients too began to benefit from foot protection therapies (Brand & Yancey, 1993). Insensitivity of the foot to pain during walking not only leaves it vulnerable for injury and poor healing, but other forms of neuropathy also make injury more likely.

Neuropathy affects the foot in several ways and the distinctions between sensory (peripheral), motor and autonomic neuropathy made in Levin's (1983) model presented in *Figure 2*, cannot be readily made. They all fall under the diagnosis of diabetic polyneuropathy. Diabetic polyneuropathy has been described to follow a time line where symptoms of the presentations described in Levin's model can be identified. Taylor and Dyck (1999) described this time line as beginning with an abnormality of nerve conduction, followed by loss of ankle reflexes and decrease of vibration perception in the toes. Further sensory loss (peripheral neuropathy) follows and signs of autonomic dysfunction (autonomic neuropathy) can be seen in the legs and feet. In the severe cases, signs of motor dysfunction (motor neuropathy) will eventually be seen with weakness of toe extension, ankle dorsiflexion, and development of toe flexion deformities (Taylor & Dyck, 1999). Polyneuropathy is a result of nutritional deficit and affects the most distal portion of the longest nerves first. As nerve damage progresses proximally along the nerve, nerve function is lost to the toes and feet in a distribution like a sock. Once damage has extended to the region of the knee, then the hands also become involved in a similar distribution like a glove. Generally, the person with diabetes is significantly ill with multiple complications of diabetes, especially cardiovascular disease), before much dysfunction of the hands is noticed (Brand & Yancey, 1993).

The co-occurrence of the diabetic complications of neuropathy and cardiovascular disease are confounding factors in using walking as exercise therapy to manage systemic severity of diabetes. As discussed in Chapter One, walking can reduce the severity of diabetes and cardiovascular disease whilst increasing the potential for incurring an injury to the insensitive foot. There is emphasis on managing cardiovascular disease because it is implicated as the cause of most of the death and much of the disability related to diabetes (Beckman et al., 2002). Cardiovascular disease affects the brain, heart and lower limbs in its non-specific form and in its specific form it occurs as microangiopathy affecting small vessels (Spittell & Brown, 1999). Atherosclerosis affects the whole population, but with diabetes its incidence increases to 2- to 4-fold that of the normal population and its clinical course is accelerated (Beckman et al., 2002). This is demonstrated in the increased risk from myocardial infarction that the person with diabetes incurs. The person with diabetes has the same risk of suffering and dying from their first myocardial infarction as the risk that the non-diabetic person has of dying once they suffer repeated myocardial infarctions (Beckman et al., 2002). Beckman et al, reported that the five year mortality rate following a myocardial infarction for those with diabetes was 50%, which is at least double that of the non-diabetic population. The epidemiological evidence reviewed by these authors confirmed that the specific presentation of cardiovascular disease, namely peripheral vascular disease, occurred at a higher prevalence with diabetes. Additionally, the extent of peripheral vascular disease was related to the duration and severity of diabetes and the level of

glycaemic control (or rather lack of control). peripheral vascular disease either presents with diabetes as intermittent claudication (Brandsma et al., 1998) or occlusion of the blood vessels below the knee. This occlusion predisposes the limb to ischaemia[7] that may result in ulceration, gangrene and, potentially, amputation. Unfortunately, controlling hyperglycaemia reduces the risk of micro-vascular (but not macro-vascular) disease, and cardiovascular disease events increase once the HbA_{1C} measured is greater than 6.2% (Beckman et al., 2002). Beckman et al. also reported that controlling hypertension limits cardiovascular disease far more effectively than controlling hyperglycaemia, and this required weight loss, smoking cessation, dietary modification and exercise. With these life style modifications and supporting drug therapies, Beckman et al. recommended that supervised exercise therapy in the form of limited, but progressively extended distance walking, be the primary prescription issued to people with diabetes.

For a person with diabetes and neuropathy, walking brings with it concerns due to their inability to sense impending injury. Foot insensitivity has been associated with the occurrence of foot ulceration by many authors (Adler et al., 1997; Armstrong, Lavery, Vela, Quebedeaux, & Fleischli, 1998; Boulton, Kubrusly et al., 1986; Sosenko, Kato, Soto, & Bild, 1990). Specifically, Sosenko et al. (1990) examined 314 people with diabetes, 91 of whom had either ulceration or a history of ulceration, and found both the presence of foot ulceration and a history of having had foot ulceration to be strongly associated with loss of protective sensation. This is in agreement with Boulton, Kubrusly et al. (1986) who preformed a case-control investigation and compared 86 people with diabetes and ulceration to 49 controls who were diagnosed with diabetes but without ulceration or history of ulceration. Armstrong, Lavery, Vela et al. (1998) explored this relationship further with 30 cases (diabetic with ulceration or history of ulceration) and 85 controls (diabetic without history of ulceration) and found that loss of protective sensation when confirmed by two methods was 100% sensitive for identifying diabetes patients at risk of ulceration. There is growing evidence that ulceration is associated with foot insensitivity and therefore, determines the role of therapeutic interventions in ulceration prevention and healing.

Establishing the level of peripheral neuropathy and therefore, sensation allows the clinician to determine when protecting the foot during walking using external and artificial means like footwear becomes necessary. Clinical tests for neuropathy of the lower limb and feet are categorised from sensitivity criteria (Grant, O'Brien, & Dyck, 1999). Grant et al. (1999) reported that nerve conduction was most sensitive, neuropathy impairment score for the lower limb

[7] Tissue ischaemia is assessed from local oxygen perfusion and is measured via the transcutaneous oxygen pressure found on the dorsal foot skin (Hauser, Klein, Mehringer, Appel, & Shoemaker, 1984)

(NISLL) questionnaire and vibration perception threshold (VPT) less sensitive, while pressure, temperature perception and ability to walk on the heels were the least sensitive.

Some clinical tests to diagnose peripheral neuropathy have limitations in their practical use in the clinical setting and these include; nerve conduction, application of the NISLL and temperature sensation assessment. The ideal test for assessing vibration and touch-pressure sensations is nerve conduction testing because this information is conducted via the large-fibres (Bartlett, Stewart, Tamblyn, & Abrahamowicz, 1998). However, nerve conduction testing is not practical in the clinical setting because it requires the expert application of electric current to sites on the lower limb proximal to the foot and ankle[8]. The NISLL is another less applicable test, even though it is the *gold standard* for neuropathy testing (Dyck & Dyck, 1999). According to Dyck and Dyck (1999) the NISLL is a reliable and valid tool when conducted by neurologists but it is not designed for clinical use due to concern for reliability and the time required to conduct and grade the nine tests for foot and lower limb testing.

Loss of temperature sensation is another diagnostic tool specifically to determine the involvement of the smaller peripheral nerve fibres, but its clinical usefulness is limited as it requires extensive testing for valid and reliable application (Sosenko et al., 1990). The methodology reports of Sosenko et al. (1990) and Bartlett et al. (1998) describe temperature sensation testing to be extremely time consuming, requiring the patient to judge perception of temperature differences between probes warmed or cooled initially at ten degrees Centigrade increments, progressing eventually to one degree increments. Clinical temperature sensation perception is unreliable due to the high inter-subject variability reported from a study of 148 healthy adults by Bartlett et al. Sosenko et al. (1990) also investigated the thresholds of vibration, pressure and temperature in people with diabetes with or without ulceration. They found temperature to be correlated to the simpler and quicker tests for vibration and pressure, and all to be associated with ulceration. Therefore, in the clinical setting, where time generally takes precedence over specificity, those tests that can quickly and reliably identify those patients at risk of ulceration are utilised.

Peripheral neuropathy testing for foot insensitivity

Determining a critical level of neuropathy that leaves the foot insensitive and at injury risk has been standardised and validated for clinical application by a number of authors under the two broad areas of vibration perception threshold (VPT) and cutaneous pressure sensation

[8] The Act of law under which Podiatry is registered and practised in most states of Australia and in several other countries, limits invasive tests and procedures to structures that are distal to the level of the ankle joint.

(Armstrong, Hussain et al., 1998; Armstrong, Lavery, Vela et al., 1998; Birke & Sims, 1986; Boulton, Kubrusly et al., 1986). Cavanagh and Ulbrecht (1994) reported that the accepted thresholds to diagnose the existence of sensation loss and potential for foot injury are based on the statistical analysis of clinical tests that require the patient to judge between graduated sensations rather than only a yes/no observation. Dr. Andrew Boulton has reported extensively on procedures used in studies into the health of the diabetic foot and they utilised the biothesiometer for determining VPT (Boulton, 1990; Boulton, 1991; Boulton, 1992; Boulton et al., 1987; Boulton, Kubrusly et al., 1986). The biothesiometer is an electronically controlled instrument that has a variable-rate vibrating tip that is controlled by a voltage input of 0 to 50 mV. The tip is placed on the apex of the hallux and the voltage is adjusted until the level that the patient can no longer feel the tip vibrating is established. The vibration resulting from 25mV has been reported to delineate the 90^{th} percentile of the VPT at the hallux in healthy older adults (Bloom, Till, Sönsken, & Smith, 1984). While a VPT of greater than 25mV at the hallux is reported to be an effective predictor of foot sensory loss and ulceration risk (Boulton, Kubrusly et al., 1986; Young, Breddy, Veves, & Boulton, 1994). The measurement of VPT is an effective clinical indicator, but there is growing evidence that other sensory measurement may also be useful.

Evidence is growing that the measurement of pressure sensation is an effective clinical indicator for sensory loss. Sosenko et al. (1990) and Armstrong, Lavery, Vela et al. (1998) have reported on the associations that both VPT determined by the biothesiometer and pressure sensation threshold from Semmes-Weinstein monofilaments hold with the presence of ulceration in the diabetic population. Semmes-Weinstein monofilaments are nylon fibres of different diameters that are attached to a handle. The size of the filament determines how much mass is required to make the filament bend. The tip of the filament is applied perpendicular to the skin at several locations on the foot and the patient is asked if and where they can feel the filament while their eyes are closed. Lack of perception of the pressure applied from a 5.07 diameter (that bends with an applied mass of 10 gram) monofilament is predictive of a level of neuropathy that identifies a person with diabetes to be at risk of ulceration (Armstrong, Lavery, Vela et al., 1998; Kumar et al., 1991). Due to their portability, small cost and minimal training needed, S-W monofilaments predominate as the clinical diabetes neuropathy-screening tool.

Diabetic foot ulceration classification and prevalence

The locations and prevalence of ulceration on the foot have been reported by several authors (Armstrong, Lavery, & Harkless, 1998; Birke & Sims, 1986; Ctercteko, Dhanendran, Hutton, & LeQuesne, 1981; Sosenko et al., 1990). Two of these reports specified the ulceration location

incidence in detail, and this is presented in Table 1. This is in agreement with other authors who reported the plantar hallux, 1MPJ and fifth MPJ to be the commonest sites for ulceration to occur (Ctercteko et al., 1981). Sosenko et al. (1990) appeared to have a similar combined hallux and digits ratio (45%), but their MPJ area result was much lower (12%), while their mid-foot result was much higher (20%). Therefore, ulcerations may occur on any part of the foot and this thesis will include the most prevalent ulceration locations that are the plantar hallux and 1MPJ.

Table 1

Foot ulceration incidence per anatomical locations reported for adults with diabetes and peripheral neuropathy.

Plantar foot region	Percentage of ulcerations on foot (%)	
	Armstrong, Lavery, & Harkless (1998)	Birke & Sims (1986)
Hallux	30	25
Lesser digits	23 (apex: 10%, dorsum: 13%)	15
1MPJ	22	19
2-4 MPJ	23	18
5 MPJ	9	15
Midfoot	4	6
Heel	1	2

MPJ = metatarsal phalangeal joint

The level of classification of ulceration determines the level of concern and clinical intervention required (Lavery, Armstrong, & Harkless, 1996). Lavery et al. (1996) developed and Armstrong, Lavery, and Harkless (1998) validated The University of Texas Wound Classification System to assist clinicians to standardise their approach to diabetes foot ulceration management and it is presented in Table 2. Their classification system relies on three basic questions. These questions are: ‘How deep is it?’, ‘Is it infected?’ and ‘Is it ischemic?’. The depth of the ulceration is then graded as either being 0, 1 or 2, while the infection or ischemic state of the ulceration is graded in four stages, being Stages A to D.

Table 2

The University of Texas Diabetic Wound Classification System.

		Grade			
		0	1	2	3
Stage	A	Pre or post-ulcerative lesion completely epithelialized	Superficial wound, not involving tendon, capsule, or bone	Wound penetrating to tendon or capsule	Wound penetrating to bone or joint
	B	with infection	with infection	with infection	with infection
	C	with ischemia	with ischemia	with ischemia	with ischemia
	D	with infection and ischemia	with infection and ischemia	with infection and ischemia	with infection and ischemia

From D. G. Armstrong, L. A. Lavery, and L. B. Harkless (1998) Validation of a diabetic wound classification system. *Diabetes Care*, 21(5), pp. 855-859.

As ulcerations increase in both depth and stage, the prevalence of amputation also increases (Armstrong, Lavery, & Harkless, 1998). These authors further reported that ulceration which extended to the bone were 11 times more likely to result in amputation, and in the presence of infection or ischaemia, this risk increased to 90 times. Ulceration that is categorised with infection or ischaemia (Stage C or D), or penetrates into tendon or bone (Grade 2) requires medical intervention and is beyond the level of management with footwear alone and is beyond the scope of this thesis. Ulceration that is categorised as Grade 1 and Stage A and potential ulceration categorised as Grade 0 Stage A are relevant to this thesis because footwear is integral to their management. According to Armstrong, Lavery, and Harkless, Grade 1 and Stage A ulceration described 25.8% of the 300 diabetes foot ulcerations assessed by them, and a further 4.2% were potential ulceration (Grade 0 Stage A). Combination of these ulceration categories leaves 30% of ulceration to be primarily managed with footwear. Unfortunately, evidence to the efficacy of common footwear and footwear modifications to protect ulceration from walking pressures is lacking, leaving footwear as therapy prescription to be *ad hoc* and healing to be unpredictable. This thesis will address this lack of evidence, and potentially reduce the undue suffering resulting from poor clinical outcomes of 30% of people with diabetes, neuropathy and plantar ulceration.

Footwear and ulceration

The role of footwear in foot ulceration

Ulceration develops predominately at those sites on the foot that endure the highest pressure when walking and especially when a callus has formed (Edmonds & Watkins, 1999; Young et al., 1992). Therefore, it makes sense that healing cannot occur if the injury is not adequately protected and mechanical trauma is ongoing (Cavanagh et al., 2001). Shoes are the primary means of protecting insensitive feet. When a shoe upper doesn't fit well, then injuries will occur where the shoe exerts direct pressure onto the foot and tissue ischaemia results. Such sites are commonly the medial, lateral or dorsal forefoot and toes, or the dorsum of the foot (Coleman, 2001). It has been reported that 93% of ulceration in the diabetic and neuropathic population occurred in the forefoot (Edmonds et al., 1986). Of particular interest, Edmonds et al. reported, from a footwear perspective, that ulceration on the dorsal and plantar surfaces were approximately evenly distributed. Since dorsal ulceration are invariably shoe related, then the reported distribution indicates that approximately half of all ulceration could be avoided very simply by footwear that is appropriately sized and fitted (Cavanagh et al., 2001). The report by Uccioli et al. (1995) contributes to knowledge of the potential risks from everyday footwear with their study of people with diabetes and a history of healed ulceration. These people were assigned to wear either their own footwear or were supplied with well-fitted footwear with padded insoles. The results showed that footwear is associated with ulceration because after one year 58.3% and 27.7% reulcerated in the group with their own footwear and the therapeutic footwear, respectively (Uccioli et al., 1995). Therefore, potentially, it's the proper use of footwear will not only influence ulceration healing but also have a role in prevention of foot injury.

The footwear sole and force dispersion

Injury on the plantar surface of the foot is related to the shoe sole and insole's ability to transfer pressures. Pressure transfer or dissipation is described as the cushioning ability of the shoe and is the protective function afforded by shoe outsoles and insoles (Cavanagh et al., 2001). Cushioning is a general concept that has several meanings, but mechanically it can be defined as "controlling the energy of a collision" (Cavanagh et al., 2001). When addressing the cushioning ability of an insole it is important to note that the forces of walking are only dispersed , and not altered in magnitude. Dispersion of the forces away from the fragile skin over prominent bony points of the plantar foot using different materials or different shaped insoles allows a greater area of the foot to

cope with the same force. Therefore, this results in a lower pressure being experienced by the foot, and this coping is described mechanically as damping (Cavanagh et al., 2001). Damping means that the pressure applied to the bony points are not met by a shoe outsole that acts as a spring and pushes the forces away, but is both transformed from mechanical energy into thermal energy and dispersed to adjacent areas. There is an abundance of data describing the damping properties of common insole materials (Boulton, Franks, Betts, Duckworth, & Jard, 1984; Brodsky, Kourosh, Stills, & Mooney, 1988; Foto & Birke, 1998).

Another way of dissipating adverse pressure away from prominent injury sites is to influence the load to move differently. This relieves high pressure areas and transfers it to less vulnerable areas (Edmonds & Watkins, 1999). There are several approaches to transfer the load to other sites and these include shaped insoles or orthoses, rocker-sole modifications to therapeutic shoes and casts or walking devices. The most widely investigated has been the total contact cast (TCC) (Armstrong & Athanasiou, 1998; Armstrong & Stacpoole-Shea, 1999; Coleman, Brand, & Birke, 1984; Guzman, Fisher, Palladino, & Stavosky, 1994; Helm, Walker, & Pulliam, 1984; Kominsky, 1991). The TCC is applied directly and firmly to the non-weight bearing foot and leg in such a manner that when the cast is walked on, the cylindrical leg component bears some of the loads normally experienced by the foot (Armstrong & Stacpoole-Shea, 1999). There are are also removable forms of casting that are termed walkers and both the TCC and walkers are successfully utilised to heal ulceration (Armstrong & Stacpoole-Shea, 1999; Baumhauer, Wervey, McWilliams, Harris, & Shereff, 1997; Boulton, Bowker et al., 1986).

The most common means to dissipate pressure away from prominent injury sites is to alter the weightbearing surface and this is achieved by using padded and moulded insoles or dressings (Armstrong, Liswood, & Todd, 1995; Holmes & Timmerman, 1990). A moulded insole is generally made in a sandwich manner where a cushioned material is adhered over a more rigid material that is moulded to the foot shape. Moulded insoles have been reported to redistribute pressure away from plantar foot sites and to do so far more effectively than flat insoles (Lord & Hosein, 1994). However, there are severe limitations on pressure study into insole efficacy due to individual patient and insole variations in addition to instrumental measurement uncertainties (Lord & Hosein, 1994). Insoles and dressings have also been indicated as the cause of foot injury and the paper by Armstrong and Athanasious (1998) discussed the injury risk potential if insole design did not adequately control load transference away from potential injury sites.

Load transference away from potential injury sites and ulceration is affected by the use of rigid modifications to the shoe outsole. Outsole modifications frequently take the form of either a rocker or a roller sole that is manufactured to replace the normal shoe sole and are made by specialist shoe technicians guided by prescription from a clinician. The rigid outsole acts to

prevent the need for the forefoot to flex at the metatarsophalangeal joints. Reduced flexion lessens the prominence of the metatarsal head component of the joint and thus reduces the exposure of the fragile plantar skin to injury during loading (Nawoczenski et al., 1988; Schaff & Cavanagh, 1990). The rocker-sole affects change in load transference by encouraging the foot to increase the midstance time (Albert & Christensen, 1994; Brown et al., 2004; Schaff & Cavanagh, 1990). Rocker modifications are a well-accepted method of lessening plantar forefoot loading while walking (Nawoczenski et al., 1988). However, little data exist to demonstrate their benefit to the diabetic and neuropathic population to whom they are supplied, and to select the ideal rocker position or angle to prescribe (Brown et al., 2004; Cavanagh et al., 2001; Peterson, Perry, & Montgomery, 1985). Evaluating rocker-sole efficacy to lessen plantar pressures and load timing on ulceration is the aim of this thesis and the evidence towards understanding the effect on pressures when walking in rocker-soles will be discussed in the following section.

The responsibility to ensure proper shoe applications rests with the clinician and, in combination with careful instruction and education related to foot care, most people with diabetes can expect to avoid skin injury to their feet (Coleman, 2001). Unfortunately, even with an attentive clinician and compliant patient, shoes are not reliable for total ulceration management and if used in isolation will usually prolong the time needed to heal (Coleman, 2001) or reulceration will occur (Cavanagh et al., 1996). This is because most shoe modifications are prescribed as the result of trial-and-error experience and training that is based on the empiric findings of shoemakers of previous generations, and not based on experimentally derived evidence (Coleman, 2001). Even though evidence clearly shows that high peak pressures on discrete points of the plantar foot are an accepted risk for foot ulceration, there are little objective, experimentally derived data to support most shoe therapy (Armstrong & Lavery, 1998; Cavanagh, Simoneau, & Ulbrecht, 1993; Lavery, Vela, Fleischli, Armstrong, & Lavery, 1997; Schaff & Cavanagh, 1990).

Footwear is the mainstay of Grade 1 Stage A therapeutic interventions and prevention, but its use as a therapeutic device must also conform to the social and fashion expectations of the patient (Payne, 2000a). Fashion changes over time, but Dahmen, Haspels, Koomen, and Hoeksma (2001) found that the ageing person may unknowing contribute to injury to their feet when they purchase inappropriate fashionable shoes, or continue to wear a favourite shoe-style once a change in the shape or size of the foot has occurred. This is in agreement with Chantelau and Gede (2002) who found, in a case-control study (568 older adults with diabetes and insensitive feet and 100 healthy age-matched controls) of the foot length and breadth, that the foot breath was wider than standard dress shoes in more than two thirds of those studied. In a similar study, Burns, Leese, and McMurdo (2002) reported that the footwear of 47 (72%) patients admitted to a general rehabilitation hospital ward were ill fitting. Of these patients, ten (15%) had ulceration and the

shoes were of incorrect length. These studies show that patients may be using footwear un suitable to protect their feet, suggesting that they are potentially unaware of the risks that inappropriate footwear poses to their feet and ultimately, their general mobility and health.

Dahmen et al. (2001) identified that limited communication on the part of the clinician may be a factor in diminished patient compliance with footwear because, in their study population, the rationale behind footwear selected was often unclear to both the patients and carers. The lack of efficacy evidence of footwear to protect ulceration prevents a standard of care approach to footwear selection, severely limiting the guidance for clinicians to select the appropriate footwear for their patients. It is not surprising therefore, that the clinician's communications with patients and carers regarding footwear selection has not been clearly understood by the recipient.

Footwear is categorised by its design (Ashry, Lavery, Murdoch, Frolich, & Lavery, 1997; Cavanagh et al., 2001; Chantelau & Gede, 2002; Flot, Hill, Yamada, McPoil, & Cornwall, 1995; Janisse, 1995; Lavery, Vela, Fleischli et al., 1997; Litzelman et al., 1997; Payne, 2000a; Reiber et al., 1997; Reiber et al., 2002). Payne (2000a) described the categorisation of footwear to fall under four major headings that relate to the therapeutic use in diabetes. The categories are; athletic shoes, extra-depth shoes (commonly known as *therapeutic* shoes), therapeutic shoes with modifications and custom made shoes.

Athletic shoes are the first line of footwear prescription to the adult with diabetes according to Chantelau et al. (1990). They reported that athletic footwear are recommended to all people who exercise. Some of the features that make the athletic shoe the ideal first line choice include; the sole is cushioned, the upper is soft, the bindings are adjustable and secure, the toe box is deep and the generic insole can be replaced with a custom insole. People with diabetes may also select these shoes for non-therapeutic reasons such as acceptable price range and socially acceptable appearance.

Athletic shoes have been reported by Lake (2000) to be unsafe for healthy people, because the cushioning component of the sole limits the impact experienced and felt by the person, therefore, they continue the activity and allow potentially dangerous high forces to be inflicted on the feet and limbs. However, when the foot is insensitive, Litzelman et al. (1997) reported that the limited impact experienced is beneficial and protective to the feet.

According to Uccioli et al. (1995) as athletic shoes have evolved and become more readily utilised by the diabetic population, it has become less likely that therapeutic footwear would be prescribed. The message from Tennent (2002) in the Diabetes Australia –Victoria patient information publication suggests the regular use of athletic shoes for exercise, but falls short

regarding everyday street footwear selection. It states, “Wear exercise shoes such as sports shoes that are in good repair to reduce overuse injuries of the feet and minimise the development of blisters” (p 5). Flot et al. (1995) and Uccioli et al. (1995) both reported that the new generation of street shoes that are based on athletic shoe design hold a great appeal to people with diabetes because their feet are protected and appear socially acceptable. What the literature does not provide the clinician with is evidence regarding the efficacy, of an Oxford style therapeutic shoe with prescribed modifications over an athletic shoe, to transfer plantar pressure away from ulceration, and this thesis will address this lack of evidence.

Therapeutic shoes were defined by Payne (2000a), as footwear specifically designed to accommodate and enhance the function of the foot when it’s shape cannot be accommodated in a standard shoe or it is not biomechanically sound. The therapeutic shoe follows the design and construction of the oxford shoe. The oxford style is analogous to the common laced public-school shoe and the typical male dress shoe. There are critical design features that take the appearance of an oxford style to the function of a therapeutic shoe. Flot et al (1995) reported the depth and squareness of the toe box and the extra depth of the shoe overall, which allows for the addition of a custom insole, to be important features, while several authors have stated that the rigidity of the mid-sole shank and heel counter to be optimal shoe features (Litzelman et al., 1997; Ulbrecht et al., 1994; Walsh, 1996). There is a down side with this shoe type that several authors have reported and it is in the overall good materials and construction that gives a long lasting and quality shoe, but imposes risks to the foot while the long wearing-in or softening process is followed through (Litzelman et al., 1997; Reiber et al., 2002; Ulbrecht et al., 1994). As discussed earlier, evidence is lacking to the efficacy of the therapeutic shoe to protect the foot from walking pressures, and therefore, it is unknown whether it is the modification of the shoe or the shoe style itself that provides any ulceration protective benefit and this thesis aims to contribute to answering this question.

According to Ulbrecht et al. (1994) there are so many techniques and devices for modifying a therapeutic shoe that the process of prescribing a particular shoe and modification for a particular patient is *ad hoc*, and remains largely an art. Shoe modifications are described by the part of the shoe affected. These are the body of the foot affected by the shoe upper, the foot-to-shoe interface affected by the shoe insole and the functioning of the foot as the body link to the ground affected by the shoe outsole. Within these general categories there are many uses. Specifically, upper modifications have a role in accommodating particulars of toe or foot deformity or size, improving on the binding of the shoe to the foot, and purely aesthetic improvements. Unfortunately, Chantelau and Gede (2002) found that the aged foot is wider than the range of standard shoe sizes for between 35 and 93% of aged men and 56 and 90% of aged women.

Therefore, if we review the reports discussed earlier by Cavanagh et al. (2001) and Edmonds et al. (1986), where they expected that attention to shoe fitting would prevent up to half of ulceration events from occurring, particularly on the toes and medial and lateral forefoot, then education regarding appropriate footwear is required. Good fitting education is especially imperative when an insole or padded sock is used within the shoe.

It is a frequent oversight in the literature that excludes the mention of the role of the sock in addition to using shoes to protect the diabetic foot. Padded (therapeutic) socks were found to provide a substantial and significant reduction in adverse walking pressures under the feet of 10 people with diabetes and insensitive feet (Veves, Masson, Fernando, & Boulton, 1990) and eight healthy people (Flot et al., 1995). Veves et al. (1990) found that the pressure reduction from the socks was effective over the whole forefoot, and was still below the pressures of barefoot walking after three and six months of use. However, Flot et al. (1995) did not find the pressure reduction to be consistent over the forefoot, but limited to the plantar hallux and central forefoot. The study of Veves et al. also found a significant pressure reduction when wearing athletic socks, but this reduction was not as great as when wearing the therapeutic socks. They concluded that padded athletic socks might protect insensitive diabetic feet. There are three main limitations on the applicability of the results from these studies. The potential effect of shoes, measurement device and different populations is unknown. Veves et al. used a pressure measurement plate without shoes and a diabetic population, whereas Flot et al. used an insole pressure matrix in shoes in a healthy population.

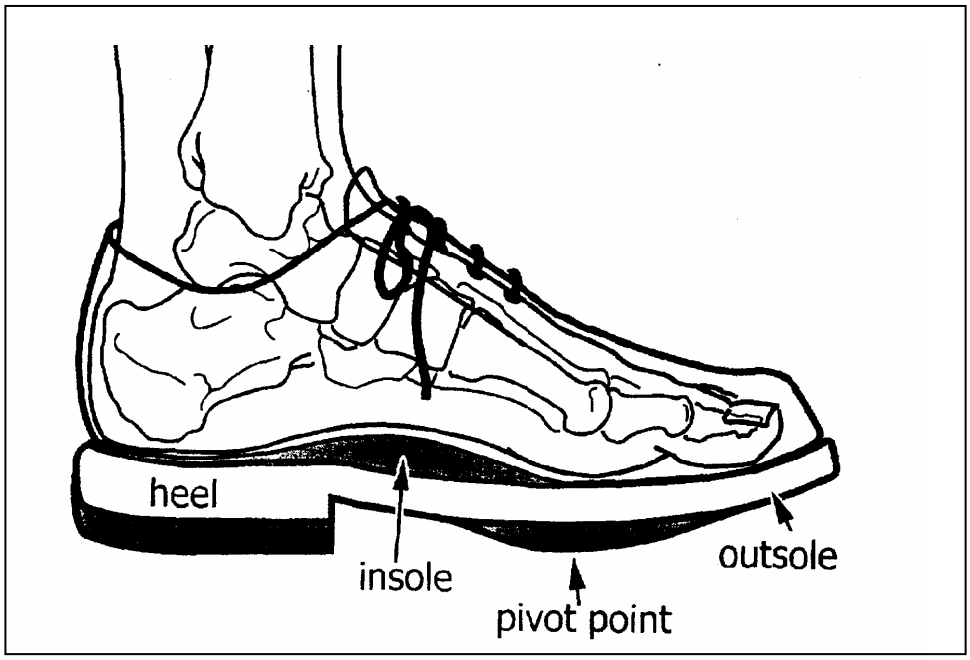
There needs to be an element of caution when selecting socks due to the volume that therapeutic socks take up in a shoe according to Murray, Veves, Young, Richie, and Boulton (1993). Their evaluation into the compliance and satisfaction to use therapeutic socks and shoes in 86 people with diabetes found ulceration arose in one subject from direct injury caused by the creasing of excessive sock material bulk. Even though, this is only a potential injury prevalence of less than two percent, this finding is in agreement with a study that found that the dorsal toe seam on a commercially available padded athletic sock could impose up to a ten-fold increase in localised pressure (Stacpoole-Shea, Walden et al., 1999). Additionally, to study therapeutic socks, 80 of the 86 people studied by Murray et al. (1993) required therapeutic shoes to be provided because their own shoes did not have sufficient volume to accommodate the padded therapeutic socks. These studies suggest that therapeutic socks have several advantages in diabetic foot protection, but they also bring risks, in that the creation of a too tight shoe may be the source of potential injury risk, and therefore, this approach necessitates careful fitting between the sock and the shoe.

Within the shoe, insole devices (termed insoles, inserts or orthoses) are utilised to protect particular sites on the plantar foot from walking pressures, to accommodate bony protrusions,

protect ulceration, to support the foot structure, or modify walking gait. Insoles come in three main forms; cushioned, semi-rigid and rigid. Insoles may be custom-made or prefabricated and dissipate pressures, and may also be used to locate experimental padding against the foot to avoid the risks associated with skin injury from adhesives (Albert, 1981; Brodsky et al., 1988; McPoil & Cornwall, 1992).

Custom made insoles that makes total contact with the weight-bearing components of the foot was highly successful in reducing walking pressures (Janisse, 1995; McAllister et al., 1991; Mueller, Strube, & Allen, 1997). The debate around the evidence or primarily lack of evidence to support the clinical selection of either custom made cushioned, semi-rigid or rigid devices to modify and improve foot function has been the focus of many reports; (Ashry et al., 1997; Bennett, Miskewitch, & Duplock, 1996; Boulton et al., 1984; Cross, Sane, Dey, & Kulkarni, 1995; Holstein, Larsen, & Sager, 1976; Lemmon, Shiang, Hashmi, Ulbrecht, & Cavanagh, 1997; Novick et al., 1991; Reiber et al., 1997) and will indirectly be addressed by the thesis studies that aim to encourage the standardisation of the protocol for in-shoe walking pressure measurement.

Shoe outsole modifications are prescribed to alter the pattern and magnitude of pressure on the foot, or improve inequalities in limb length during walking. The rocker-sole modification made to therapeutic shoes is illustrated in Figure 3and are readily prescribed yet poorly evaluated (Cavanagh et al., 2001). The rocker-soled shoe has a break in the contour of the outsole (pivot point) which means that there is little motion through the metatarsophalangeal joints during the push-off phase of gait (Bauman, Girling, & Brand, 1963; Cavanagh et al., 2001; Mueller et al., 1997; Nawoczenski et al., 1988; Schaff & Cavanagh, 1990). Various forms of this modification have been reported to reduce the pressure borne on the plantar surfaces of the MPJ region by 20 to 50% compared to walking in flexible soled shoes or regular dress shoes (Nawoczenski et al., 1988; Schaff & Cavanagh, 1990). Computerised pressure measurement of in-shoe walking have shown that in addition to differences in pressure, that the time that weight is born on segments of the foot is increased in all areas of the foot except the forefoot when wearing a rocker-soled shoe (Cavanagh et al., 2001; Schaff & Cavanagh, 1990). These authors suggested that these changes in both pressure and time explain the mechanism by which a rocker-soled shoe protects the forefoot from pressures. Unfortunately, evidence into the efficacy of rocker-soled shoes to reduce walking pressures are limited in their applicability to clinical practise for two reasons. The lack of study and reporting standards means that reports are not comparable and the reality of the differences between the measures (errors and variability) are unknown, and study so far, has been conducted on subjects without ulceration. The thesis studies will address both these limitations by standardising the protocol for plantar pressure measurement and studying rocker-sole modifications in people with diabetes, neuropathy and plantar ulceration.



From: Dahmen, R., Haspels, R., Koomen, B. & Hoeksma, A. F. (2001) Therapeutic footwear for the neuropathic foot. An algorithm. *Diabetes Care*, 24(4), pp 705-709.

Figure 3. Therapeutic shoe with a full-contact insole and a rocker-sole with the pivot point beneath the metatarsophalangeal joints.

The decision to prescribe a rocker-soled shoe clinically is not straight forward, as there are several design variables to select from. These variations include the position of placement of the break in the contour of the sole, and the angle that the break makes with the rear foot section of the sole. A number of investigations have revealed that the rocker-sole designs can influence the efficacy of the shoe to reduce pressures experienced by the foot during walking and the forefoot results reported are summarised in Table 3.

Table 3

Summary of results of investigations into rocker-sole shoe design efficacy to reduce pressure on the forefoot compared to other shoes/designs.

Rocker design		Comparison shoe	Results of % reduction in rocker from comparison shoe			Population	Authors
Angle/height	Pivot point		Hallux	1MPJ	Forefoot		
2.5cm high	Under MPJ	1.7cm proximal to MPJ			NSD	12 adult men with Leprosy & neuropathy	Bauman et al. (1963)
30 degree	Under MPJ	Same unmodified	PP -31*	PP -16*		20 healthy adult men	Nawoczenski et al. (1988)
	50% shoe length	60% shoe length	NSD	NSD	NSD		
24 degree & 3.5cm high	67% shoe length	Same unmodified	PP -63* PTI -1	PP -64* PTI -33*		8 healthy adult men on treadmill	Schaff & Cavanagh (1990)
20 degree	Proximal to MPJ residuum	Unmodified with toe filler			PP -16*	30 adults with DM & forefoot amputation	Mueller et al. (1997)
11 degree	67% shoe length	Traditional post op shoe			PP -21* FTI -8	16 health adult women	Fuller, Schroeder, & Edwards (2001)
23 degree	65% shoe length	Different style with rockers of 5 & 10 degree at 60 & 65% shoe length			PP -32	10 adult women with DM & neuropathy	Praet & Louwerens (2003)
1.2cm high	Proximal to MPJ	Same unmodified	PP -71*(R) -75*(L) PTI -30*(R) -41*(L)	PP -13*(R) -7*(L) PTI -5*(R) -9*(L)		40 healthy adults	Brown et al. (2004)

* Significant difference reported at p=0.05, NSD = No significant difference found, R = right foot, L = left foot, PP = peak pressure, PTI = pressure-time integral

When prescribing a rocker-sole modified shoe the position of the pivot point is made either by selecting it to align with the foot structure, or at a percent of the length of the shoe. The other prescription decision is what degree of angle of the fore sole is required to positively affect forefoot pressure. Nawoczenski et al. (1988) investigated several rocker-sole designs in healthy young adults. The out-sole designs tested had the rocker pivot point position placed at either 50 or 60% of shoe length and were beneath the MPJ. They reported that the 50% rocker-sole pivot point position effectively reduced pressure over all sites on the forefoot; whereas the rocker-sole pivot point position placed directly beneath the MPJ was not as effective under the fifth MPJ. It is difficult to interpret the clinical usefulness of these results as the authors used two measures of the angle that the rockers made with the sole of the shoe. One rocker pivot point shape was described in the standard manner using measurement of the angle that the fore-sole made with the rear-sole in degrees (30 degrees). The other rocker-soles were rounded at the pivot point and this was described in percent radius of the arc to the rear-sole of the shoe. The arcs tested were at fore-sole radii of 125, 75 and 60% with the rear-sole. They concluded that the 75% rocker-sole radius with the pivot point placed at 50% of the shoe length was the most successful at reducing forefoot pressures. These results do not agree with the later report by Cavanagh et al. (2001) who reported that the optimal rocker placement for reducing MPJ region pressures was in the region of 55 to 60%. However, plantar hallux pressure reduction was shown to be much less in these computations than that reported by Nawoczenski et al. and the reason for this is not apparent.

Even though the reports reviewed uniformly discuss the role of rocker-sole modifications on peak pressure reduction for forefoot ulceration management and protection, none of the reports investigated pressures experienced on an actual ulceration. Consequently, there is a dearth of experimental evidence to show that these modifications have any effect on reducing pressure and protecting forefoot ulceration at all. Therefore, this thesis aims to address this uncertainty and investigate the efficacy of various rocker-sole pivot positions and angles to reduce in-shoe plantar pressure measures on adults with diabetes, neuropathy and plantar forefoot ulceration.

Regardless of the footwear modification concerned, there is a lack of standards both for in-shoe plantar pressure measurement in the research and clinical setting. Lack of standards leaves shoe selection to be *ad hoc* and patients' safety when prescribed therapeutic footwear interventions cannot be assured (Litzelman et al., 1997; Miller, 1993). To understand the lack of evidence it is useful at this stage to look at the means to which footwear has been selected and evaluated historically in the context of diabetes.

Footwear and foot protection from walking pressures

Non-computer-assisted identification of localised high pressure areas

Therapeutic footwear usually in the form of a specific shoe type, in-sole or sole modification is considered inappropriate if it is directly seen as a contributing factor in the pathoaeitology of ulceration. A direct causal link may seem to be obvious between wearing a particular shoe and an ulceration event, especially when the shoe upper is concerned. Such an example is when a narrow shoe is worn and ulceration occurs on the medial or lateral bony prominences of the forefoot. The question remains to whether the shoe in- or out-sole, is appropriate when proper shoe fit has been assured? There are several observational methods that are employed by clinicians to make judgements about shoe soles. These primarily focus on signs of material damage or aging on the shoe. To localise a sign of shoe damage to a specific injury the least a clinician does is to mark the foot with a transferring substance (such as lip stick) and observes signs of the substance transfer to the shoe after walking.

Objective measures of therapeutic shoe efficacy are necessary to ensure that appropriate therapy has been prescribed. Historically, the role of pressure in the aetiology of plantar foot ulceration has been observed using devices that intensify ink or an image proportional to pressures (Barrnett, 1954; Bauman et al., 1963; Benbow, Chan, Bowsher, Williams, & Macfarlane, 1994; Elftman, 1934; Hughes, 1993; Quaney, Meyer, Cornwall, & McPoil, 1995).The pressure sensitive sock was one of the first devices that could accurately identify the location of and facilitate the reporting of high-pressure regions on the foot within a shoe. The pressure sensitive sock contains tiny ink impregnated wax capsules that break under pressure and stain the sock leaving a pressure map for interpretation (Brand & Yancey, 1993; Coleman, 2001). These images were clinically applicable for visualisation of localised pressure, but results were not quantifiable. However, the introduction of computer assisted devices that serve both functions, in that they produce visual images of pressure, as well as provide measurements for evaluation and experimental research.

Computer-assisted identification and quantification of localised high pressure areas

Experimental testing of the effect of pressures on different shoes and their materials can be loosely categorised into testing external to, or within a shoe. External testing takes the form of either bench-based machine or human subject tests (Lake, 2000). Mechanical tests involve

machinery, which can evaluate resistance and compressibility of materials to pressures, or employ weighted missiles that are dropped to test the shock attenuation properties of a material (Lake, 2000). These non-human subject tests are necessary to control the testing conditions to gain accurate or preliminary data, and are especially essential for procedural testing prior to and to minimise risk and inconvenience to human subjects (Stacpoole-Shea, Walden et al., 1999). The effect that different shoe materials have on pressures experienced by the foot have primarily been assumed from tests conducted external to the foot-shoe environment at the shoe-ground interface (McPoil & Cornwall, 1992). The disadvantage with external-testing procedures is that only assumptions, and not actual evidence, can be derived from the data about the effect on the foot-shoe interface.

Several different computer-assisted instruments are available to quantify foot pressure either on the floor surface or within the shoe during walking. These have primarily been limited to the realm of the research laboratory because of high cost and the skill and time required for their accurate use. However, with the advances in computer assisted technologies, reducing cost and growing computer literacy, pressure measurement is available more widely and this has translated to include the clinical setting. Traditionally, clinical applications of pressure measurement have been limited to barefoot walking measured via a pressure plate housed in the floor over which the patient walks. The relevance, accuracy and reliability of this data has been questioned due to it not measuring the gait from both limbs or footsteps in sequence, and that barefoot walking is unusual for most people, and prohibited for the diabetes population (Alexander, Chao, & Johnson, 1990; Arcan & Brull, 1976). However, it is still the primary means of both clinical and experimental pressure measurement due to its ease of use and lower cost than in-shoe pressure measure devices.

In-shoe pressure measurement takes two main forms. These are discrete sensors placed relevant to a specific site on the foot or shoe, or matrices of sensors placed in the shoe in the form of an insole. These instruments have been the focus of many reports describing their relevance, usability, and technical limitations (Abu-Faraj, Harris, Abler, & Wertsch, 1997; Ahroni, Boyko, & Forsberg, 1998; Bauman, Krabbe, & Farkas, 1992; Brown, Rudicel, & Esquenazi, 1996; Cavanagh, Hewitt, & Perry, 1992; Davis, Perry, Neth, & Walters, 1998; Franks, Betts, & Duckworth, 1983; Kernozek, LaMott, & Dancisak, 1996; Luo, Berglund, & An, 1998; McPoil, Cornwall, & Yamada, 1995; Sarnow et al., 1994; Stacpoole-Shea, Shea, & Lavery, 1999; Wertsch, Webster, & Tompkins, 1992; Woodburn & Helliwell, 1996a; Zhu et al., 1990). Their application to shoe study and diabetic gait has yet to be standardised. The lack of standards limits the usefulness of research reports as variations in the applications of the technologies and treatments of data prevents the accurate comparison of results or an understanding between what are valid measurements and interpretations (Amos, McCarty, & Zimmet, 1997).

Reducing plantar pressure to non-adverse levels

When a point of high pressure is measured on the foot of a person with diabetes and peripheral neuropathy, with or without ulceration, then the aim of therapy will be to lower the pressure. However, without standardisation of pressure measurement instrumental use, an absolute threshold value for ulceration risk has yet to be agreed upon (Cavanagh et al., 1992; Cavanagh, Perry, Ulbrecht, Derr, & Pammer, 1998; Cavanagh et al., 2001). The existence of a threshold pressure for ulceration has also not been established because agreement on the variables of measurements of pressure that are useful for ulceration assessment have not been established (Barnett, 1998). Primarily reports present the absolute or peak pressure measured, but this has varying interpretations dependant on sensor type, size, location and conditions of use (Ahroni et al., 1998; Kernozek et al., 1996) and there is not consensus regarding the units of pressure used for reporting (Barnett, 1998). Influence of pressures during the stance time of the foot during walking gait has been proposed as potentially more useful than absolute values for determining ulceration risk (Duckworth, Boulton, Betts, Franks, & Ward, 1985; Schaff & Cavanagh, 1990). There is a dearth of literature specifically to direct experimental study using pressure measures (Barnett, 1998) and this is especially critical due to the growing extent to which these measures are being applied to therapy selection in the diabetic and neuropathic population. This thesis will examine the absolute pressure and pressure-time values in the presence of ulceration in people with diabetes and neuropathy to determine their usefulness for experimental study into shoe therapies.

Foot and shoe plantar pressure measurement

Differences between the pressure measurement results obtained from pressure plates and in-shoe pressure measurement systems led to in-shoe systems being recommended for all evaluations involving the feet of people with diabetes and neuropathy (Schaff & Cavanagh, 1990). This recommendation places in-shoe pressure testing at the foot-shoe interface during walking as the mainstay of scientific enquiry into design and efficacy of protective shoes for prescription to the diabetic population (Bauman et al., 1992; Linge, 1996). The usefulness, however, of study to clinical practice for shoe selection is limited due to the lack of a standard protocol for data acquisition and analysis for this type of measurement instrument. A lack of standardisation means that studies are not comparable, severely limiting their translation into clinical standards of care.

Computer assisted in-shoe plantar pressure measurement systems began discrete pressure measuring sensors that acted as timing switches. Foot specific sensor technology has developed

inline with electronic and computer technologies so that not only can the time that loading occurs, but also the magnitude of pressure can be measured (Alexander et al., 1990). This has been successfully utilised to both assist the individual patient clinically and experimentally validate the assumption that high pressures are experienced at sites of diabetic ulceration (Barrett & Mooney, 1973; Birke, Franks, & Foto, 1995; Boulton et al., 1987). However, the rapid advancement in the technology has brought with it a lack of basic testing that would have not only established procedural standards, but also baseline data to which researchers and clinicians may refer (Finch, 1999; Mueller & Strube, 1996). This thesis will address the lack of baseline in-shoe dynamic plantar pressure measures from the population of people with diabetes, neuropathy and plantar forefoot ulceration from archival and new data analyses based on experimentally derived standard procedures. These standardised, baseline data will not only allow the efficacy of therapeutic rocker-sole modifications to be established, but also allow repetition of these procedures for ongoing critique and contribution to the body of knowledge in this field.

Practicalities and measurement uncertainties

Computer assisted in-shoe pressure measurement has the practical advantage of being applicable to both the research and clinical environment. In particular, the computer reports on many specific variables obtained from multiple sensors that measure over the plantar surface of the foot simultaneously (Finch, 1999; Mueller & Strube, 1996). For research applications these variables and data can be data-mined to assist in answering specific questions. However, the matter of which variables are useful to the clinical investigations of the diabetic foot has not been satisfactorily established. The literature has reports on peak and mean pressures, pressure-time integrals, peak and mean forces, force-time integrals and variations on timings. This is far below the capabilities of these computerised in-shoe pressure measurement systems. For example, the *Pedar*™ system supplies data that can be analysed within the *Novel-win Group Mask Evaluation*™[9] computer program to provide twenty-one individual pressure variable reports for every site selected on each foot (Novel Electronics Incorporated, 1998a). This thesis will address the uncertainty regarding whether all or a few of the multiple variables obtained from standard reports from in-shoe dynamic pressure measurement are useful for determining the efficacy of footwear to protect ulceration on the foot of people with diabetes from walking impact pressures.

Clinically, whilst in-shoe pressure measurement is applicable, it is not always practical, due the purchase and maintenance cost of the systems and the personnel time required to analyse and

[9] Novel Electronics Incorporated, St. Paul, Minneapolis, USA.

report on the data. With standardised procedures, technician training for data collection and analysis could also be standardised and thus facilitate time efficient building of standardised databases. Trained assistance and standardised databases would free the clinician to focus on individual patient interpretation and therapeutic intervention efficacy investigation. Cavanagh et al. (1996) reported testing and retesting the one patient when walking in different interventions and based on their positive clinical outcomes, they recommended that all patients with diabetes and insensitive feet have access to this type of test. However, provision of trained assistants, in addition to the purchase cost of the instrumentation currently makes testing unlikely due to third-party insurance companies and health management organisations refusing to, or severely restricting, reimbursement for this clinical test. Reimbursement is limited due to the lack of efficacy evidence, standards of care and the emphasis that both government and health management organisations place on treatment of injury or illness rather than prevention (Finch, 1999). . Therefore, this thesis will conduct clinically relevant research into footwear currently prescribed with the assumption that it protects ulceration from walking pressures. The results from the thesis studies are expected to provide clinicians with guidance to select the most effective rocker-sole shoe design when individual in-shoe assessment is either unavailable or impractical.

There are some practical disadvantages to collecting in-shoe pressure data that require careful procedural considerations. The ability to gain data from sensors inside the shoe has the practical limitation of needing a cable connection between the sensor and the collection device. This physical presence of the tethering to the collection device is problematic in itself and can contravene Kelvin's Law[10] (Finch, 1999). Collection devices can either be in a form that is worn/carried by the subject, or tethered by a longer wire to a stationary desk unit. The device that is worn/carried by the subject has the advantage of allowing data collection away from the constraints of the laboratory, but has the disadvantage of preventing examination of preliminary data at the same time as data collection. The device that requires the sensors and subject to be tethered have the disadvantage of limiting the subject to walking within the laboratory but allow continual on-line data monitoring. The imposition of the sensors within the shoe needs careful procedural consideration in addition to their tethering for data collection. The placement of the sensors into the shoe under the foot appears to ideally provide insight to the foot shoe interface, but the validity of the data has been questioned because the sensors are flat and does not conform to the shape of the foot or insole (Cavanagh et al., 1992; Finch, 1999).

[10] Kelvin's Law states that the act of measurement or observation should not affect the quantity being measured or the behaviour being observed (Cavanagh et al., 1992).

The most practical disadvantage to collecting in-shoe pressure data is the subject of inquiry itself; the human. The foot being the point of interaction between the earth and the walking person means that the data collected is limited by the consistency of human movement. Human footsteps have been anecdotally described to be 'as variable as snowflakes' and it is common practice in human gait analysis to collect at least two walk repetitions and use the average of the two in the final analysis (Craik & Dutterer, 1995). However, there is no consensus to how many step repetitions are required for analysis of in-shoe plantar pressure measures. As little as only one step have been reported by Conti, Martin, Chaytor, Hughes and Luttrel (1996), while four hundred steps were reported by Brown, Wertsch et al. (2004). Kernozek et al. (1996) addressed this question for healthy individuals tested while walking on a motorized treadmill. They reported that at least eight steps were required for excellent reliability for analysis of peak pressure and pressure-time integrals. However, the applicability of these recommendations for the patient population with diabetes, neuropathy and plantar forefoot ulceration is unknown and will be addressed by this thesis.

The consistency, or lack of it, in the walking and in-shoe plantar pressure measurement of the diabetes person with insensitive feet and ulceration has as yet not been adequately addressed. It is accepted that the insensitive foot lacks the sensory input to vary its movements on the ground and therefore, subjects localised sites on the plantar foot to repetitive stresses resulting in ulceration. However, Cavanagh, Perry, Ulbrecht, Derr and Pammer (1998) reported that the walking gait of people with diabetes and insensitive feet was not less variable than healthy walking. Further study is needed to clarify this point due to this result being contrary to the clinical assumption, and limitations in the generalisability of these results from the study's small sample size and lack of subjects with ulceration (i.e. 13 subjects with diabetes and neuropathy but without ulceration)

Once in-shoe pressure data is collected, standard procedures are lacking for data analysis and transformation for presentation and interpretation of the results. These standard procedures include ensuring that all data included in analyses are valid, and there are sufficient repeated walking steps for the measurement to be stable and reliable, and the accuracy of the measures is known so that valid conclusions can be drawn. Without standard procedures based on these concepts, the pressures during walking for the population of people with diabetes, neuropathy and plantar forefoot ulceration cannot be determined. Without these baseline figures being expressed within the understandings of the above mentioned conceptual constraints, the actual difference between walking in several shoes cannot be confidently differentiated from normal variability or systematic error. This thesis will address the concerns for standard procedures for measurement and uncertainties of analysis and reporting of in-shoe plantar pressure measures that were raised in this review of literature in the following chapter.

CHAPTER THREE

DEVELOPMENT OF THE IN-SHOE PLANTAR PRESSURE MEASUREMENT PROTOCOL

The concept map of the thesis presented in Chapter One indicates that clinical ulceration protection using shoe modification is not evidence-based. This may result in unpredictable ulcer healing and, too commonly, surgery is required to amputate the ulcerated limb. This chapter addresses the lack of standardisation of in-shoe plantar pressure measurement and describes development of the in-shoe plantar pressure measurement protocol used for data collection and definition of the limits for result interpretation for the studies contained in this thesis. The protocol developed incorporates results from a protocol analysis of in-shoe pressure measurement reports, and measurement uncertainties were defined from analyses of archival data.

Rationale and purpose

Physical health can be narrowly defined as the absence of discrete pathology, and health practitioners rely upon the classification and measurement of bodily function to determine the appropriate treatment to return the body to health (Finch, 1999). The need to measure the function of the unhealthy foot has lead to the development and refinement of the technology behind in-shoe plantar pressure measurement systems. In 1998, International Protocol Guidelines For Plantar Pressure Measurement (IPGPPM) were reported because many aspects regarding foot pressure measurement procedures had not been standardised (Barnett, 1998). Even though procedural standards and therefore, measurement limits are yet to be defined and published, a relationship between plantar ulceration and dynamic pressures under the foot has been confirmed in the population with diabetes and foot insensitivity (Cavanagh et al., 1993; Cavanagh et al., 1996). Clinically, the visual representations of the foot-shoe interface provided by the plantar foot pressure measurement systems are viewed on a monitor or in print form and assist in confirming clinical opinion, patient education and therapy marketing. However, procedures for their use, both in research and clinical practice have not been standardised, thus the variability of protocols used

prevents accurate comparison of and evaluation of the results reported (Barnett, 1998; Redmond, Lumb, & Landorf, 2000). The greatest limitation is in the inability to define results as normal or abnormal due to the lack of a definition of acceptable and threshold measurement values for normal dynamic human foot pressures (Cavanagh et al., 1996). Normal and threshold measurement value definitions are also lacking because any values would be dependant upon the protocol and the instrument used. This is further complicated because different instruments produce different measures of the same foot due to the size, resolution and characteristics of the sensor employed (Cavanagh et al., 1993).

The IPGPPM, which are reproduced in Appendix A, are contained in a report by Barnett in 1998 that was compiled from group discussions of plantar pressure measurement system users who attended the Fourth Footpressure Special Interest Group Meeting held in 1997. The IPGPPM are in the form of suggestions, comments, questions and some specific recommendations. To achieve consistency in usage of and reporting from these systems, specific and systematic evidence-based protocol guidelines are required for the procedures. Such procedures are; subject accommodation, footwear type and usage, data collection volume, data analysis and filtering and results reporting. Thus the purpose of this chapter is to develop a standardised protocol for application of the studies in this thesis and to identify the limitations for application of the results in respect to reliability, precision, accuracy and which variables to select for thesis study into ulceration.

Chapter outline

Specifically, Chapter Three examines Research Question One (a – d) and, in so, doing determines procedures to standardise collection, analysis and reporting of dynamic in-shoe plantar pressure measures relevant to shoe study in the diabetic population. This is achieved through protocol analysis of research reports in Part I and analyses applied to archival in-shoe plantar pressure data in Part II (a-d). The aims and approaches used in Parts I and II are described as followed:

Part I

In this section the IPGPPM have been refined by eliciting of procedural theory through protocol analysis of research reports.

Part II: This section utilised archival data and is in four parts:

Part II (a)

This part described and demonstrated a method for checking data obtained from dynamic in-shoe plantar pressure measurement to confirm mid-gait step data validity.

Part II (b)

This part examined Research Question One (a) and (b) and defined the reliability and precision obtained from repeated steps. Specifically, these analyses determined *a priori* how many steps were required for the calculation of a reliable average step and its associated precision for utilisation in the thesis studies.

Part II (c)

This part examined Research Question One (c) and defined the number of repeated steps required for maximum practical accuracy. Specifically, this analysis determined *a priori* how many steps were required for the calculation of an accurate average step for utilisation in the thesis studies.

Part II (d)

This part examined Research Question One (d) and determined which dynamic in-shoe plantar pressure measurement variables and at which anatomical regions for use in analyses for ulceration identification in the thesis studies.

Operational definitions

Anatomical regions abbreviations

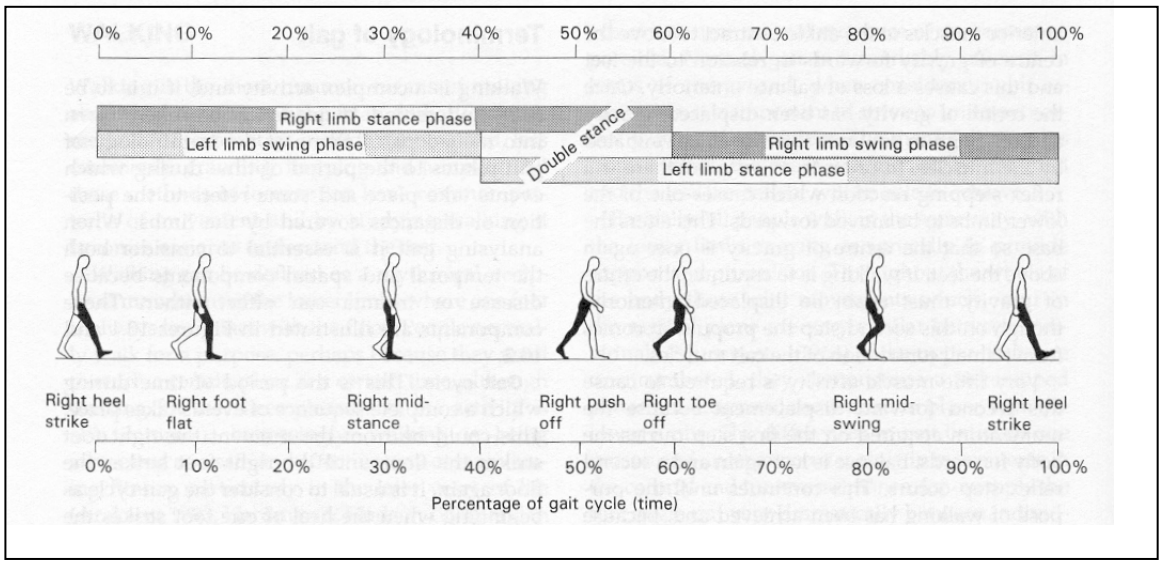
Unless otherwise stated, the anatomical regions on the plantar foot are defined and abbreviated as follows; hallux (Hallux), second to fifth toes-digits (Di), first metatarsophalangeal joint region (1MPJ), second to fifth metatarsophalangeal joints region (2-5MPJ), midfoot (Mf), Heel (Heel) and whole plantar foot-total (Total foot).

Ulceration location and abbreviations

Unless otherwise stated, ulcerations are categorised by the anatomical region that they occur in.

Gait cycle terminology and timing

The gait cycle is presented in *Figure 4*. Stance phase for each limb occurs over 60% of the total gait cycle, and is defined as 100% of the stance phase for that limb.



From Trew, M. (1997) Function of the lower limb. In M. Trew & T. Everett (Eds.), *Human movement An introductory text* (3rd ed., p. 158) New York: Churchill Livingstone Trew, 1997.

Figure 4. Terminology and timing of the gait cycle.

Definitions of in-shoe plantar pressure variables

Peak pressure

The highest pressure in kilopascal experienced by any one active sensor within an operator-defined plantar foot region.

Mean pressure

The average pressure in kilopascal experienced by active sensors within an operator-defined plantar foot region.

Area

The area in centimetre squared of the mean pressure image that is contained within an operator-defined plantar foot region.

Time

The time in milliseconds that any one sensor was active within an operator-defined plantar foot region.

Force

Force is derived from the pressure measured from sensors of known area using the formula:
Force = Pressure x Area

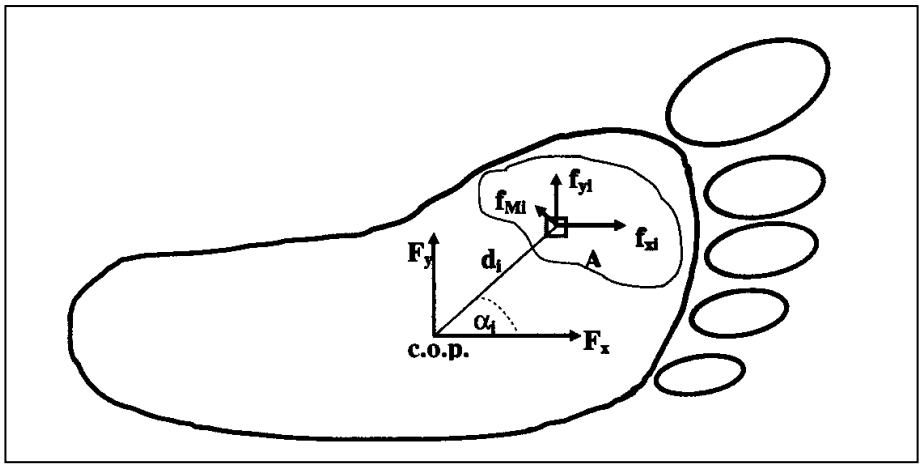
The total force is a sum of all tangential forces acting on the foot and these forces are described in *Figure 5*.

Force-time integral

A measure in newton-second of the area under the force-time graph calculated using finite analysis with the sum of the peak force obtained at each time interval (50 Hertz) multiplied by the number of time intervals.

Pressure-time integral

A measure in kilopascal-second of the area under the pressure-time graph calculated using finite analysis with the sum of the peak pressure obtained at each time interval (50 Hertz) multiplied by the number of time intervals.



From: Uccioli, L., Caselli, A., Giacomozzi, C., Macellari, V., Giurato, L., Lardieri, L. et al, (2001) Pattern of abnormal tangential forces in the diabetic neuropathic foot. *Clinical Biomechanics, 16*, 446-454 (Figure 1 p 448)

Legend: Tangential forces acting on an elementary area corresponding to a single pressure sensor; *fxi* and *fyi* contribute to the global tangential forces Fx (anteroposterior force) and Fy (mediolateral force), respectively; *fMi* (free tangential force) contributes to the moment that acts about a vertical axis passing through the centre of pressure (C.O.P.) of the total foot. *A* is a hypothetical area on which we may desire to compute the resultant tangential forces.

Figure 5. The total force is a sum of all tangential forces acting on the foot.

Variable abbreviations, units of measurement and significant figures

Unless otherwise stated the variables will be denoted in tables and figures by the abbreviation, unit of measurement and significant figures as follows:

Variables that are measured to whole numbers (no decimal places) are:

- peak pressure (PP) in kilopascal (kPa),
- time (T) in millisecond (ms),
- pressure instant at peak occurrence (PPms instant) in millisecond (ms),
- loading time (LT) in millisecond (ms)

Variables that are measured to two decimal places:

- area (A) in centimetre squared (cm^2),
- pressure-time integral (PTI) in kilopascal second (kPa s) ,
- force (F) in newton (N),

- force-time integral (FTI) in newton second (N s),
- begin of loading time (LT begin) in percent of the stance phase of gait (%),
- end of loading time (LT end) in percent of the stance phase of gait (%),
- loading time (LT) in percent of the stance phase of gait (%), and
- pressure instant at peak occurrence (PP instant) in percent of the stance phase of gait (%)

Data processing definitions

Average step

The value derived from the addition of the data result from several single steps divided by the number of single steps included in the calculation.

Mask or Box

The method of defining the anatomical region of interest (Mask: Pedar™ system, Box: F-scan™ system).

Procedures for dynamic in-shoe plantar pressure measurement with the Pedar™ system

Description of the Pedar™ system

The Pedar™ system is a computerised insole sensor system that is used to record and evaluate dynamic and static real time vertical pressure distribution inside the shoe and under the foot. The sensors are formed into an insole that is 2 mm thick and is semi-flexible. The matrix configuration of the sensors provides for identification of each sensor for location and timing of the occurrence of the pressure. Each insole has 85 sensors that operate on the principle of capacitance and exhibit a resolution of approximately 0.5 sensors/cm^2. The maximum sampling frequency when using both insoles is 50 Hertz.

The main advantage of the Pedar™ system is in the use of capacitance-based sensors for pressure measurement. The capacitance sensors are not significantly affected by the physical effects of testing such as creep and temperature (McPoil et al., 1995). The Pedar™ sensors have a reported accuracy of at least plus or minus five percent within the normal use temperature range of 10 to 40 degrees Centigrade (Novel Electronics Incorporated, 1998b).

There are two hardware related limitations of this system. The main limitation is the insole sizes. The sensor matrix is made into the shape of an insole, which means that only the length of the insole can be readily fitted to the participants' foot. This may leave some of the medial and lateral forefoot overlapping the insole and limits investigations into the medial and lateral forefoot in some individuals. Insoles are available in multiple sizes and widths, however, cost limits the number of insoles in the laboratory setting. The other limitation is the potential affect on free and natural walking from the physical presence of the wires that connect the data logger, worn at the subject's waist, to the insoles and the cable connection from the data logger to the computer. However, a wireless data logger that removes the cable connection has reduced this limitation since the completion of data collection for the thesis studies.

There are two main data application related limitations of this system. The first limitation is the sensor resolution (Cavanagh et al., 1992), which equates to the sensors in some instances being larger than some components of measurement (eg. digits) and anatomical points of interest may fall at the junction between sensors and therefore, be missed. The second limitation is that the sensors only measure vertical pressures and not horizontal or shear forces and these forces are hypothesised to contribute to ulceration formation in the diabetic and neuropathic foot (Armstrong & Athanasiou, 1998; Davis, 1993). This limitation is a focus of technological investigation and it is expected that measurement of shear forces between the foot and the shoe will one day be incorporated into in-shoe pressure measurement (Davis et al., 1998).

Collection of raw Pedar™ data

The procedures, including calibration for dynamic in-shoe plantar pressure-testing using the Pedar™ system were conducted as described in the Users Manual [Novel Electronics Incorporated, 1998 #2868] in addition to those procedures determined from the analyses that follow in this chapter. The specific procedures for data collection for the thesis studies are discussed in detail in Chapter Four.

Processing of raw Pedar™ data

Processing of raw Pedar™ data begins with the selection and transformation of the walking trial into individual left and right steps. The Pedar-Filter™[11] software provides a graphical representation of the force-time data for the entire trial from which individual steps can be visually identified. The software automatically eliminates the first and last steps and minimises data noise errors with the use of a force filter with a default of five percent of the mean peak force. If the timing of stepping is critical to the research question under investigation, then a minimum and maximum time can also be set to filter out steps. This feature was not employed as variable time has been reported to be a normal component of mid-gait walking (McPoil, Cornwall, Dupuis, & Cornwell, 1999).

To determine steps to select or eliminate for analysis, the consistency of mid-gait stepping is visually identified from the cyclical pattern of the force-time plots. Step data is selected by deleting all other steps All mid-gait steps retained while the starting, ending and distinctly different steps are deselected. Following the selection of mid-gait steps, each force-time graph representing a single selected step is converted by a standard software function into an individual data file and exported into the Novel-win analysis software.

Each step data was visualised on the monitor and the plantar foot was divided into areas of interest for analysis using the Novel-win Multi-mask™ software according to the method reported by Cavanagh, Rodgers and Iiboshi (1987). A separate mask file is defined for each subject and the left and right feet. The Mask file is saved and applied to each of that subject's steps to ensure consistency. Visual inspection is performed for the mask of each subject, and small alterations are made if necessary to ensure that the correct anatomical structures are in the appropriate masks. Consistent application of the masking regions over all steps for each subject is possible because of the in-shoe nature of the experiment where the movement of the foot relative to the shoe is minimal. The Novel-win data is saved in an ASCII format for exporting into Excel where the variables are labelled and an appropriate spreadsheet built for exporting into SPSS Release 8.0 for statistical analyses.

[11] Novel Inc. St Paul USA

Part I: Refinement of international protocol guidelines for plantar pressure measurement

Rationale and purpose

Standardisation for conducting investigations and reporting on gait measures is an ongoing process, as measurement systems develop to ensure that reports can be readily understood and allow for straightforward comparisons. It has become the role of special interest groups or specialist committees to initiate and propose recommendations through discussion papers towards standardisation (Wu & Cavanagh, 1995). The IPGPPM is such a discussion paper and does not actually provide guidelines for in-shoe plantar pressure measurement as the title suggests, but rather identifies areas of agreement and disagreement between users, and proposes areas that need clarification. Therefore, to determine and standardise the protocol for thesis studies of in-shoe plantar pressure measurement, an analysis of archival research reports was undertaken and the procedural theory underlying the variety of protocols applied to these measures were tabulated.

Source of protocols for analysis of in-shoe plantar pressure measurement procedures

Research reports that utilised in-shoe plantar pressure measurement were identified by analysing journals that included reports related to gait analysis and diabetes including: *Diabetes Care, Diabetic Medicine, The Foot, Journal of the American Podiatric Medical Association, Foot & Ankle, Foot & Ankle International, Journal of Foot & Ankle Surgery, Archives of Physical Medicine and Rehabilitation, Journal of Bone and Joint Surgery, Gait and Posture, Journal of Prosthetics and Orthotics, Physical Therapy and Clinical Biomechanics*. Retrieved reports were manually searched in addition to computerised searching by inputting key words into Proquest and Medline. Computerised searching were limited to the English language, peer reviewed publications and full papers, but were not limited by year. The key words used to further limit the search were: diabetes, foot ulceration, plantar pressure, footwear, insoles, orthoses, total contact cast, gait analysis and foot-care.

Data analysis

A total of 129 reports were obtained and screened for inclusion in the protocol analysis. Reports were selected for inclusion in the analysis if they utilised in-shoe plantar pressure measurement and tested more than one subject. Reports were excluded if they reported on force or pressure plate/mat measurement of plantar pressure of outside the shoe or of a bare foot, were review articles, clinical case discussions or single-case studies.

Twenty-seven research reports published between 1992 and 2004 met the criteria for protocol analysis and the reports are cited in Appendix B. The protocols within each report were analysed for content within defined categories, their range and frequency to gauge possible deficiencies in the selected reports. The following categories were coded for analysis:

- Category: Subjects
  Group size, gender, adult or child, diabetes, and other disease or health status.

- Category: Pre-data collection protocol
  Instrument used, standardisation procedures for in-shoe measurement including socks or shoes, and if a baseline sock or shoe was used.

- Category: Data collection protocol
  Speed of walking (treadmill, metronome or self selected pace), number of trials conducted, number of steps retained for analysis, and method of step selection.

- Category: Data analysis protocol
  Regions of the plantar foot defined for analysis, variables analysed, reliability or accuracy testing, and units of reporting.

Even though all but six of the reports selected were published before or in the same year that the IPGPPM were published, they will be discussed in view of the recommendations of the guidelines.

Results

The subjects reported were either homogenous with respect to health status or were within homogenous groups. The number of subjects investigated in each study is presented in Table 4. Of the 12 reports that included diabetic subjects, there were less than ten in five reports, between 10 and 15 in four reports, and 25, 44 and 51 each in single reports. Both genders were included in

all but one report of males only, all reports were of adults and, apart from the diabetic reports, one involved subjects with rheumatoid arthritis while all other reports involved healthy people.

The socks used during testing were standardised in nine reports and of these, seven reports stated that standard socks were provided and two reports stated that the subject wore their own socks. Standardised shoes were provided for testing in 15 reports, while seven reports stated that the subject wore their own shoes and three reports tested therapeutic devices such as plaster casts. Five reports stated that both shoes and socks were standardised together. Eight reports stated that a standardised shoe measure was obtained as a baseline measure to make comparisons to another shoe or footwear therapy such as insoles.

Fifteen reports stated that the subject was prepared prior to testing. Subject preparation included statements in singular reports of ten, five or one minute walking to warm up, five reports had practice trials, one report stated the subject took ten steps prior to data collection, while another report stated that the subject wore the testing shoes for four hours prior to data collection. Fourteen reports stated the number of trials that were conducted during testing. These included five trials in three reports, three trials in six reports, two trials in two reports, four trials in one report, while only one trial was conducted in two reports. Twenty-five reports stated the number of steps that were used in the analysis of each limb of each subject and these are presented in Table 4. The step data selected for analysis was stated as mid-gait or middle in six reports, while one report each stated either “a representative step”, “acceptable steps”, all steps, the first four steps, the first eight steps, the third step or randomly selected steps were analysed.

Regional analyses of the plantar foot were stated in all but one report, but there was a definite lack of standardisation with 22 different defined foot regions analysed, and these are presented in Table 5.

The mean peak or maximum pressure variable was reported in all but one report. The other variables reported were: pressure-time integral and peak force (five reports each), contact time (three reports), area (three reports) and the instant of peak force or pressure were reported once each. The reliability of the data obtained was tested and described in 11 of the 27 reports.

The units of pressure measurement were reported in all but two reports. The kilopascal was the most common unit (15 reports). The other units reported were: pounds per square inch (four reports), kilogram per centimetre squared (two reports), Newton per centimetre squared (two reports) and a single report used gram per centimetre squared.

Table 4

Sample size and number of steps analysed per subject's limb investigated for in-shoe plantar pressure measurements protocols analysed.

Sample size	Steps analysed	Instrument	Walking Control	Study
4	6	Pedar™	Treadmill	McPoil, Cornwall & Yamada (1995)
5	50	Pedar™	N/R	Shaw, Hsi, Ulbrecht, Norkitis, Becker & Cavanagh (1997)
6	3	Fscan™	Self determined	Lord & Hosein (1994)
8	40	Pedar™	Self determined	Lavery, Vela, Ashry, Lanctot & Athanasiou (1997)
8	5	Fscan™	Self determined	Albert & Rhinoie (1994)
9	N/R	Fscan™	Self determined	Martin & Conti (1996)
10	12	Fscan™	N/R	Brown, Rudicel & Esquenazi (1996)
10	1	Fscan™	Self determined	Conti, Martin, Chaytor, Hughes & Luttrel (1996)
10	8	Fscan™	N/R	Mueller & Strube (1996)
10	N/R	Fscan™	Self determined	Novick, Stone, Birke, Brasseaux, Broussard, Hoard et al. (1993)
10	3	Fscan™	Self determined	Randolph, Nelson, Akkapeddi & Levin (2000)
10	20-32	Footscan™	Self determined	Praet & Louwerens (2003)
11	6	Fscan™	N/R	Lavery, Lavery & Quebedeax-Farnham (1995)
11	3	Fscan™	N/R	Rose, Feiwell & Crachiolo (1992)

Table 4 *continued*.

Sample size	Steps analysed	Instrument	Walking Control	Study
12	16-24	Pedar™	Self determined	Rozema, Ulbrecht, Pammer & Cavanagh (1996)
13	4	Fscan™	Self determined	Mueller, Sinacore, Hoogstrate & Daly (1994)
22	14	Pedar™	Self determined	Redmond, Lumb & Landorf (2000)
25	40	Pedar™	Self determined	Lavery, Vela, Lavery & Quebedeaux (1997)
25	10	Pedar™	Treadmill	Kernozek, LaMott & Dancisak (1996)
30	12	Pedar™	Self determined	VanZant, McPoil & Cornwall (2001)
35	5	Fscan™	Self determined	Mandato & Nester (1999)
39	50	Pedar™	Self determined	Cavanagh, Perry, Ulbrecht, Derr & Pammer (1998)
39	11-15	Pedar™	Self determined	Perry, Ulbrecht, Derr & Cavanagh (1995)
40	400	Interlink™	Self determined	Brown, Wertsch, Harris, Klein & Janisse (2004)
51	4	Fscan™	N/R	Ahroni, Boyko & Forsberg (1998)
109	3	Fscan™	N/R	Sarnow, Rosenblum, Veves, Chrzan, Giurini & Habershaw (1994)
144	5	Fscan™	Self determined	Woodburn & Helliwell (1996b)

Legend: N/R Not reported

Table 5

Anatomical regions of the plantar foot defined for analysis from in-shoe plantar pressure measurements.

Plantar foot region	Anatomical regions defined for analysis	Number of reports
Whole foot	Whole foot	5
	Site of highest pressure on whole foot	3
Digits	All digits	3
	Hallux	8
	2nd toe	2
	3-5 digits	1
	2-5 digits	3
Forefoot	Forefoot	7
	All MPJ	2
	Medial forefoot	2
	Lateral forefoot	2
	1MPJ	10
	2MPJ	4
	3MPJ	1
	3-5MPJ	4
	2-5MPJ	2
Midfoot	Midfoot	10
	Medial midfoot	1
	Lateral midfoot	1
Heel	Heel	16
	Medial heel	2
	Lateral heel	1

Discussion

As expressed in the IPGPPM, the results of the current analysis confirm a lack of standardised protocol for in-shoe plantar pressure measurement (Barnett, 1998). In-shoe plantar pressure measurement is especially ideal for study into the effect on pressures from therapeutic shoe interventions experienced by the insensitive diabetic foot. This is reflected by diabetic subjects being the focus of 40 percent of the reports that met the criteria for analysis. The lack of standardisation of the procedures conducted means that there is limited scope for comparability between these studies. Therefore, clinical footwear therapy and shoe prescription has little solid evidence to treat or prevent ulceration and lower limb amputation in the diabetic population. The same lack of standardisation and result comparability for the large volume of healthy subjects' data is a primary limitation in the development of this analysis as a clinical tool. For clinical applicability, the IPGPPM confirmed that there needs to be well-defined average measures and confidence limits for the healthy population. It is from a healthy population data set that true differences can be identified that represent the effect of the disease on plantar pressures, and from which appropriate therapeutic and preventative interventions can be developed and prescribed.

Four in-shoe plantar pressure measurement systems were utilised in the reports and the IPGPPM acknowledged that different systems require specific standardised protocols for calibration, data collection, analysis and reporting. Separate protocols are required, as differences exist in the sensor size and type, and the methods of data smoothing employed by the software (Graf, 1993; Young, 1993). The IPGPPM require that the manufacturer's protocols be acknowledged and understood, and it be stated that the protocols have been adhered to in any report produced. This received only a cursory comment in several reports. No reports discussed procedures for the establishment of the uncertainties associated with the measures and variables obtained from this analysis. Nonetheless, these statements do not improve the comparability between reports due to the lack of documentation of the inherent errors, variability, reliability and precision that can be expected. Without knowledge of these uncertainties, the study of diabetic footwear efficacy would lack scientific rigour and be of limited clinical usefulness, and resolving these issues is the focus of Part II of this chapter.

The standardisation of the socks and shoes used during data collection in over a quarter of the reports is in agreement with the IPGPPM (Barnett, 1998). The issuing of socks and shoes to subjects is supported by the IPGPPM, as it provides scientific rigour to limit the differences found in the results of the dependent variable under investigation. However, the use of each subject's socks and shoes is supported by the IPGPPM, if the purpose of the investigation is to provide clinical information on the change in a individual subject's gait pre and post intervention (Barnett,

1998). The shoe sole has been reported to affect plantar pressure measures (Rose et al., 1992) and therefore, a standard shoe was used for preliminary or baseline data collection in a quarter of the reports. Other than Brown (1996), who stated that their subjects wore their new shoes for four hours as preparation prior to data collection, any potential effects from shoe age lacked clarification. The standard shoe was generally described as being a minimal effect shoe (examples are the canvas oxford and the boat shoe) or were an unmodified form of the test shoe. However, wearing an unprepared minimal effect shoe may not be in compliance with the IPGPPM, that states that the shoes used during testing should reflect real-life footwear (Barnett, 1998). The selection of the standard sock is another protocol weakness identified, as it was not described in any report. As sock material has been shown to affect plantar pressure measures (Veves et al., 1990), the selection of the standard sock for in-shoe plantar pressure measurement in this thesis was determined experimentally and is described in Chapter Four.

Sixty percent of the reports reviewed conformed with the IPGPPM recommendation with regard to the subject walking at their normal comfortable pace. Speed was only verified instrumentally and visually in one report each, but as speed has been reported not to affect plantar pressure measures (Kernozek et al., 1996), then the lack of confirmation is acceptable. Even though the use of a treadmill is not representative of normal overground walking, its use to control the walking speed in three reports ensured consistency to answer specific speed related and reliability questions.

In 13 reports there were six different subject preparation procedures stated. The IPGPPM provide limited guidance in this area other than to report that; *the researcher must control the inserting of the sensors into the shoe*, and for *bedding in time be allowed* for the foot-sensor-shoe environment (Barnett, 1998). This procedural weakness could affect the validity of the data obtained especially for the F-scan™ system due to time and temperature dependant limitations of the resistive ink sensor components (Ahroni et al., 1998; Luo et al., 1998; Sumiya, Suzuki, Kasahara, & Ogata, 1998; Woodburn & Helliwell, 1996a). Additionally, the cables that connect the in-shoe sensors to a data collection device (leg cables), and this device to the computer (umbilical cables), may also invalidate data due to potential gait changes made to accommodate for them (Finch, 1999; Walsh, 1994). A simple procedure to ensure minimal intrusion of the cables is to observe the subject's gait with and without the leg cables and adjust them until visual consistency is ensured, and for an assistant to walk behind the subject holding the umbilical cables to minimise their drag. These procedures were utilised for all studies in this thesis, but since their completion these procedures are of less concern as some cables have become redundant and replaced with wireless technology.

The number of trials conducted and the number of steps retained for analysis from each trial is another weak procedural area. The ten reports that utilised data from at least three trials and used

the mean value calculated from these trials in their analyses are following standard procedures for anthropometric laboratory measurement (Pederson & Gore, 1994). Recording several trials ensures that there is adequate data obtained for minimising error, but also ensures against total loss of subject data in the case of instrumentation error or malfunction. Additionally, if a rest period occurs between trials, then the physical effects of fatigue and the sensor effects from temperature and time can be minimised. The two reports that obtained data from only one trial, and the 12 reports that did not state how many trials were conducted, should be reviewed with caution because without repeated data collection trials, errors cannot be identified or reliability assumed, potentially resulting in invalid conclusions being drawn. Ideally, once protocols are standardised, inconsistencies within the measurement will be determined and external verification of gait laboratories, systems and procedures will bring this analysis method into line with other clinical laboratory standard requirements.

Using the criterion of a minimum of nine repeated steps, collected in a series, being required for calculation of an average step with acceptable reliability from in-shoe pressure measurement (Kernozek et al., 1996), only eleven studies could be assumed to have utilised sufficient steps. Without adequate data to ensure reliability, the reader cannot have confidence in the conclusions drawn from 16 of the reports analysed. Additionally, the eleven studies that analysed between 12 and 400 steps may have imposed excessive physical burdens on the subjects and added time and analysis burden on to the investigators without notable gain. These reports with more than 12 steps analysed could be assumed to have ensured reliable data based on the mathematical fact that by the inclusion of more values, the true central measure will be exposed as opposing positive and negative values will cancel each other out (Portney & Watkins, 1993). A further question arises from these results, and this is how the number of steps included, influences the reliability of the data. Eleven reports stated that their data were ‘reliable’, even though they encompassed the full range of steps (2-400 steps), included both healthy and diseased subjects and were conducted with both in-shoe plantar pressure systems. This suggests that reliability of in-shoe plantar pressure measurement may not be influenced by step volume analysed, subject health nor by different systems used for data collection. Without knowledge of the validity, accuracy, reliability and precision of plantar pressure measures for specific healthy and diseased sample populations, the general applicability of these studies is unknown and, as suggested by the IPGPPM, this thesis investigated the inconsistencies of these measures (See Part II of this chapter)

The IPGPPM stated that the step data should be selected from the mid-gait section of a trial; however, only seven reports made a statement that confirmed that they complied with this requirement. Selection of mid-gait steps makes not only logical sense for limiting the type of walking steps that are analysed, but also ensures consistency between subjects within a protocol.

The reports that stated selecting “a representative step’, “acceptable steps” or “randomly selected” steps for analysis bring into question their results and conclusions for three reasons. Firstly, due to the lack of definition of step selection and therefore, lack of scientific rigour; and secondly the lack of definition of the gait phase that was studied limits the general applicability. Finally, these selection methods also bring into the analysis the possibility of investigator bias, and the questions of ‘representative of what?’, ‘acceptable to whom?’ and ‘what method of randomisation?’ need to be asked. The reports that used all steps or the first three or four steps, limit their usefulness to understanding different walking gaits, as they are actually analysing accelerating and decelerating walking steps mixed in with mid-gait steps, and are therefore, measuring a variable other than, and are not generally applicable to, mid-gait walking. Other than selecting only steps from the middle section of each walking trial, only one report stated that they checked the data visually for consistency after each trial and repeated the trial if inconsistencies were found (Praet & Louwerens, 2003). There was no reported method of confirming the validity of each subject’s steps selected as being consistent mid-gait steps. The validity of mid-gait steps for this thesis was confirmed with a method of filtering steps based on consistent measures of the area of the plantar foot and is described in Part II of this chapter.

The definition of anatomical plantar foot regions for analysis as described by the IPGPPM was not utilised in any reports, including those published after 1998; a deficiency that exacerbates the lack of reference standards. Potentially, the authors were either unaware of the guidelines or did not find the defined anatomical regions to be suitable to address their research question. Ideally, software modifications could be provided that would allow investigators to both address their specific question, and compute the IPGPPM defined regional analyses for contribution to a reference database. The validity of the definition of the anatomical plantar foot regions was not confirmed in any reports and further research should be encouraged to facilitate rapid and accurate identification of regional plantar foot anatomical regions. A simple identification procedure for the 1MPJ was utilised for the thesis, and is described in Chapter Four.

Only eight pressure, force, area or time variables were stated in the reports. This is surprising as the Novel-win software that is used to analyse the data obtained from the Pedar™ system automatically calculates 14 variables for each operator-defined region on the plantar foot. Unfortunately, variable exclusion reasoning was not discussed and potential explanations for this observation could be that that the investigators had found that the other variables were of no value to answer their question, or that the other variables have been ignored for time efficiency. The IPGPPM confirmed that the effect of the many variables supplied on gait requires investigation. It is also stated that the variables specifically affected by ulceration and useful for investigation of

the site of ulceration need investigation and this thesis addresses selection of useful variables in Part II of this chapter.

Although all reports stated their results in numbers to two decimal places, this may not be appropriate in regard to significant figures. This is especially a concern for the Pedar™ system that reports raw pressure data and time variables as a whole figure (no decimal places) and also reports its accuracy as five percent, which is once again a whole number. Two decimal places are acceptable for the calculated Pedar™ variables as they are reported with this detail. A thorough investigation of the validity of the variables measured and calculated by the Pedar™ system are beyond the scope of this thesis and in discussion of the thesis studies validity is assumed. In regard to appropriate significant figures, the variables of pressure and time will be reported as whole numbers (no decimal places), but other calculated variables will be reported with two decimal places.

The IPGPPM was published in 1998 and it is pertinent at this point to compare the protocols of the six reports analysed that were published in following years and these are summarised in Table 6. All six reports were of the study of healthy adults and the only procedure that was uniformly standardised in accordance with the IPGPPM was the selection of middle trial steps for analysis. All six studies could be assumed to have analysed reliable data due to selecting greater than nine steps for each subject for analysis.

Conclusion of Part I

The protocol analysis of reports that used in-shoe plantar pressure analysis has found that a standardised protocol is lacking. Additionally, where the IPGPPM are clear in defining a procedure, other than selection of mid-gait steps, these have not been universally applied since its publication in 1998. Therefore, for this thesis, where the IPGPPM are not clearly defined, a default position was adopted based on the considered assessment of the results of this protocol analysis and this is presented in Table 7.

Table 6
Summary of protocol procedures reported since publication of IPGPPM in 1998.

Study	n	Preparation procedure		Footwear standardisation		Trials	Selection of steps	Unit
		Instrument	Subject	Shoes	Socks		(number)	
Mandato & Nester (1999)	35	Calibration after 3min for temperature equilibration	N/S	N/S	N/S	1	Middle (10)	psi
Randolph, Nelson, Akkapeddi & Levin (2000)	10	Calibration after 5min for temperature equilibration	N/S	Own shoes	N/S	3	Not S/S (9)	psi
Redmond, Lumb & Landorf (2000)	22	N/S	Minimal acclimation time	Standard athletic	N/S	3	Not S/S/turning (14)	kPa
VanZant, McPoil & Cornwall (2001)	30	Calibration	2 practice trials	Standard sport	Standard cotton	3	Middle (12)	kPa
Praet & Louwerens (2003)	10	Calibration	Acclimation time	Standard therapeutic	N/S	2	Midgait consistency checked (N/S)	N/cm^2
Brown, Wertsch, Harris, Klein & Janisse (2004)	40	Calibration	10-15 minute acclimation	Standard therapeutic	N/S	1	Continuous walking (400)	kPa

N/S: Not state; S/S: Starting or stopping steps of each trial.

Table 7

Summary of the protocol for in-shoe plantar pressure measurements compiled from the protocol analysis.

Protocol for in-shoe plantar pressure measurements
The sensors are calibrated as per the manufacturers specifications
The shoes and socks worn are standardised and the type are reported
The same shoe and sock is retained for that subject for all trials
Subjects are trained and practice to acclimate to testing procedures and warm-up the sensors
Subjects rest for a defined and reported time between trials to minimise fatigue and discomfort/pain
Data collection sessions are conducted to minimise subject boredom and burden
Interventions tested are randomised to minimise a learned or practice effect
The first trial is rejected and not analysed
Three to five data collection trials are conducted to achieve more than eight mid-gait steps from each limb tested
The starting, stopping and turn around steps are rejected and not analysed
The method for step selection and validity checking is based on a quantifiable variable and is reported
The repeated steps data are averaged to form a representative step for each limb for statistical analyses
The unit of pressure measurements is kPa

Part II: Archival analysis of in-shoe plantar pressure measurements

The overall purpose to the studies in this part of the thesis is to test Research Question One (a – d) and determine the reliability, precision, and accuracy of results and to select the variables for study investigation into ulceration in the population of people with diabetes, neuropathy and forefoot ulceration. Each study within this part has a specific purpose and these will be stated as each study is introduced.

Source of archival data

The data set was compiled from the archives of research data collected and analysed under the supervision of Associate Professor Lawrence Lavery DPM MPH in the Department of Orthopedics, Podiatry Service at the University of Texas Health Science Center at San Antonio, Texas USA[12]. The data were the result of in-shoe plantar pressure measurements using the Pedar™ system on people with diabetes, neuropathy and forefoot ulceration while they walked overground at their normal comfortable pace. All procedures were carried out at the University of Texas Health Science Center (UTHSC) at San Antonio, Department of Orthopedics, Podiatry Service Biomechanics Laboratory in Texas, USA with the approval of the UTHSC and University Health System Institutional Review Boards and the informed consent of the subjects. The results of the studies are reported in the literature:

Lavery, L., Vela, S., Fleischli, J., Armstrong, D. & Lavery, D. (1997). Reducing plantar pressure in the neuropathic foot – A comparison of footwear. *Diabetes Care*, *20*(11), 1706-10.

Lavery, L., Vela, S., Lavery, D. & Quebedeaux, T. (1997). Total contact casts: Pressure reduction at ulcer sites and the effect on the contralateral foot. *Archives of Physical Medicine and Rehabilitation*, *78*(11), 1268-1271.

[12] Data were collected by the Research Fellows: Steven Vela, John Fleischli, David Armstrong or Terri Quebedeaux.

Subjects

The archival sample contained data from 39 subjects (30 males) aged 52.82 (SD 9.74) years who were diagnosed with Type 2 diabetes mellitus over a duration of 14.23 (SD 10.37) years and who were obese (BMI mean 30.27, SD 4.70 kg/m^2). All subjects were diagnosed with peripheral neuropathy and this was confirmed by their hallux being insensitive to the application of 25 mV induced vibration during a biothesiometer test. Their feet were insensitive to pain with a vibration perception threshold above 25 mV (mean 39.77, SD 13.04). Thirty-four subjects had a single ulceration per foot and five subjects had a single ulceration on both feet. The distribution of ulceration is presented in Table 8.

Table 8

The number of diagnosed plantar forefoot ulcerations per location.

Plantar forefoot ulceration location	Number of ulcerations
First metatarsophalangeal joint (1MPJ)	17
Hallux inter-phalangeal joint (Hallux)	14
2-5 metatarsophalangeal joint region (2-5MPJ)	13
Total number of ulcerations	44
Total number of feet	78

Procedures utilised for the collection of the archival data[13]

The subjects were fitted with appropriately sized canvas oxford sneakers with thin rubber soles (Reebok) for baseline measures of walking. These shoes were new and selected due to the large range of sizes available in this model for both men and women. They had soft uppers that were deemed not to have injury risk potential to the skin and the thin and flexible soles would not require or be affected by 'wearing in'. The socks worn during testing were the subject's own and were consistently used through out testing. The Pedar™ insole sensor of the appropriate size was

[13] The procedures are reported in the literature (Lavery, Vela, Fleischli et al., 1997; Lavery, Vela, Lavery et al., 1997) and confirmed by personal communication with Associate Professor Lawrence Lavery and his Research Fellow, Mr. Steve Vela.

placed into the shoes between the sock and the shoe's insole for measuring dynamic plantar foot pressure. The sensors were tethered to a backpack unit that was also tethered by a 10 m cord to a Pentium 200[14] desktop computer. Prior to testing, the sensors were calibrated over a range of 0 to 600 kPa using a pneumatic pressure vessel as per the User's Manual [Novel Electronics Incorporated, 1998 #2868]. To minimise intrusion of the leg cables on the subject's gait, the chief investigator observed the subject's gait from parallel and perpendicular angles during a practice trial with and without the cables. The cables were adjusted accordingly and the practice trial repeated. To minimise gait effects from the cable dragging behind the subject, an assistant walked approximately two metres behind the subject holding and taking the tension off the cable. Once prepared and fitted to the device and appropriate shoe, the subject walked at least three preparatory trials along the 10 m walkway in the shoes and equipment to accommodate to the testing equipment, area and procedures before data collection began.

Data collection and processing

The walking gait data were collected at 50 Hertz using the Pedar™ on-line software from four trials where the subject was instructed to walk at their normal and comfortable pace. The walking trial was visually monitored for disturbance from consistent stepping and speed. The middle eight steps were selected from the 12 remaining steps after the starting and stopping steps had been automatically eliminated. A total of 32 steps for each limb were evaluated.

[14] Intel, Santa Clara, California, USA

Part II(a) Data checking to ensure the validity of normal 'mid-gait' walking steps

Rationale and purpose

Part I described how for in-shoe plantar pressure measurements, multiple steps are collected, from which some steps are selected to create a mean step value from each limb to be used for data analysis and hypothesis testing. Unless the steps included in the average step calculation are from consistent mid-gait walking, the step data will not be reproducible, leaving the investigator less able to make valid conclusions and generalisations about their investigation's contribution to understanding mid-gait walking.

Defining inconsistency of data to instigate data validity checking may have clinical implications. What are seen as irregular or outliers by the researcher may be clinically insightful. The risk of altering the data and reducing clinical implications during the checking process was minimised by the researcher being an experienced senior clinician.

To ensure a data set of consistent and valid mid-gait steps, three procedures were applied. Firstly, the subjects practiced and became consistent at the testing activity prior to data collection. Secondly, visual monitoring of trials for mid-gait irregularities allowed those trials to be eliminated and repeated. Thirdly, starting and stopping steps were eliminated from the steps collected from each limb and trial. The resulting data set was checked to ensure that it did not contain inconsistent steps. If so these steps were removed. Inconsistent steps that were undetected during visual checking contributed to inconsistent step data.

Data set checking methods, mainly semi-automated, for mid-gait step consistency ensure high quality data sets but represent considerable processing time. Unfortunately, data checking methods for in-shoe plantar pressure data have not been reported and are another area that lacks protocol standardisation and therefore, limits the general applicability of these data.

To reduce the processing time cost of data checking for inconsistent steps, a method of steps consistency identification based on the variable of the (total) area of the plantar foot (TAF) is proposed. The TAF was chosen to identify step consistency as it is influenced by altered function during the gait cycle (Cavanagh, Sims, & Sanders, 1991) and therefore, is sensitive to inconsistent steps. A change in TAF is reflected by a higher or lower value than the majority of the steps measured because more or less sensors were activated in that footstep than during consistent mid-

gait steps. Therefore, the consistency of the TAF must be confirmed in addition to following the three current procedures to ensure valid conclusions about in-shoe pressure measures of mid-gait walking are made.

Inconsistent mid-gait steps are defined as those steps with TAF that are outliers or extreme outliers according to the box plot function (SPSS Incorporated, 1998). Outliers and extreme outliers are defined as data that are more than one and a half or three times the inter-quartile range above or below the third or first quartile, respectively. Descriptively the box plot function places a 'box' around the middle 50 percent of the data with the 25^{th} and 75^{th} percentile being represented by the upper and lower edges of the box. Whiskers identify the highest and lowest values excluding outliers and extreme outliers.

To detect inconsistent steps in the data set, two approaches are considered; the semi-automated method using the semi-automated (box plot) with visual crosschecking methods, or the fully automated method using algorithmic methods. The first approach is extremely time consuming because it requires the production of a box plot for each individual limb within which inconsistent steps are visually identified as outliers and extreme outliers following which they are located in the data set for deletion. The second approach is to use automatic tools, which use an algorithm to mathematically detect and delete the steps identified as inconsistent according to the same rules of the box plot function, without the production of and visual checking of the box plot graph.

A fully automated method with the option of checking using graphing was investigated by Bisquay, Freulon, de Fouquet and Lajaunie (1999) when data checking geostatistical data from oceanography studies. They used automated detection of inconsistent data that could be confirmed via graphical means prior to deletion by an operator and this method was found to keep a good balance between the processing time and the quality of validation.

The purpose of this study is two fold: firstly, to propose that data checking be conducted using the TAF measure, and secondly, to evaluate if fully automated deletion of inconsistent steps can replace the more time consuming semi-automated graphical production with visual checking and deletion method.

Data analysis

For this analysis the subjects who had ulceration to both feet were not included as they were assumed not to be representative of the target population for the thesis studies, and three subjects who had incomplete data were excluded; leaving 31 subjects and 62 limbs for analysis.

To examine the data to detect inconsistent steps using the semi-automated method, the TAF data from each limb were graphed using the box plot function provided in SPSS. This resulted in 62 graphs for visual interpretation and cross-referencing to the data spreadsheet for the investigator to detect and delete inconsistent steps.

The fully automated method rapidly shortcut the semi-automated process by flagging the inconsistent steps directly in the data spreadsheet, which were then checked by the investigator to validate the automation, in the same manner as the semi-automated method.

All data were examined for and confirmed as being normally distributed using Proportion probability (P-P) plots with the proportion estimated using the Rankit formula. In a P-P plot, if the data are from a normal distribution, then the plot points will cluster around a straight line (SPSS Incorporated pp 431-435). The calculation of a two tailed *t*-test with unequal variances was performed to test if the pre-validity checked and post-validity checked sample data were representative of the same population (Portney & Watkins, 1993; SPSS Incorporated, 1998).

Results and discussion

Seventy-eight (4.22%) steps within the 1848 steps in the data set were flagged as inconsistent by both the semi-automated and automated methods. The box plot of the data from limb three is presented in *Figure 6* and demonstrates the presence of inconsistent steps data (an outlier and an extreme outlier). *Figure 6* shows a shaded box that encapsulates the limits of the 25^{th} and 75^{th} percentiles, and bars extending away from the box (whiskers) representing the highest and lowest values excluding extreme outliers (asterisk) and outliers (circle) The box plot shows that the outlier step is very close to the consistent mid-gait step values, but the extreme outlier step is quite different. In this example, the outlier step (circle) is slightly bigger than the consistent mid-gait steps and would have resulted from an altered step that activated more in-shoe plantar pressure sensors and, therefore, a larger measured TAF. The extreme outlier step, however, is much smaller than the consistent mid-gait steps and would have resulted from an altered step that activated fewer in-shoe plantar pressure sensors and therefore, a smaller measured TAF. These inconsistent steps are visible in *Figure 7* where the unchecked measured values for this limb are displayed.

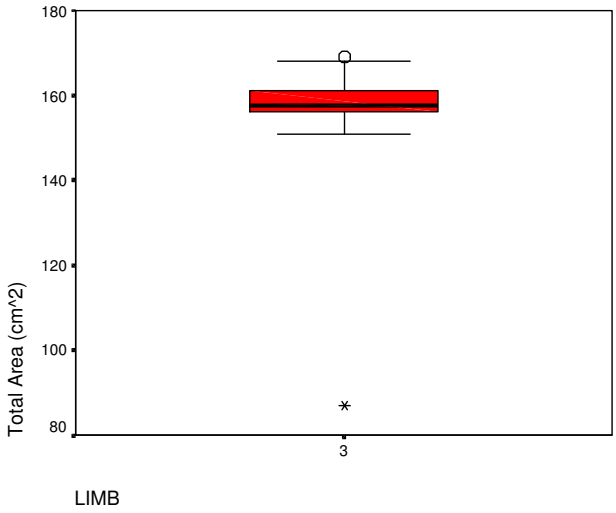


Figure 6. Box plot graph result from the variable of total area of the foot (TAF) of limb number three showing one outlier (shown as a circle outside the whiskers) and one extreme outlier (shown as an asterisk outside the whiskers) step data point.

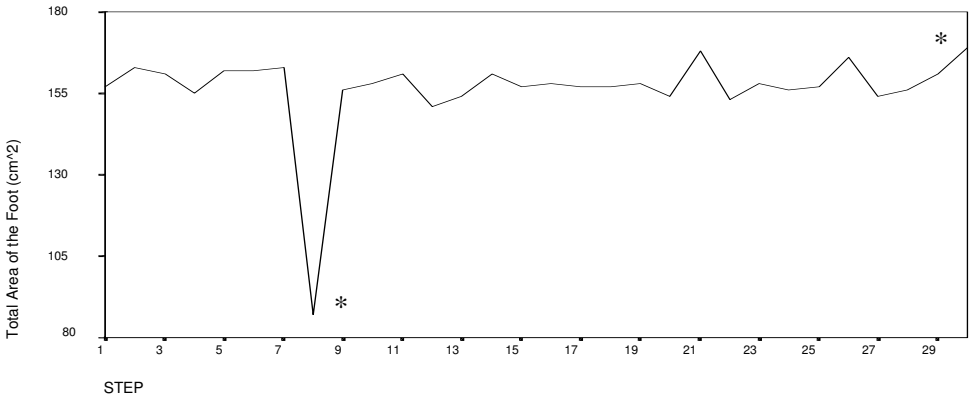
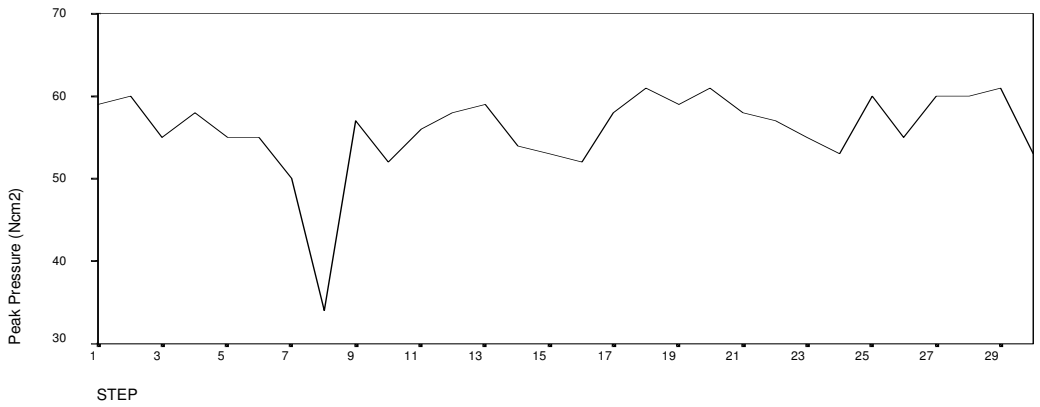
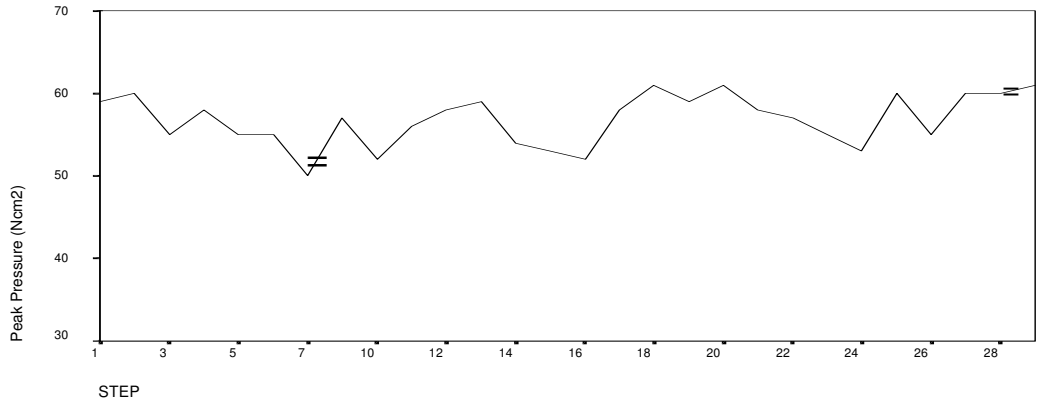


Figure 7. The total area of foot (TAF) variable for each step for limb number three was plotted and outliers and extreme outliers are highlighted with an asterisk. Step 8 (extreme outlier) was much smaller and step 30 (outlier) was slightly bigger than the other steps and therefore, inconsistent and inconsistent mid-gait steps.

The effect on the variable of Peak pressure TOTAL for limb three after elimination of inconsistent steps is shown in Figure 8 and demonstrates the improved consistency in the data set with the checking process.



(a) Before validity checking of data from limb three



(b) After validity data checking and cleaning of data from limb three

Figure 8. The measures from the variable of peak pressure over the whole foot (Total) of each step was plotted for limb three before and after validity checking and cleaning.

The elimination of inconsistent step data from limb three is reflected in reduced variability as demonstrated in the descriptive statistics calculated before and after validity checking and presented in Table 9. Three two-tailed *t*-tests of equality of means with unequal variances were performed on the variables of peak pressure-total, pressure-time integral-total and TAF for the data set. The alpha values presented in Table 9 confirmed that the pre- and post-validity checked data sets were from the same population and therefore, the validity of the data set had not been compromised by the checking for and elimination of inconsistent steps.

Table 9

The descriptive statistics results for limb number three calculated before and after mid-gait validity checking.

Variable	Checking stage	Mean	SD	Min	Max	alpha
Area-total	Before	149.50	12.49	87.0	169.0	
	After	151.07	8.73	130.0	169.0	p=0.99
Peak pressure-total	Before	541.3	45.8	340.0	610.0	
	After	544.5	38.0	440.0	610.0	p=1.0
Pressure-time interval-total	Before	218.6	27.3	50.5	255.9	
	After	221.2	16.3	193.8	255.9	p=1.0

Conclusion

The purpose of this analysis was to propose a method to standardise mid-gait consistency checking of in-shoe pressure data using the TAF. Data checking using TAF was found to be necessary as inconsistent steps were identified in the data set that was created using the current procedures for ensuring consistent mid-gait steps.

The use of box plots of each limb's TAF step measures were found useful to detect inconsistent mid-gait step data. However, the use of automated inconsistent steps detection was found to be a more time effective approach and will be utilised to ensure consistent mid-gait steps in the thesis studies.

Part II(b) Reliability and precision of in-shoe plantar pressure measurements

Rationale and purpose

Reliability of in-shoe plantar pressure measures for healthy adults who were walking on a treadmill, are reported by Kernozek et al. (1996) for the Pedar™ system, to be dependent on the number of repeated step measures included in the average step calculation, and independent of speed. The purpose of this analysis is to test Research Question One (a and b) and utilise the study design of Kernozek et al. to determine *a priori* the number of steps required for the reliable average step calculation for adults with diabetes, neuropathy and forefoot ulceration during normal walking. In addition, the study aims to determine the clinical usefulness of reliable measures by calculation of the associated precision (Van Gheluwe, Kirby, Roosen, & Phillips, 2002) for each variable measured on defined anatomical plantar foot regions. The coefficient of variation (CV%) is an index that describes variability expressed as a percentage and reduces the difficulty inherent in making comparisons across variables of different measurement units(McPoil et al., 1999).

Data analysis

The validity-checked data set described in Part II(a) was exported into Excel and new average step variables were calculated that included increasing numbers of steps (4-24 steps) for the average step calculation. Twenty-four steps was the maximum number of steps that were available for all limbs after inconsistent steps had been removed. A paired *t*-test with unequal variances was performed between the left and right limbs for each variable to determine if the left and right limbs data could be pooled. The *t*-test showed that left and right limbs were not significantly different (p=0.464) and therefore, the limbs were pooled resulting in 62 limbs for analysis. Pooling of both limbs of data would violate statistical assumptions if an out come from the measurement was sort. However, as the following analyses are for the purpose of understanding the nature of the data and not an outcome measurement, statistical violation was accepted. These data were imported into SPSS Release 8 for statistical analyses.

Statistical analysis

A series of intra-class correlation coefficients (ICC (3,k)), where 3 denotes the model of ICC and where *k* denotes the number of raters[15]; were performed using a repeated measures design (Eliasziw, Young, Woodbury, & Fryday-Field, 1994; McPoil & Cornwall, 1998). The ICC Model 3 is chosen when the results of interest are from a single rater, and in this study it was the Pedar™ in-shoe pressure measurement system. Therefore, the resulting ICC used was Model 3 with a single rater (ICC(3,1))The alpha statistic obtained from the ICC(3,1) determines the level of reliability between the average of the successive steps data for each limb, variable and anatomical location as obtained from the single rater (the Pedar™ system) The ICC(3,1) alpha is a dimensionless reliability coefficient that ranges from zero to one, where perfect reliability is defined by the ICC(3,1) alpha equalling one and acceptable reliability is above 0.80 (Eliasziw et al., 1994).

The Standard Error of Measurement (SEM) is a statement of statistical precision and was calculated to provide the clinically useful 95% confidence interval (95% CI) in the units of measure of the variable (Portney & Watkins, 1993). The SEM is derived from the standard deviation (SD) of the set of measures obtained and the reliability coefficient using the following formula:

$$SEM = SD\sqrt{1 - ICC}$$

In addition, the 95% CI is calculated using the following formula:

$$95\%CI = measure \pm 1.96 * SEM$$

The coefficient of variation (CV%) is a statement of variability and it is calculated from the precision values to allow comparison between variables of different units. The CV% is calculated using the standard deviation (SD) and mean ($\overline{X}$) in the following formula:

$$CV\% = \frac{SD}{\overline{X}} * 100$$

Reduced variability of the precision values and therefore, high precision, is shown by a low CV%. Acceptable variability for plantar pressure measures has not been reported for measures of adults

[15] All clinical measurements require that a human observer, or *rater*, is part of the measurement system (Portney & Watkins, 1993) pp 60.

diagnosed with diabetes, neuropathy and ulceration. This study will contribute towards the suggestion made by McPoil (1999) that less than 15% be acceptable

Results

The number of steps required for inclusion in the reliable calculation of the average step results for variables measured over the whole foot, those variables requiring the greatest number of steps and peak pressure will be discussed as follows, while the complete results are presented in Appendix C.

The number of steps required for inclusion in the calculation of the average step results for variables measured over the whole foot to achieve acceptable reliability and their associated precision are presented in Table 10. Calculations of reliability and precision are not applicable when the measure value is constant and this applies to the variables that measure the limits of time in percent of the whole foot, but are included in Table 10 for completeness. Other than the variable measuring pressure instant of peak (%), variables that measured the whole foot were reliable with only two steps included in the calculation of the average step.

Table 10

The number of steps required to calculate the average step for variables measured over the whole foot (Total foot) to reach acceptable reliability (ICC> 0.80) and their associated precision (95% CI)

Variable (Total foot) (n=62 limbs)	Number of steps for reliable average step (ICC > 0.80)	Precision (95% CI in variable unit)
Area (cm^2)	2	0.72
Force (N)	2	1.19
Force-Time Integral (N s)	2	3.65
Loading Begin (%)	Not applicable*: 0%	Not applicable*
Loading End (%)	Not applicable*: 100%	Not applicable*
Loading Time (%)	Not applicable*: 100%	Not applicable*
Loading Time (ms)	2	61.67
Pressure Instant of Peak (%)	5	15.56
Pressure Instant of Peak (ms)	2	163.16
Peak Pressure (kPa)	2	41.40
Pressure-Time Integral (kPa s)	2	10.90

*Not applicable because calculations are not possible on constant values, such as zero or 100 percent.

The average step calculation reached acceptable reliability for the majority of variables measured on defined anatomical regions with either two or three steps included in the calculation. However, seven variable measures on defined anatomical regions required between four and eight steps to be included in the calculation of the average step, to achieve acceptable reliability, and these are presented with their precision in Table 11.

Table 11

Variables measured on defined anatomical regions that required more than three steps to be included in the calculation of the average step to reach acceptable reliability (ICC > 0.80) and their associated precision (95% CI)

Variable (n=62 limbs)	Anatomical region	Number of steps for reliable average step (ICC > 0.80)	Precision (95% CI in variable unit)
Force (N)	1MPJ	4	5.16
Force-Time Integral (N s)	1MPJ	4	1.30
Loading begin (%)	1MPJ	4	4.86
Loading end (%)	1MPJ	7	0.45
Loading Time (%)	1MPJ	6	3.65
Pressure Instant of Peak (%)	2-5MPJ	8	7.40
Pressure Instant of Peak (%)	Hallux	4	4.87

The variable peak pressure as measured over defined anatomical regions is most commonly reported in the literature as shown earlier in this chapter, and the results for reliability and precision are specifically presented in Table 12.

Table 12

The reliability and precision of the variable of peak pressure per anatomical region.

Variable (n=62 limbs)	Anatomical region	Number of steps for reliable average step (ICC > 0.80)	ICC alpha	Precision (95% CI in kPa)
Peak Pressure (kPa)	1MPJ	2	0.87	70.6
	2-5digits	2	0.93	9.1
	2-5MPJ	2	0.96	35.3
	Hallux	2	0.92	16.8
	Heel	2	0.96	30.8
	Midfoot	2	0.87	25.0

The average precision per variable (all anatomical regions combined) as expressed in variable units and CV%, is presented in Table 13. The variability of the measures were unacceptably high (44 to 139%) (acceptable CV%<15% (McPoil et al., 1999)) and therefore, precision was low.

Table 13

The average precision in variable units is shown against the average variability in CV% per reliable variable (all anatomical regions combined).

Variable (all anatomical regions combined) (n=62 limbs)	Average precision in variable unit	Average variability in CV%
Area (cm^2)	0.93	81.38
Force (N)	2.36	82.71
Force-Time Integral (N s)	1.94	81.87
Loading Begin (%)	4.64	58.50
Loading End (%)	2.18	139.49
Loading Time (%)	4.82	53.32
Loading Time (ms)	52.79	61.46
Pressure Instant of Peak (%)	7.39	52.69
Pressure Instant of Peak (ms)	63.19	75.16
Peak Pressure (kPa)	32.70	61.10
Pressure-Time Integral (kPa s)	12.20	44.46

Discussion

The results of the reliability analysis are in agreement with Kernozek et al. (1996) and indicate that a high level of reliability for in-shoe plantar pressure variables can be obtained using the Pedar™ system. Therefore, these results suggest that the same number of repeated steps can reliably be utilised to calculate the average step for both healthy and diabetic, neuropathic and ulcerated sample populations whether walking normally or on a treadmill. The similarity in reliability between the two study populations is also supported by the report by Cavanagh et al. (1998), who reported that the variability of plantar pressure measures did not differ between the diabetic and normal populations.

The majority of variables exhibited acceptable reliability coefficients after only three steps. However, at least eight steps were needed to achieve acceptable reliability in all variables for all

anatomical regions of the foot. Therefore, at least eight repeated steps are required for reliable calculation of the average step if all in-shoe plantar pressure variables are utilised in analyses of the population of adults with diabetes, neuropathy and forefoot ulceration.

The protocol analysis from Part I of this chapter showed that peak pressure was the most commonly reported variable from in-shoe plantar pressure-based research reports and this analysis showed that it was reliable for all anatomical regions with only two repeated step measures utilised in the average step calculation. Even though few of the reports analysed in Part I reported their reliability, it can be assumed to have been acceptable because their analyses included at least two or more steps.

The precision varied substantially between variables and anatomical regions suggesting that even though few steps are required to calculate a reliable average step, these measures are not clinically useful due to the poor precision. These results are in agreement to other such measures, including the goniometric measurement studies of Van Gheluwe et al. (2002) , who found that although measures were reliable, they were not clinically useful due to the large SEM (and therefore, 95% CI) associated with the measures.

The clinical application of the measures of precision can be demonstrated from the reliable variable measures of peak pressure. The precision varied from reliable measures of ±9.1 kPa on the 2-5 digits to ±70.6 kPa on the first MPJ. To put these results into context, the average reliable measure for the first MPJ region was 361.3 kPa and its precision was 70.6 kPa. These results translate that the clinician can be 95% confident that the true measure of peak pressure on the 1MPJ was between 290.7 and 431.9 kPa (mean ± 70.6 kPa) Therefore,, if the condition of measurement was changed, for instance to see the effect of a different shoe on the patient population, the treatment measure would need to be less than 290.7 kPa or more than 431.9 kPa at the first MPJ, before the clinician could confidently know that the treatment was influential on the first MPJ.

The low precision found across all variables as measured on the combined areas of the plantar foot shows that, even though variables can be reliably measured with only a few steps, they are highly variable and therefore, of limited clinical usefulness. Hence, if investigations using in-shoe plantar pressure measurements are to be clinically useful, then sufficient step data must be included in the average step calculation to improve precision and ensure accurate conclusions are drawn. The accuracy of these measures are unknown, and whether the inclusion of additional steps will result in advantageous accuracy and therefore, precision improvements to warrant extra step data collection and analysis is also unknown.

Conclusion

The first purpose of the study was to address Research Question One (a) and determine the number of repeated steps that were required for inclusion for the calculation of the average step to be reliable for the population of adults with diabetes, neuropathy and forefoot ulceration. To achieve acceptable reliability, then at least eight repeated step measures were required when conclusions were to be drawn from all variables available from the Pedar™ system. When measures of peak pressure were only of interest, then only two repeated steps were required for acceptable reliability to be achieved. The second purpose of study was to test Research Question One (b) and determine the precision associated with a reliable average step. At the level that the average step was reliable, then precision was very low and did not reach acceptable variability (CV < 15%).

When data are reliable, then its' usefulness for study on a clinical population is dependant on the precision and accuracy. Therefore, the following study will determine the number of repeated step measures required for inclusion in the average step calculation to achieve the maximum practical improvement in accuracy and their associated clinically useful precision limits.

Part II(c) Accuracy of in-shoe plantar pressure measurements

Rationale and purpose

The previous section showed that in-shoe plantar pressure measurement is reliable when very few repeated steps are included in the calculation of the average step, but with these few steps comes low precision. Data cannot be properly interpreted without estimates of reliability, precision and accuracy for each variable and each anatomical location. For thesis study, the knowledge of the number of step data required for maximum practical accuracy to be achieved in the average step is required. Specifically, knowledge of the accuracy of these data would be useful to decide whether extra data collection above the number of steps required for reliable data is warranted.

Additionally, for comparability of expected variability across variables, the calculation of the coefficient of variation is made. Therefore, to address Research Question One (c), the purposes of this section are two fold: first, to determine the critical number of repeated steps for optimum accuracy using the statistical methods of Besser, Kmieczak, Schwartz, Snyderman, Wasko and Selby-Silverstein (1999) and second, to determine the variability associated with repeated steps and compare this across variables, using the statistical method of Sekiya, Nagasaki, Ito and Furuna (1997).

Data analysis

The mid-gait consistency checked data set used in the previous study was utilised for these analyses.

Statistical analysis

The method described by Besser et al. (1999) was performed to obtain the error in percent (accuracy). The method utilises the 95% CI and expresses it as a percent of the mean measured value for each average step (including two to 24 steps), variable and anatomical region. The 95% CI were obtained from a series of two-way analysis of variance (ANOVA) functions, with the two factors being the average of two to 24 steps and the variable for each limb and the series being

each anatomical region. The accuracy results for each limb were averaged and formatted in Excel and then imported into SPSS.

At low step numbers, the validity of the average step cannot be assumed to contain sufficient data to reflect the true average step due to the mathematical fact that, by the inclusion of more values, the true central measure will be exposed as opposing positive and negative values will cancel each other out (Portney & Watkins, 1993). To check the validity of the accuracy of the averaged step data, especially at a low number of steps, a series of regression curve fitting functions were performed. A natural log based curve was found to best fit the data. An accuracy curve was calculated using this formula for the average step values for each variable and anatomical region (SPSS Incorporated, 1998). The formula for the natural log based curve was calculated as follows:

$$Log_n Y = b_o + b_1(1/t)$$

where Y is the calculated value on the vertical axis, b_0 and b_1 are the function coefficients to fit the measured data, and *t* represents the number of steps (two to 24 steps) included in the average step (SPSS Incorporated, 1998).

The first differential (change in accuracy over change in number of steps (dA/dS)) of the accuracy curve was calculated for each variable and anatomical region to identify the maximum practical or optimal number of repeated steps required in the average step calculation until further steps resulted in less than one percent improvement in accuracy. Additionally, extrapolation was performed to assess the potential accuracy that would be achieved if 50 repeated steps[16] were included in the analysis. The number of repeated steps that achieved accuracy to within 5%[17] of 50 steps was also determined. To avoid the problems caused by the infinite series generated when differentiating natural log functions, iteration with an accuracy of 0.001%was performed (Dobinson, 1969). Of critical importance is to note that the accuracy determined here, is the accuracy inherent in the measurement, and not in the instrument. The Pedar™ system has a documented accuracy of at least 5%.Therefore, each accuracy value determined must then have ±5% added to account for instrument error (Novel Electronics Incorporated, 1998b). In order to evaluate the inherent variability within and across different variables the coefficient of variation (CV%) (Portney & Watkins, 1993) was calculated for each limb using the formula described in the previous study.

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[16] Fifty steps was selected as this was the maximum number of steps reported from the Pedar™ from studies of adults with diabetes analysed in the protocol analysis (See Part I of Chapter Three).

[17] Five (±) percent was chosen as this is the reported accuracy of the Pedar system (Novel Electronics Incorporated, 1998b).

The CV% for each individual limb, for each variable and anatomical region, were added together and divided by the number of limbs to obtain the average CV%. As introduced in the previous study, an acceptable CV% and CV% range for in-shoe plantar pressure variables per anatomical region has not been established, but McPoil et al.(1999) selected CV% values less than 15% to indicate reduced variability.

Results

As was expected, the accuracy for all variables and anatomical regions, improved as more mid-gait steps were included in the calculation of the average step. The regression curve fitting function fitted the results to a natural log based curve with an r-squared level that was above 0.97 for all variables and anatomical regions, and these were significant ($p<0.001$) for all variables and anatomical regions.

The protocol analysis in Part I of this chapter showed that the peak pressure was the most commonly reported variable from in-shoe plantar pressure analyses and this variable, as measured over the whole foot (peak pressure-total), will be used to demonstrate the analysis method and results. The regression curve-fitting plot for the variable of peak pressure-total is presented in *Figure 9* and the SPSS output is presented in Table 14.

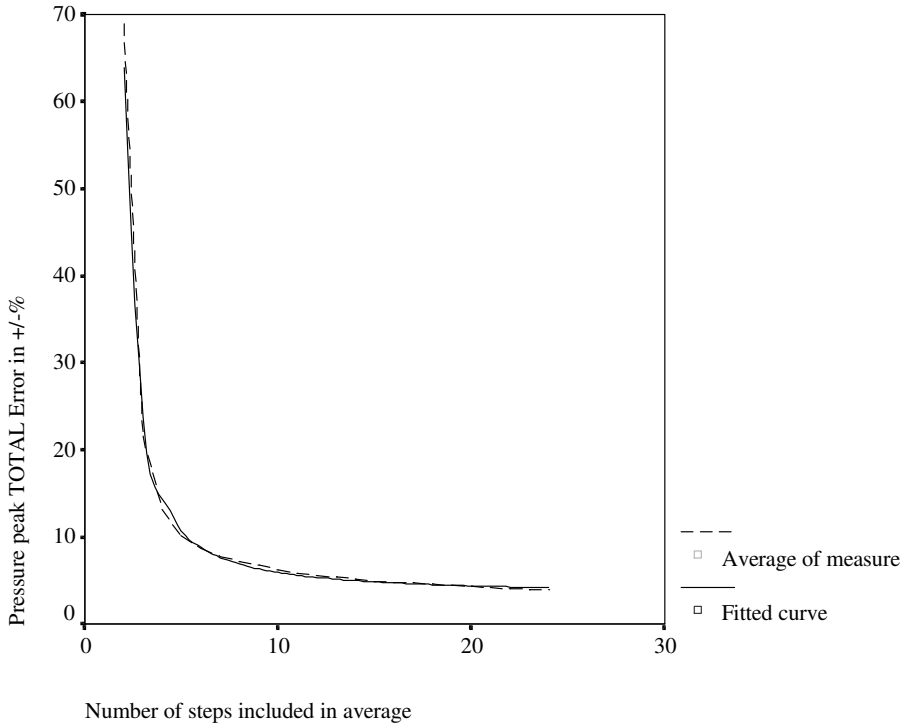

Figure 9. Fit of the natural log curve from the regression equation to the results of the accuracy (error %) versus the number of steps included in the calculation of the average step for the peak pressure-total variable.

Table 14

SPSS output for regression curve fitting analysis for the analysis of the inclusion of 24 steps in the calculation of the average step from the peak pressure-total variable.

Dependent variable	r-squared	Degrees freedom	F-stat	p-value	b_0	b_1
Peak pressure-total	0.994	23	3415.89	<0.001	1.1816	5.9510

The number of repeated steps included in the average step calculation was plotted against the accuracy (error %) for peak pressure-total and is presented in *Figure 10*. The number of repeated steps included in the average step calculation was obtained at two points where dA/dS (0.5 and 1.0) was considered virtually flat and these results are presented in Table 15 and Appendix D. When dA/dS was equal to 0.5, it corresponded to 8.69 steps (nine repeated steps) and when dA/dS equalled 1.0 it corresponded to 6.88 steps (seven repeated steps) steps. Additionally, the minimum number of repeated steps required for the calculation of the average step to be within 5%[18] of that calculated to be likely at 50 steps was 6.08 (seven repeated steps) The accuracy associated with nine steps was ±6.31 % and at seven steps was ±7.63 %, while at 50 steps it was ±3.67 %.

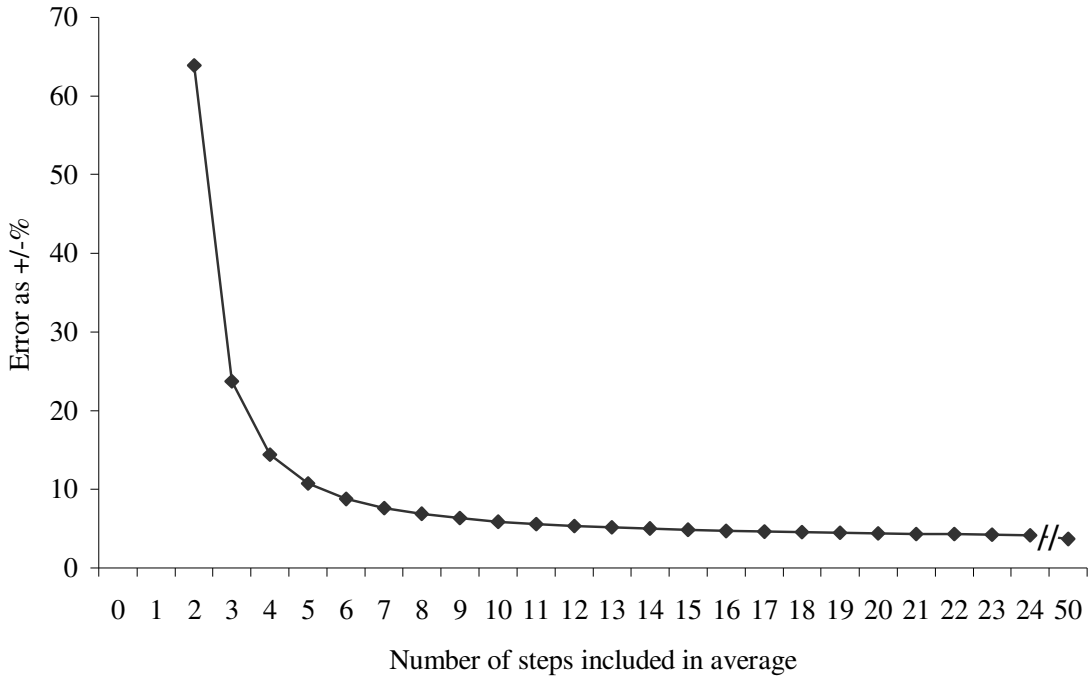

Figure 10. The accuracy (error %) for peak pressure-total and the associated number of repeated steps included in the calculation of the average step.

[18] As the accuracy of the Pedar™ system is reported to be five (±) percent, the accuracy potentially available within five percent of fifty steps is not achievable.

Table 15

The number of steps required for inclusion in the calculation of the average step and the accuracy achieved for the regression line to be within 1 and 5% of flat, and the number of steps and accuracy achieved within 5% of the accuracy achievable with 50 steps included in the average step calculation.

Variable n=62 limbs	Anatomical region	dA/dS<1%		dA/dS<0.5%		dA/dS_{50}-5%		50 steps Accuracy
		Steps	Accuracy	Steps	Accuracy	Steps	Accuracy	
Peak pressure (kPa)	1MPJ	9	12.17	12	10.29	10	11.38	7.03
	2-5digits	8	11.57	11	9.59	9	10.72	6.49
	2-5MPJ	7	8.11	9	6.82	7	8.11	4.15
	Hallux	9	12.87	12	10.94	10	12.06	7.54
	Heel	7	7.61	9	6.32	7	7.61	3.71
	Midfoot	9	13.59	12	11.53	10	12.73	7.92
	Total foot	7	7.63	9	6.31	7	7.63	3.67
Pressure-time integral (kPa s)	1MPJ	10	13.27	13	11.52	11	12.55	8.14
	2-5digits	10	14.64	13	12.89	11	13.92	9.42
	2-5MPJ	8	10.85	11	8.90	8	10.85	5.89
	Hallux	10	15.22	13	13.37	11	14.46	9.71
	Heel	8	11.19	11	9.28	8	11.19	6.29
	Midfoot	10	13.18	12	11.94	10	13.18	8.22
	Total foot	7	6.91	9	5.76	6	7.91	3.42

The variability results for in-shoe plantar pressure measurements (CV%) for the variable peak pressure-total are presented in *Figure 11* and show that this variable has an average relative variability of 8.81% (SD=6.04%: range 0.04 to 43.88%) and does not improve markedly after approximately nine steps are included in the average step calculation. Practically, these results mean that with nine steps included in the calculation of the average step for peak pressure-total, that we are 95% confident that the true mean value is within ±6.31% of our measured mean value which incorporates data variability of 8.81%. Therefore, the overall uncertainty (percent error) of the measure of peak pressure-total includes the measurement percent error of ±6.31% plus the documented instrument accuracy of ±5% which results in ±11.31% overall percent error.

Other variables and anatomical regions required more or less steps to calculate the average step. The highest number of steps required were 14 and this was determined for the variables of force-time integral (2-5Digits), loading begin (%) (1MPJ) and pressure instant of peak (ms) (Midfoot). The highest average variability was associated with the variable pressure-time integral, which ranged from CV% of 14.54 at the 2-5MPJ to 22.81 at the 2-5 digits. The lowest average variability was associated with the variable area, which ranged from CV% of 0.66 at the heel to 9.20 at the 2-5 digits.

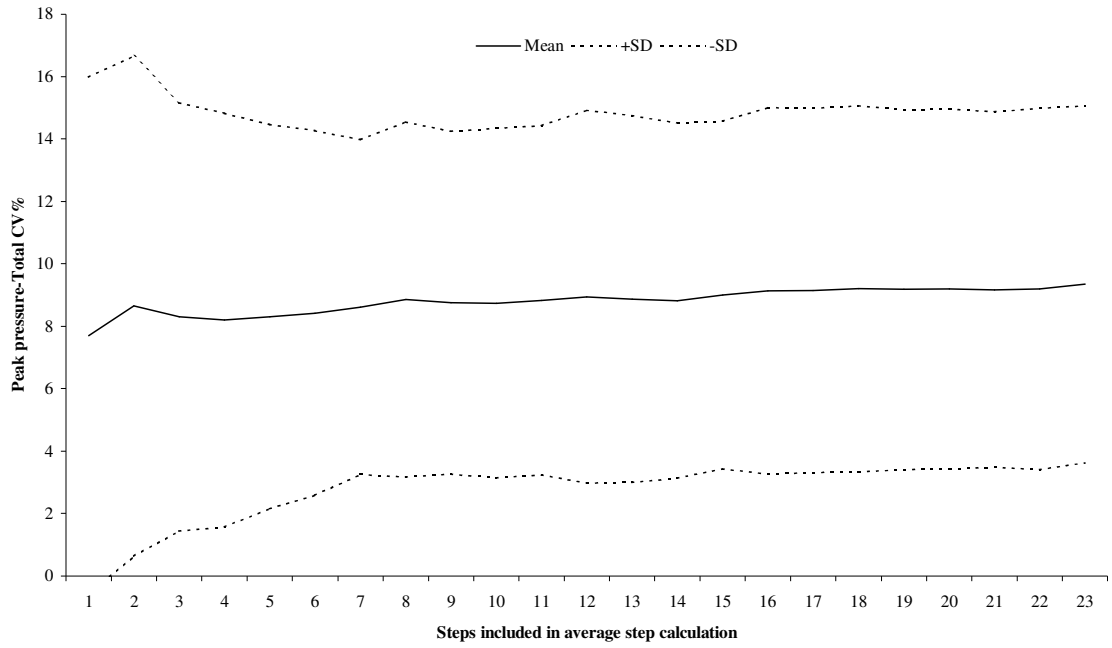

Figure 11. The variability (CV%) of peak pressure-total per number of repeated steps included in the average step calculation.

Discussion

Two methods that both relate to the inherent variability within in-shoe plantar pressure data were calculated. The percent error provided a value for the residual uncertainty around the mean value attributed to the average step, and this uncertainly was used to determine the critical number of repeated steps. The CV% provided a value for the spread of the data around the mean value attributed to the average step, but the criterion of 15% is not uniformly appropriate for all variables and anatomical regions in the population of adults with diabetes, neuropathy and forefoot ulceration. Both methods show that there is little gain in reducing the uncertainty and variability associated with the average step once at least nine steps are included in the calculation for the variable peak pressure-total (percent error = ±11.31% (±6.31% measurement error + ±5% instrument error)).

A limitation to the general applicability of these results is the lack of external verification. It is unknown whether these results would apply to another sample of people with diabetes, neuropathy and forefoot ulceration, and even if these results would hold if the data were acquired on the same sample, but in a different laboratory. However, as both the archival data and the thesis study data were collected and analysed in the same laboratory, this limitation is assumed consistent.

Conclusion

The aim of this study was to address Research Question One (c), and determine the number of steps required to be included in the calculation of the average step for maximum practical accuracy to be achieved and to determine the variability associated with this accuracy. To achieve the maximum practical accuracy and minimal variability, then at least 14 steps were required to be included to calculate the average step if all variables and anatomical regions were under investigation. However, if only the peak pressure-total was of interest, then the inclusion of at least nine steps in the average step calculation results in a mean value that can be interpreted with an overall accuracy (percent error) of ±11.31%.

Part II(d) Selection of in-shoe pressure variables useful for location-specific ulceration exploration[19]

Rationale and purpose

The preceding studies of this chapter have demonstrated that the measures obtained from in-shoe plantar pressure analyses using the Pedar™ system are reliable and their associated precision and accuracy is maximised when sufficient steps are included in the average step calculation. Additionally previous research reviewed in Chapter Two demonstrated that measures of in-shoe pressures under the foot of a person with diabetes and neuropathy are elevated at the site of ulceration. Therefore, the key to the safe and effective prescription of therapeutic interventions and enhancement of their role in ulceration management is the identification and modification of specific sites with high pressures. The current challenge to the clinician and researcher when examining the complex pressure-time data generated from the Pedar™ system is to decide which information it provides is useful for location specific ulceration identification and pressure modification. Part one of this chapter demonstrated that most research reports based on these measures only discuss the peak pressure results at the site of their interest. There are, however, 13 other variables automatically generated by the standard software and all variables are also calculated for each anatomical region defined on the plantar foot. Some variables can be automatically excluded from analyses, as they are a constant number, for example the beginning of loading on the foot as a percent of the stance time is always zero while the ending of loading time as a percent is always 100. The archival data set utilised in this chapter contains 72 variables. Therefore, the purpose of this section was to address Research Question One (d) and identify which variables were useful to identify the location of known forefoot ulceration.

Data analysis

The mid-gait consistency checked data set used the previous section was utilised for these analyses.

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[19] This study has been published: Stacpoole-Shea, S., Shea, G. & Lavery, L., (1999) An examination of plantar pressure measurements to identify the location of Diabetic forefoot ulceration. *The Journal of Foot and Ankle Surgery* 38(2), 109-115 (Stacpoole-Shea, Shea et al., 1999).

Statistical analysis

The steps data from each subject were treated as replications and were averaged to calculate a mean and standard deviation for each variable. The Levene's test for homogeneity of variance was performed as an aid to determine the statistical method to be used for the *post hoc* analysis for the analysis of variance (ANOVA) function. An alpha level of 5% was selected as the threshold for significance for all analyses unless stated otherwise. The Levene's test results revealed that the equality of group variances could not be assumed due to skewness in some variables. Therefore, a Dunnett's T3 test was selected as being appropriate for the *post hoc* analysis due to it not requiring the assumption of equality of variances to be met (SPSS Incorporated, 1998).

In order to evaluate that the significantly different variables were not different measures of the same variable, a Pearson's product correlation coefficient (r) was calculated. An r-value of one indicates that there is a perfect relationship and that the two variables are measuring the same variable. An r-value that is closer to zero indicates a weaker relationship and therefore, the two variables are not measures of the same variable. Linear regression was performed to provide the r^2 values. The r^2 value is a measure of how much of the change in one variable can be attributed to or predicted by the change in the other variable.

Discriminant analysis using Fisher's liner discriminant functions was used to determine classification function coefficients that were calculated for each ulceration location category[20] using the variables determined from the ANOVA *post hoc* analysis. The classification function coefficients produced for each variable were multiplied against the measured value for the variable for each subject and these results were summed for each potential ulceration location. The sum value was adjusted with the constant provided by the analysis, and the ulceration category with the highest result was the most likely site for the ulceration to be present for that subject.

Sensitivity and specificity formulas were applied to the correctly and incorrectly identified classification results. Sensitivity is the likelihood that someone with a target condition, in this case ulceration on a particular forefoot location, is correctly identified as having ulceration at that location and is defined by the formula (Dorland, 2003):

Sensitivity = true positive/(true positive + false negative)

[20] Unless otherwise stated, ulceration are categorised by the anatomical region that they occur in.

Specificity is the likelihood that someone without the target condition/ulceration, is correctly identified as being target condition/ulceration-free and is defined by the formula (Dorland, 2003):

Specificity = true negative/(false positive + true negative)

Results

Timing variables were not found to be significantly different between ulceration categories, but the gait variables are presented to describe the population. The population walked with a mean cadence of 125.8 (SD 18.2) steps per minute, stance time of 0.59 (SD 0.02) seconds, stride time of 0.96 (SD 0.03) seconds and time in double limb support time of 0.12 (SD 0.01) seconds.

Five variables were found from the ANOVA and *post hoc* analysis to be significantly different between ulcerations, and these were peak pressure on the 1MPJ and 2-5MPJ and pressure-time integral on the whole foot (total), 1MPJ and 2-5MPJ. The descriptive results are presented in Table 16, the ANOVA results are presented in Table 17 and the *post hoc* results that showed significant differences are presented in Table 18.

Pearson's product correlation coefficients (r) were calculated and the r-value results indicate that, while most of the different variables are related they are not identical and the results are presented in Table 19. The closer the correlation or r value is to 1, the higher the likelihood that the two variables are measures of the same thing. This is demonstrated in the variables that are correlated at the $p = 0.01$ level or equal to 1. The smaller the r value the less likely that the variables are measures of the same thing and this is evident in the r values of the variables that are correlated at the $p \geq 0.05$.

Table 16

The results for peak pressure and pressure-time integral per ulceration category and anatomical region.

Dependent Variable	Anatomical region	Ulceration category*	Mean	SD	Min	Max
Peak pressure (kPa)	Total foot	1MPJ	501.95	113.57	329.80	680.00
		2-5MPJ	504.24	106.16	281.30	677.00
		Hallux	431.33	81.00	264.40	546.90
	Hallux	1MPJ	196.97	125.46	39.10	426.90
		2-5MPJ	215.40	77.92	98.30	383.40
		Hallux	233.74	95.41	74.40	392.30
	1MPJ	1MPJ	471.93	144.10	181.90	680.00
		2-5MPJ	369.42	102.74	190.70	540.60
		Hallux	285.24	95.40	162.20	526.50
	2-5MPJ	1MPJ	343.04	114.58	149.00	544.70
		2-5MPJ	463.98	126.36	226.30	677.00
		Hallux	386.23	91.84	169.40	535.60
Pressure-time integral (kPa s)	Total foot	1MPJ	164.71	32.20	113.20	236.40
		2-5MPJ	174.89	29.62	134.60	223.20
		Hallux	141.14	30.43	90.30	192.10
	Hallux	1MPJ	27.96	22.19	3.10	80.10
		2-5MPJ	35.88	20.45	7.10	72.70
		Hallux	38.94	21.80	7.10	72.70
	1MPJ	1MPJ	114.52	34.79	48.60	179.80
		2-5MPJ	85.45	20.67	45.30	112.80
		Hallux	72.46	24.28	28.70	130.30
	2-5MPJ	1MPJ	86.08	20.44	50.10	116.90
		2-5MPJ	121.68	33.66	61.90	177.60
		Hallux	93.73	24.53	52.80	142.70

*Ulceration category populations are 17 for 1MPJ, 13 for 2-5MPJ and 16 for Hallux.

Table 17

The ANOVA results that showed significant differences between ulceration groups for peak pressure and pressure-time integral.

Dependent Variable	Anatomical region	Groups	Sum of Squares	Degrees freedom	Mean Square	F	Sig.
Peak pressure (kPa)	1MPJ	Between	288620.89	2	144310.44	10.42	<0.00
		Within	595403.42	43	13846.59		
		Total	884024.30	45			
	2-5MPJ	Between	108641.36	2	54320.68	4.42	0.02
		Within	528164.69	43	12282.90		
		Total	636806.05	45			
Pressure-time integral (kPa s)	Total foot	Between	8932.45	2	4466.23	4.68	0.01
		Within	40996.61	43	953.41		
		Total	49929.06	45			
	1MPJ	Between	15279.43	2	7639.71	9.86	<0.00
		Within	33332.07	43	775.16		
		Total	48611.50	45			
	2-5MPJ	Between	9972.36	2	4986.18	7.32	<0.00
		Within	29306.54	43	681.55		
		Total	39278.90	45			

Table 18

Dunnett's T3 post hoc analysis results that showed significant differences between ulceration groups for peak pressure and pressure-time integral.

Dependent Variable	Anatomical region	Ulcer group 1	Ulcer group 2	Mean Difference (ulcer group 1-2)	Std. Error	Sig.	95% CI Lower limit	95% CI Upper limit
Peak pressure (kPa)	1MPJ	1MPJ	Hallux	186.69	40.99	<0.00	79.55	293.84
	2-5MPJ	1MPJ	2-5MPJ	-120.94	40.83	0.04	-235.03	-6.86
Pressure-time integral (kPa s)	Total foot	2-5MPJ	Hallux	33.75	11.53	0.02	5.27	62.23
	1MPJ	1MPJ	2-5MPJ	29.06	10.26	0.02	3.17	54.95
	1MPJ	1MPJ	Hallux	42.06	9.70	<0.00	15.79	68.32
	2-5MPJ	1MPJ	2-5MPJ	-35.61	9.62	0.01	-63.15	-8.07

Table 19

Pearson's product correlation coefficients (r) of variables that are significantly different between ulceration locations (PP: Peak pressure (kPa) and PTI: Pressure Time-Integral (kPa s))

r	PP 1MPJ	PP 2-5MPJ	PTI 1MPJ	PTI 2-5MPJ	Total foot PTI
PP 1MPJ	1	0.271*	0.821**	0.143	0.546**
PP 2-5MPJ		1	0.160	0.725**	0.447**
PTI 1MPJ			1	0.342**	0.653**
PTI 2-5MPJ				1	0.695**
Total foot PTI					1

*Correlation is significant at the 0.05 level (2-tailed)
**Correlation is significant at the 0.01 level (2-tailed)

As an extension of the Pearson's product correlation coefficients, linear regression (r^2) was performed to show how much the change in one of the paired variables was attributed to, or predicted by the change in the other paired variable and are presented as follows:

- The peak pressure on the 1MPJ is explained by 67.3% of the pressure-time integral on the same location.
- The pressure time integral at the 2-5MPJ is explained by 48.3% of the pressure-time integral of the whole foot.
- The peak pressure at the 2-5MPJ is explained by 52.5% of the pressure-time integral at the 2-5MPJ.

Discriminant analysis was performed using the five variables determined from the ANOVA *post hoc* analysis to provide a mathematical model for determining the most likely location of ulceration on the forefoot. The prior probabilities for each ulceration category were assumed equal and the classification function coefficients results are presented in Table 20. The value for each variable for each subject is multiplied against the classification function coefficient and the results for each variable summed and the sum value is adjusted by the constant provided. The ulceration category with the highest value is the most likely site for ulceration to be present on that subject.

Table 20

Classification function coefficients results for the mathematical model to determine most likely ulceration location.

Variable	Anatomical region	Classification function coefficients for ulceration categories		
		1MPJ	2-5MPJ	Hallux
Peak pressure (kPa)	1MPJ	0.02	0.04	-0.13
	2-5MPJ	0.19	0.18	0.29
Pressure-time integral	Total foot	1.28	1.41	1.25
(kPa s)	1MPJ	0.61	-0.05	0.55
	2-5MPJ	-0.31	0.33	-0.40
Constant		-17.55	-20.06	-13.88

The model was found to accurately determine the location of the ulceration in 69.6% of subjects and the classification results are presented in Table 21

Table 21

The classification results showing numbers of subjects and their correctly and incorrectly predicted ulceration category membership.

	Ulceration category	Predicted ulceration category membership			Total
		1MPJ	2-5MPJ	Hallux	
Count	1MPJ	12*	1	4	17
	2-5MPJ	2	10*	1	13
	Hallux	1	5	10*	16
	Uncategorised cases	10	13	13	36
%	1MPJ	70.59*	5.88	23.53	100
	2-5MPJ	15.38	76.92*	7.69	100
	Hallux	6.25	31.25	62.5*	100
	Uncategorised cases	27.78	36.11	36.11	100

* Correctly classified

Subjects who were placed in a predicted ulceration category membership different from their true ulceration category are incorrectly classified. The correct and incorrect classification results were utilised to calculate the sensitivity and specificity of identifying ulceration using in-shoe pressure measurement and these results are presented in Table 22.

Discussion

The analysis did not find evidence to suggest that ulceration location was related to walking gait variables. The population walked at a rate that is comparable to normal healthy adults even though being neuropathic means that they lack both local and spatial sensory feedback to control their gait (Courtemache et al., 1996; Zhu, Wertsch, Harris, & Alba, 1995). The average overground walking cadence of the data set (125.77 steps per minute) compared favourably with the treadmill

Table 22

Specificity and sensitivity results from application of the discriminate analysis model.

Ulceration category	Specificity (%)	Sensitivity (%)
1MPJ	71	90
2-5MPJ	87	85
Hallux	69	83

walking study of people with diabetes by Walker, Helm and Lavery (1997) (126.86 steps per minute). There was smaller variability in the cadence in this population as demonstrated by a standard deviation of 18.17 steps per minute as compared to the 31 steps per minute reported by Walker et al. (1997). This difference may be potentially explained by differences between treadmill and overground walking or because the subjects of Walker et al. were interrupted by an auditory signal when they walked on their ulceration. Doing higher cognitive tasks has been shown to interfere with walking (Mueller, Minor et al., 1994). The population's cadence (125.77 (SD 18.17) steps per minute) was faster than the studies of people with diabetes reported by Courtemache (1996) of 102.5 and Mueller (1994) of 106.3 (SD 8.0) steps per minute. Stride time measured in both studies (Courtemache et al., 1996; Mueller, Minor et al., 1994) (1.15 (SD 0.09) sec) and our population were comparable (1.04 (SD 0.08) sec). As step length was not measured in our population it is assumed that the subjects' higher cadence may be due to their taking shorter steps to maintain their comfortable speed.

As the peak pressure and pressure-time integral were significantly related in the location of ulceration, the result that loading time was definitely not related to ulceration presence suggests that the pressure component within pressure-time interval is most relevant. Timing of the application of peak pressures on ulcerated and ulceration-free feet were found to have an alpha value equivalent to choosing random numbers (p=0.5). The apparent randomness of the timing values can be explained by the high variability of these measures described earlier in this chapter and by Kernozek et al. (1996).

It was expected that, if the peak pressures had a highly statistically significant relationship to ulceration presence, then the peak forces would also be important due to their mathematical relationship. However, this was not the case and these results support the clinical assumption that

it is the area over which the force is applied that is a factor in ulceration presence on the forefoot rather than the overall force applied. This assumption can be conceptualised using the analogy of a large rock or a needle. If the same force is applied to the foot, the needle will rupture the skin, while the rock will not. Therefore, the implication is that area is critical.

The results of this analysis are in agreement with the growing body of literature that supports the fact that ulceration measured on the 1MPJ and 2-5MPJ regions exist with high pressures during walking (Armstrong, Peters, Athanasiou, & Lavery, 1998; Katoulis, Boulton, & Raptis, 1996; Lodewick, 1993; Murray, Young, Hollis, & Boulton, 1996). However, the analysis did not explain a clear relationship between hallux ulceration and pressure on the hallux and implies that there may be other structural or functional factors involved. Limitation in extension of the 1MPJ has been reported to be an aetiological factor in ulceration of the plantar hallux (Birke, Cornwall, & Jackson, 1988). The limitation of the joint, either by structural damage to the joint itself or functional restrictions from adjacent soft tissues, is reported to alter the smooth forward progression of the limb over the forefoot during the terminal stage of gait (Payne & Dananberg, 1997). Theoretically, joint limitation may make the hallux function as a rigid lever during toe off (Dananberg, Phillips, & Blaakman, 1996) and as body weight transfers forward it may trap the skin of the hallux against the ground/shoe shearing the skin from the deeper structures resulting in ulceration (Armstrong & Athanasiou, 1998; Landsman, Meaney, Cargill, Macarak, & Thibault, 1995).

To identify the actual location of the ulceration, the optimal diagnostic level of specificity and sensitivity was obtained when the five variable results were combined even though they were not all significantly different for each ulceration category site. To put these results into clinical context, a specificity of 69% meant that 31% of patients could have been misdiagnosed as having ulceration when they did not. A sensitivity of 83%, however, meant that only 17% of patients who had ulceration would have been missed and their ulceration left undiagnosed.

When implementing a clinical screening tool, the acceptability of the levels of sensitivity and specificity are taken into account (Portney & Watkins, 1993). Sensitivity, to some extent is irrelevant to this screening test because it would be likely that a visual examination would be part of the test, even if only cursory as a result of assisting the person to don the standardised socks, sensors and shoes, and the error would be quickly identified. To decide if the level of specificity is acceptable, then the consequences of incorrectly and therefore, over diagnosing people with specific ulceration when their ulceration is in another location is the issue. Clearly, if the test identified ulceration, then the person would naturally be referred to a clinician. The clinician faced with seeing ulceration in one location and test results that suggested an ulceration-free location to be ulcerated, would then have the opportunity to prescribe an intervention that protected both

regions, therefore, protecting the existing ulceration and hopefully preventing potential ulceration. Specificity however, becomes an issue when resources are limited and potentially ulceration protective interventions are prescribed to ulceration-free individuals. Such an instance would likely see the clinician attempt to convince the resource managers to the value of protecting a foot at risk of ulceration and therefore, preventing the later high resource consumption that would be required to manage ulceration.

Conclusions

The purpose of this analysis was to test Research Question One (d) and identify which plantar pressure measurement was useful to identify the location of known forefoot ulceration. The 72 variables calculated by the Novel-win software were analysed and five variables were found to be useful in correctly predicting the location of ulceration from three possible ulceration sites. The variables were: peak pressure on the 1MPJ and 2-5MPJ and the pressure-time integral on the 1MPJ, 2-5MPJ and whole foot. Therefore, on the basis of these results, only these five variables identified were selected *a priori* for statistical analyses in further thesis studies.

Chapter summary

This chapter addressed Research Question One (a, b, c and d) and demonstrated that standardised procedures for application of this research and clinical tests are lacking in the literature and, even though dynamic in-shoe plantar pressure measures in people with diabetes are reliable and accurate, they are highly variable and precision is low. Additionally, the analysis complexity of the clinical testing of in-shoe pressures has been limited with the identification of only five of the 72 potential variables as being clinically useful towards interpretation of the data for investigations of forefoot ulceration.

The next three chapters will address; the methods that are common to the thesis studies, the selection of the standard testing sock, and the safety and consistency of walking when using this protocol.

CHAPTER FOUR

METHODS COMMON TO STUDIES

Procedures

The protocol developed in Chapter Three will be utilised for all studies in addition to the procedures described in this chapter.

Description of footwear used for baseline testing

In accordance with the international protocol guidelines for (in-shoe) plantar pressure measurement (IPGPPM), the shoes, insoles and socks were standardised for all testing procedures. The baseline-test shoe was a canvas laced up oxford style athletic shoe with a thin rubber sole (Nike, Beaverton, Oregon, USA). The baseline-test shoe was specifically selected based on its upper being secured with laces, their initial ease of wearing due to the soft canvas upper and thin flexible rubber sole, and the assumption that the thinness of the sole would provide minimal shock absorption to ensure that plantar pressure measures were representative of the subjects' normal walking. The baseline sock was a *SmartKnit*™. This sock was specifically selected due to the lack of leg constriction afforded by the suspender band construction and the knitted seam that potentially posed less injury risk to the digits (Stacpoole-Shea, Walden et al., 1999).

Anatomical region verification for in-shoe plantar pressure analyses

Specific anatomical regions of the plantar foot are defined for analysis of in-shoe plantar pressures measured during dynamic gait. Identification of these sites can be problematic as the location of each anatomical site may not be obvious from the pressure image obtained. A simple pre-testing procedure was developed that allowed for identification of the centre of each anatomical region of interest. One-cent coins were taped over the sock onto the centre of the anatomical point and a

single data collection was conducted for each foot as the subject stood, with the assistance of a chair, in single limb stance. Attention was made to ensure that the coins remained located under the determined site. The raw data were processed using the Pedar Filter™ and Pedar-EMEDlink™ software and a single left and right foot data were obtained. These data were exported into the Novel-win Creation of Any Mask™ software in which *masks* were drawn around the anatomical region with the assistance of the coin image. This mask file was saved ready for use with analyses of the study data. An example of a single foot data at each stage is shown in *Figure 12*.

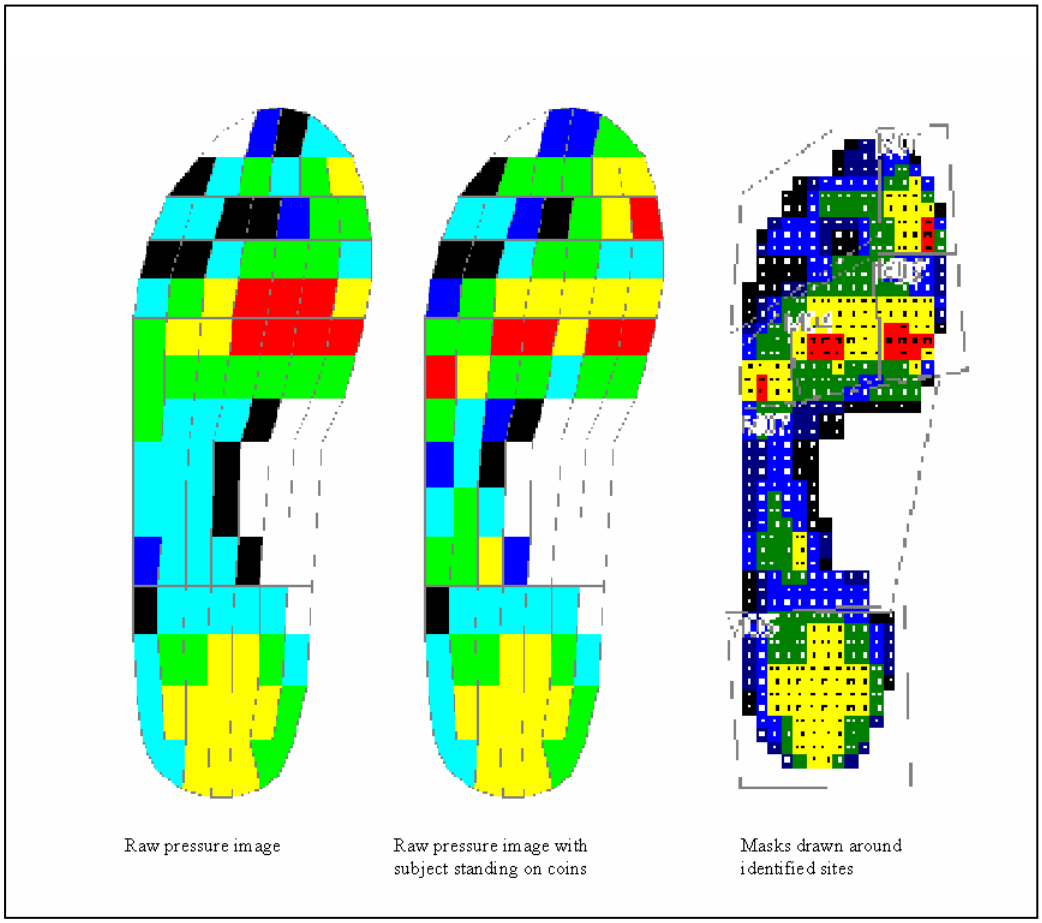

Figure 12. Identification of anatomical regions for mask drawing on the image of localised high-pressure areas associated with weight bearing on coins.

Data collection

The procedures, including calibration for dynamic in-shoe plantar pressure testing using the Pedar™ system were conducted as described in the Users Manual with the addition of those procedures determined from the analyses in Chapter Three.

Upon arriving at the laboratory, the subject was introduced to the laboratory staff and an explanation of the study given prior to informed and written consent being obtained. The subject blindly selected a card on which a subject identification code number was written. This code ensured confidentially provisions of the Institutional Review Boards. The code was recorded and the subject details were retained under lock and key in the laboratory.

The subject removed their shoes and socks, and the Chief Investigator inspected the feet and debrided any callus (Potter & Potter, 2000; Young et al., 1992), and then a new pair of standard socks was donned. The anatomical region site identification procedure was then conducted as described previously. The subject blindly selected the order of shoe or insole testing by selecting from a set of index cards. The sensors were fitted to the first testing shoe with testing insole and then to the subject and this set up was checked by encouraging the subject to walk around the laboratory. A trial practice session followed that achieved three aims; to accommodate the subject to walking within the constraints of the umbilical cord and trial method, to warm up the sensors, and to accommodate the subject to the testing shoes. The subject was instructed to walk at their own normal pace as if they were walking in the street.

In order to minimise the effect of internal shoe pressures, a zeroing process was conducted in accordance with the User's Manual, which determined the sensing threshold above which the pressure exerted from the foot onto the sensor during non-weight bearing was excluded.

One trial was conducted during which data were not collected and where system checks and subject comfort were made. Data were then collected from three trials, between which the subject rested while the data were saved onto the computer. A trial was defined as a walk to the end of the laboratory (eight metres), turn around and return to the starting point without incident. At the completion of the trials, the subject rested while a preliminary survey of the raw data were made using Pedar Filter™ software. At the end of testing, the feet were examined by the author to check for injury and any questions that the subject had were answered. Subjects were reminded to inspect their feet that night and daily in accordance with good diabetes self-management practice and to report any irregularities to the clinic nurse. The standard socks used during testing were retained by the subject, as was a copy of the consent form.

After data analysis was completed, to comply with subject participation incentives, a clinical report was made available to the subject's doctor and an appropriate pair of either insoles or shoes given to the subject. Original consent forms were filed in the subject's medical file as per Institutional Review Board requirements, while remaining shoes and insoles were made available for clinical prescription to financially-stricken patients of the High Risk Diabetic Foot Clinic.

Data processing

The raw in-shoe plantar pressure data were processed ready for analysis by following three stages within the Pedar™ system software package. The stages were:

1. Removal of unwanted step data from a trial, specifically starting, stopping and turn around steps - Pedar Filter™ software.

2. Transformation of trial data into individual step data - Pedar-EMEDlink™ software.

3. Definition of anatomical regions of interest on step data - Novel-win Multimask Evaluation™ software.

Two formats of processed step data were available ready for analysis. The formats are the measures of force, pressure (peak and average) and area from each time interval during the stance phase of the steps within each trial and the absolute value measured for each variable during each step. Within these formats are subsets of processed data divided into the defined anatomical areas of interest (masks).

Data analysis

The processed pressure data from each step was imported into Excel where it was labelled and the sample data set was formatted ready for mid-gait validity checking as described in Chapter Three prior to exportation into SPSS for statistical analyses.

Measures of subjects

Body mass index

Measures of the participants' stature and mass were standardised to Body mass index (BMI). BMI is the stature in metre squared divided by the mass in kilogram (Zeman, 1991). The stature was measured as the participant stood without shoes with their back against the wall alongside a measure chart. The chart device was aligned on the top of the participant's head and the adjacent value was recorded as their stature in metres. Body mass was measured while the subject stood in their clothes, but without shoes, on the electronic clinic bodyweight scale and the number registered by the scale was recorded as their mass in kilograms. Mass was measured by the scale to two decimal places.

Peripheral neuropathy diagnosis confirmation

As described in Chapter Two, peripheral neuropathy is diagnosed to be present on the feet, when protective sensation is lost. Loss of protective sensation was confirmed by establishment of the vibration perception threshold using a biothesiometer. The vibrating head of the biothesiometer was placed on the apex of each subject's hallux and the vibration slowly decreased via a dial until the subject could no longer feel vibration. The vibration was controlled by adjustment of voltage to the device through a range from 0 to 50 mV. The vibration perception threshold (VPT) is stated as the highest voltage recorded from the dial from which the subject continued to feel vibration. The diagnosis of peripheral neuropathy was confirmed and the test stopped when the VPT exceeded 25 mV.

Shoe size

Shoe size was obtained to determine the appropriate shoe or insole required for testing. Shoe size was measured using a male or female Branick device. The device consists of fixed heel and lateral foot placement barriers and two adjustable levers to put against the most distal and medial portions of the foot. The levers are positioned against the foot while the subject stands on the device. The measurement is read where indicated by the position of the distal and medial levers. The distal lever gives the value of the shoe size while the medial lever gives the value of the shoe width. The actual value of shoe size and width is arbitrary as it is not consistent across different shoe and insole designs and manufacturers. Therefore, the measure is used as an indicator for initial selection and then the shoe, insole and sensor are compared against the Branick device prior to fitting to the subject.

Statistical analysis

All analyses were performed using SPSS Release 8.0 for Windows. All data were examined for and confirmed as being normally distributed using Proportion probability (P-P) plots with the proportion estimated using the Rankit formula. In a P-P plot, if the data are from a normal distribution, then the plot points will cluster around a straight line (SPSS Incorporated, 1998). The inferential statistics used for each thesis study will be described in each respective chapter.

CHAPTER FIVE

SELECTION OF THE STANDARD TESTING SOCK

One study and two bench experiments were conducted due to concerns around the selection of a standard testing sock. The study and experiments were designed to address Research Question Two (a) and specifically determine the influence on pressure measurement from the sock material. The chapter also aimed to verify the anecdotal risk of increased localised pressure associated with sock seams and substantiate the extent of increased localised pressure associated with sock seams through a range of pressures.

Does the fabric of a sock affect pressures measured under the foot?

Rationale

Socks in which the fabric is thicker or padded are recommended for use when walking, as they have been reported to significantly reduce the pressures experienced under the regions of the plantar foot in healthy subjects and those with diabetes and neuropathy (Flot et al., 1995; Veves et al., 1990). However, another aspect of safety that relates to therapeutic socks is the constriction that the sock suspender band has on venous vascular drainage of the leg and two socks that are constructed so that this risk is minimised are marketed specifically to the diabetic population. The *Circulation Sock* (Red Robin, Melbourne, Australia) is constructed to minimise leg constriction and has a thicker plantar fabric resulting in a thick sewn toe seam. Although the *SmartKnit*™ sock (KnitRite Inc., Kansas, USA) does not have either a tight sock suspender band or thicker plantar fabric, it does not have the thick toe seam that is associated with a thicker sock. Even though therapeutic socks are recommended to people with diabetes due to their specialised construction, this construction limits their general use due to their significant purchase cost (approximately $AUD 12-35 per pair). The cheaper, supermarket available sports sock is an alternative sock

frequently worn by the general population, including those with diabetes (approximately $AUD 1-5 per pair, *Sport Gear* (Fruit of the Loom, Mt. Airy, USA))

Purpose

The purpose of this experiment was to determine if the fabric in the sole of selected therapeutic socks had an effect on dynamic plantar pressures and whether the sock used during in-shoe plantar pressure testing should be standardised.

Subjects

A convenience sample of 16 subjects was sought who were diagnosed with diabetes but without a history of peripheral neuropathy or forefoot ulceration to volunteer to take part in the study. Potential subjects were informed about the study via a presentation about *foot health and diabetes* that was given by the Chief Investigator at a diabetes education session in the Dietetics Department at the Texas Diabetes Institute. The Institutional Review Boards of the University of Texas Health Science Center and the University Health System gave approval for the study, and informed consent was obtained from all subjects prior to their participation.

Subjects were included if they were an adult with diabetes and were able to walk unassisted. Subjects were excluded if they had a history of peripheral neuropathy, foot ulceration, major trauma to the lower limbs or lower back, surgery to the feet, or if they had concurrent disease processes such as Parkinson's disease that limited their ability to walk consistently. All subjects who volunteered were eligible and consented to participate in the study and their positive decision was influenced by two incentives. The first incentive was that they would receive plantar pressure assessment that was normally reserved for surgical assessment and they would receive it free of charge. The second was that they would receive the therapeutic and supermarket socks worn during testing, and these would be free of charge.

The sample of 16 subjects (eight men and eight women), ranged in age from 32 to 75 years (mean 53.31, SD 12.01), height of 1.52 to 1.98 m (mean 1.71, SD 0.13) and mass of 80.91 to 154.55 kg (mean 104.80, SD 23.22). Body mass index (BMI) ranged from 24.59 to 51.80 (mean 35.80, SD 7.25), classifying three subjects as overweight (BMI 25-30) and 13 as obese (BMI>30) (Zeman, 1991).

Method

To eliminate the effect on plantar peak pressures from a shoe, the EMED™ in-floor pressure plate was used to collect and measure pressure data. All procedures, including calibration, were conducted in accordance with the User's Manual. The pressure plate was mounted flush with the floor midway along an 8 m walkway. It is a capacitance mat transducer system, with a platform dimension of 420 x 417 mm and a sensor dimension of 360 x 190 mm. Data were acquired from foot strikes to the platform composed of 2,736 individual sensors with a resolution of four per square centimetre at the default sampling rate of 50 Hertz.

The mid-gait method (Meyers-Rice, Sugars, McPoil, & Cornwall, 1994) of data collection was used and the subjects were instructed to walk at their normal comfortable pace along the flat linoleum path that included the pressure plate. To minimise the potential inconsistentation of the data from the subject targeting the plate, they were instructed to look at and walk towards a head high marker. Practice walks were conducted with the starting position being adjusted until the subject's right foot successfully landed within the surface area of the pressure plate sensor area during the walk. A chair was placed at the starting position and the subjects were instructed to sit between trials to minimise fatigue while the trial data were saved.

Peak pressure data obtained from the EMED™ system has been reported to be reliable when at least three steps are included in the calculation of the average step for each condition in healthy subjects (Hughes, Pratt, Linge, Clark, & Klenerman, 1991). However, Chapter Three showed that the variability of in-shoe peak pressure data did not become stable until at least eight steps were included in the calculation of the average step. Therefore, due to the dearth of reports to determine the number of steps required until pressure plate data variability becomes stable, it was considered that at least the in-shoe criterion should be applied. Ten successful right foot hits were obtained for each subject for each of the sock conditions and the stocking, which represented a bare foot. In accordance with the incentives for subject participation, three successful left foot hits were recorded in the stocking and a report was produced for inclusion in the subject's medical file.

The subject blindly selected labelled cards to randomise the order of sock testing. The subject's feet were inspected by the author prior to testing and any plantar was callus removed (Young et al., 1992), and the feet were inspected again prior to the subject being discharged from the testing laboratory. Subjects were reminded to inspect their feet that night and daily in accordance with good diabetes self-management practice and to report any irregularities to the clinic nurse. The subject retained the three pairs of socks used during testing and the clinical report was made available to their doctor.

Data analysis

The peak plantar pressures for each of the ten right foot strikes were exported into Novel-win Multimask Evaluation™ software for regional analysis. The plantar foot was divided into analysis regions that represented the total foot, hallux, first and second to fifth metatarsophalangeal joints and the heel. The results obtained for each region from the ten steps were treated as repetitions and summed and divided by ten to calculate an average step for each sock tested yielding the sample mean and standard deviation. The variability of the results from each subject were determined using the coefficient of variation (CV%) using the formula presented in Chapter Three and the variability of the sample average (mean CV%) and standard deviation (SD CV%) were determined.

Results and discussion

The peak pressure results for each region of the plantar foot and each sock condition are presented in Table 23. The average stocking foot pressures were highest for the regions of the total foot, 1 MPJ and 2-5 MPJ, but not for the hallux or the heel. The lowest average pressure was not attributed to a sock material. These results agree with Flot et al. (1995) who reported that the cushioning effect of sock fabric was not consistent across all regions of the plantar foot, but disagree with the report of consistency of the cushioning effect from Veves et al. (1990).

There were only small differences between the sock conditions, including the stocking, but these differences are within the limits of the variability (mean CV%) of the data. Therefore, no true difference was found and inferential statistics were not calculated. Peak pressure measures over the whole foot (Total foot) were the least variable (mean CV% range 9.4 to 11.5%, SD CV% range 5.0 to 8.6%), while other anatomical regional measures had similarly higher variability (mean CV% range 14.4 to 22.2%). These results were unexpected considering that significant differences had been reported between sock conditions in the two reports mentioned previously (Flot et al., 1995; Veves et al., 1990). The pressure reducing claims from these two reports have been widely acknowledged resulting in the wearing of padded socks being encouraged by health professionals as a routine part of the diabetes self-education message (Tennant, 2002).

Table 23

Peak pressures obtained from each region of the foot for each sock condition.

Variable	Anatomical region	Sock	Mean	SD	Mean CV%
Peak pressure	Whole foot	Circulation Sock[#]	898.9	48.2	9.4
(kPa)		SmartKnit[+]	831.4	41.5	10.0
		Sport Gear[8]	916.4	77.8	9.5
		Stocking	920.8	62.4	11.5
	Hallux	Circulation Sock[#]	524.6	99.4	20.9
		SmartKnit[+]	553.3	48.5	18.4
		Sport Gear[8]	578.1	103.4	18.1
		Stocking	499.5	72.1	19.8
	1MPJ	Circulation Sock[#]	721.7	70.4	17.0
		SmartKnit[+]	651.3	69.8	18.4
		Sport Gear[8]	724.7	144.8	22.2
		Stocking	748.1	96.0	20.5
	2-5MPJ	Circulation Sock[#]	619.9	81.3	16.4
		SmartKnit[+]	625.1	66.6	18.2
		Sport Gear[8]	611.2	118.8	21.3
		Stocking	659.1	63.0	17.6
	Heel	Circulation Sock[#]	475.5	52.0	17.8
		SmartKnit[+]	527.0	40.5	14.4
		Sport Gear[8]	552.8	103.7	18.2
		Stocking	484.6	33.4	19.2

[#]Red Robin, Melbourne Australia, [+]KnitRite, Kansas USA, [8] Fruit of the Loom Mt. Airy USA

These claims may have been made based on the significant differences obtained from the statistical calculations without consideration of the inherent variability of the data analysed. To investigate this point, the mean and standard deviation results for peak pressure at the 1MPJ region that were reported by Veves et al. (1990) were used by the author to calculate their data's variability (CV%) and these results are presented in Table 24. The variability results calculated are limited due to their being calculated from the sample mean and standard deviation results instead of each subject and then averaged, but still give an indication that the results reported are so variable (CV% range of 55.1 to 67.2%). This result brings into question the validity of the conclusions drawn. The magnitude of the difference between the variability of the thesis study

and that calculated from Veves et al. (1990) may potentially be explained by the different instruments used for data collection (capacitance versus optical pedobarography), but this cannot be verified and warrants further investigation.

Table 24

Results reported by Veves et al. (1990) with CV% calculation and units conversion (from kg.cm^2 to kPa) by the author.

Variable	Anatomical region	Sock condition	Mean*	SD*	CV%$^+$
Peak pressure	1MPJ	Barefoot	715.7	480.4	67.2
(kPa)		Experimental socks	617.6	343.1	55.1
		High density socks	617.6	392.2	63.6
		Medium density socks	656.9	392.2	58.9

* Reported by Veves et al. (1990), $^+$ Calculated by the author.

The study reported by Perry et al. (1995) are from data collected from a sock of similar material and thickness (Adler Jogger socks) to the Sport Gear (Fruit of the Loom, Mt Airy USA) sock tested in the thesis study. The studies are comparable in respect to subjects, instrument and sock, but differ in the method of data collection and the results are presented in Table 25. The study by Perry et al. measured pressures while the subjects walked with the first-step data collection method as opposed to the mid-gait method used for thesis data collection. The different method of data collection may explain why the peak pressure results reported by Perry et al. are nearly half in the mean result while having similar standard deviation compared to the thesis study result. The variability of the results from Perry et al. are similar to the thesis results for the lateral metatarsophalangeal joints and heel region, but are nearly double the thesis study results for the hallux and 1MPJ regions. Once again, the different method of data collection may explain this difference. It would not be unexpected to find more variability in the loading of the forefoot in the first step of data compared to mid-gait steps, because expected higher variability underlies the elimination of the first (and last) steps during walking when measuring pressure for in-shoe analyses.

Table 25

Results reported by Perry et al. (1995) with CV% calculation and units conversion (from N.cm^2 to kPa) by the author.

Variable	Anatomical region	Sock condition	Mean*	SD*	CV%$^+$
Peak pressure	Hallux	Adler Jogger socks	307	128	41.69
(kPa)	1MPJ		326	140	42.95
	2 MPJ + 3-5 MPJ		390	97.5	24.61
	Heel		304	72	23.68

Conclusion

The results from this thesis study show that there is no clinically applicable difference between sock material and 'barefoot' for dynamic plantar pressures measured at a resolution of four sensors per square centimetre. Therefore, for dynamic in-shoe plantar pressure measurement at the lower resolution of two sensors per square centimetre, the selection of the standard sock can be based on clinical logic and not sock fabric. To minimise the potential risk to the leg from constriction from the suspension band, a suspension band-free sock was chosen for the standard sock. However, if the plantar material is to be discounted, then the choice becomes between the construction methods of securing the toe seam of the socks; sewn or knitted. The anecdotal potential for irritation and skin injury risk from the bulk of a sewn seam is unverified and is the focus of the following experiment.

Verification that sock seam bulk is associated with localised high pressure[21]

Rationale

Irritation from footwear is one of the most readily preventable factors leading to ulceration in the high-risk diabetic foot (Burns, Leese, & McMurdo, 2002; Chantelau & Gede, 2002). Irritation from the sock fabric being trapped between the foot and the shoe has been confirmed in one case and anecdotally in others as being a causative factor in ulceration (Murray, Veves, Young, Richie, & Boulton, 1993). The role of socks has received substantially less attention than shoes and insoles in their potential role in causing foot ulceration. Experimental evidence has not been reported to verify whether the bulk of the fabric in a sock seam could exert sufficient localised pressure to compromise the skin integrity of the diabetic and neuropathic foot. Naturally, it would be unethical to conduct experiments to verify this assumption in humans without first establishing sound laboratory-bench based evidence. Therefore, a laboratory-bench test was designed to test the assumption that an increase in pressures of greater than 40% in the laboratory could suggest that a sock seam trapped between the foot and shoe could potentially be of sufficient pressure magnitude for the skin of the diabetic and neuropathic foot to be at risk of injury.

Purpose

The purpose of study was two-fold; first, to determine in the laboratory, if a sock seam could form a measurable and identifiable local focus of high pressure and, secondly, to verify any difference in localised pressure between the seam and no-seam areas of socks made of different fabrics.

Method

The two socks with sewn seams (seamed socks) used in the previous experiment (*Sport Gear*: Fruit of the Loom, Mt. Airy, USA and *Circulation Sock*: Red Robin, Melbourne Australia) were

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[21] This study has been published in abstract form Stacpoole-Shea, S., Walden, G., Villarreal, E., Gitter, A., Lavery, L & Armstrong, D. (1999) Could seamed socks impart unduly high pressure to the diabetic foot? (Abstract) *Diabetes, 48(S1) A17.* This study is cited and discussed in: Cavanagh, P. R., Ulbrecht, J. S., & Caputo, G. S. (2001). The biomechanics of the foot in Diabetes Mellitus. In J. H. Bowker & M. A. Pfeifer (Eds.), *Levin and O'Neal's The Diabetic Foot* (6th ed., pp. 125-196). St. Louis: Mosby Inc.

compared against the sock with a knitted seam (seamless sock) (*SmartKnit*: Knit-rite Inc., Kansas City, KS). The F-scan™ In-sole Pressure Analysis System was selected to measure pressure in the experiment because its high resolution of four sensors per centimetre was found during pre-testing to be sufficient to identify the location of the seam. The Pedar™ system's sensor resolution of two sensors per centimetre was found during pre-testing to be insufficient to identify the location of the seam on the sock-seam sample.

The image of raw pressure data from the sock sample with a sewn seam compressed in the apparatus obtained during pre-testing using the F-scan™ software is presented in *Figure 13* and the seam area is clearly visible in the image. The F-scan™ sensors have been reported to have limitations on pressure measurement and that the limitations are temperature and time dependant due to the resistive ink method of sensor construction (Luo et al., 1998; Sumiya et al., 1998). However, due to the temperature stability afforded by the laboratory environment and procedural minimisation strategies to limit sensor activation time, these limitations were assumed negligible. A protocol error of 10% was accepted as a limitation of the unit of measures.

Procedures

A new sensor was utilised for each sock condition tested to take advantage of the standardisation achieved through factory equilibration. The system was calibrated and all software procedures were conducted as described in the User's Manual.

The socks were prepared for testing by removing their plantar surface therefore, exposing the seam freely for placement against the sensor and removing the material bulk of the upper sock portion. The sensor and the sock sample were 'sandwiched' between two flat and non-compliant 3mm thick metal plates and the apparatus is presented diagrammatically in *Figure 14*. Two non-compliant surfaces were utilised due to the assumption that the inner of a shoe and bony prominences on the foot are non-compliant. A 65 kg mass applied vertical mass to the apparatus[22]. Sixty-five kilograms was selected to represent the applied force of an adult body mass. Sensor data were captured using the default sensing thresholds from five trials of eight seconds each at the default sampling frequency of 50 Hertz for each sock condition.

[22] As the acceleration was zero it is substituted with gravity in the calculation of force and therefore pressure: F=mg.

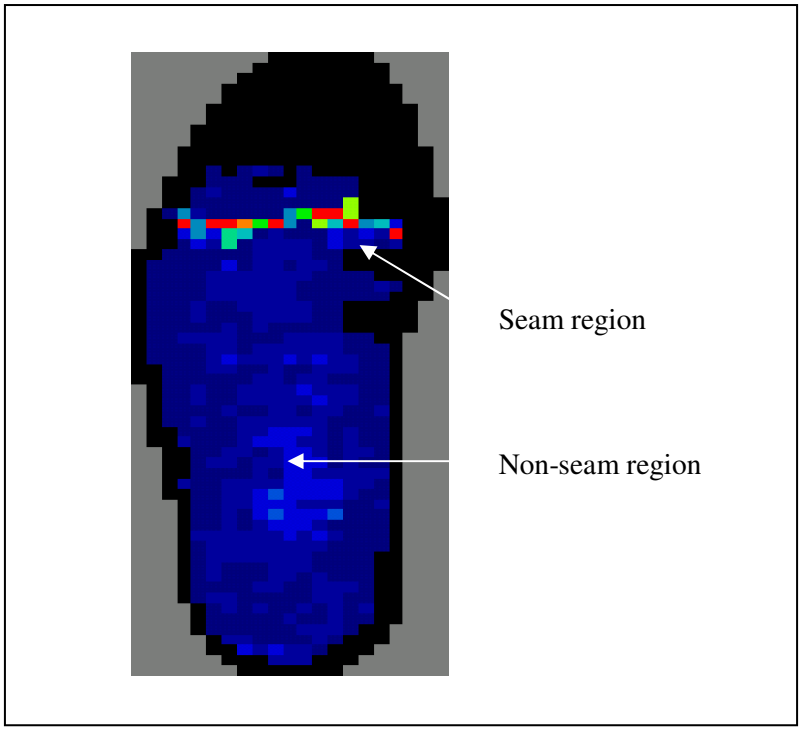


Figure 13. Image of raw pressure data as obtained from a sock sample under load using the F-scan™ system and software.

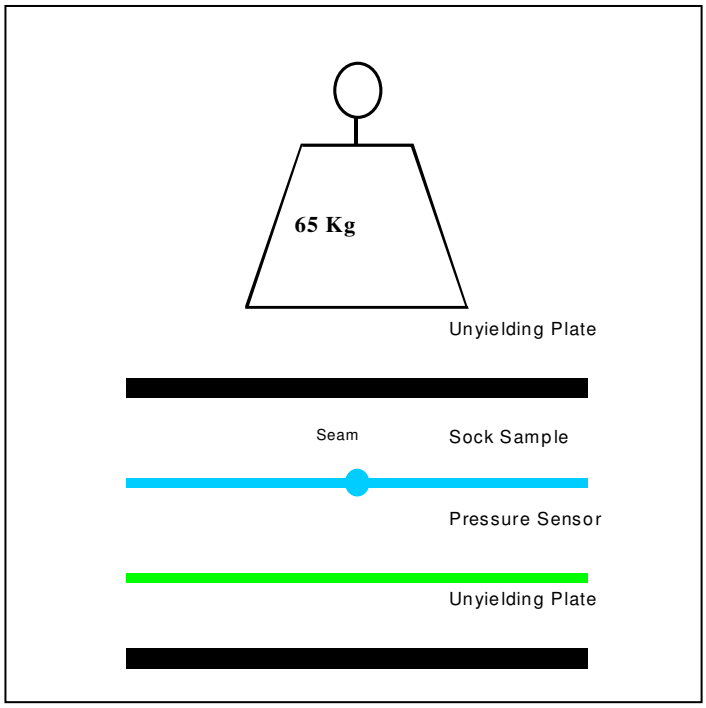


Figure 14. Diagram of the sock sample testing apparatus.

Data analysis

The seam area and a non-seam area of each sock sample were identified and were 'boxed' to create an object file for analysis. To facilitate identification of the knitted seam a preliminary data collection was carried out with a matchstick placed adjacent to the seam. Peak pressure data were analysed over a standardised area using the F-scan™ 4.11[23] software at three time points from the eight seconds of continuous data collected for each trial and exported into Excel for spreadsheet preparation and calculation of descriptive statistics.

Results and discussion

The results support the anecdotal clinical evidence that a sock seam can lead to a focus of high pressure. Sewn seams were found to form a region of high localised pressure as demonstrated in the raw data image shown in *Figure 13* and the three dimensional image provided by the F-scan™ software and shown in *Figure 15*. The magnitude of the pressure measured at the sewn seam was found to be 1000% (ten times) that measured at the non-seam areas of the socks and this is shown in *Figure 16*. The pressure measured at the sewn seams was slightly higher on the therapeutic sock compared to that of the supermarket sock and this is attributed to the physically thicker material and seam of the therapeutic sock. The pressure measured at the knitted-seam region was found to be equivalent to the non-seam areas of the socks. The level of pressure measured under load at the seam (438.2 and 394.4 kPa) is less than was reported to correspond with known peak pressures on the plantar foot in persons with neuropathy and diabetes (700 kPa) (Armstrong, Peters et al., 1998). Whether the level of pressure recorded at the seam is sufficient to cause ulceration to the foot remains unknown and further in-shoe pressure testing of the dorsal and lateral foot is recommended.

[23] Tekscan, Boston USA

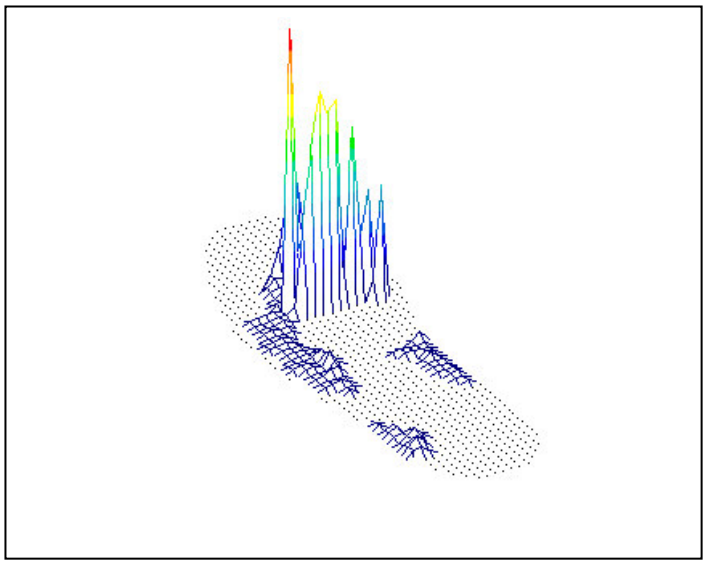
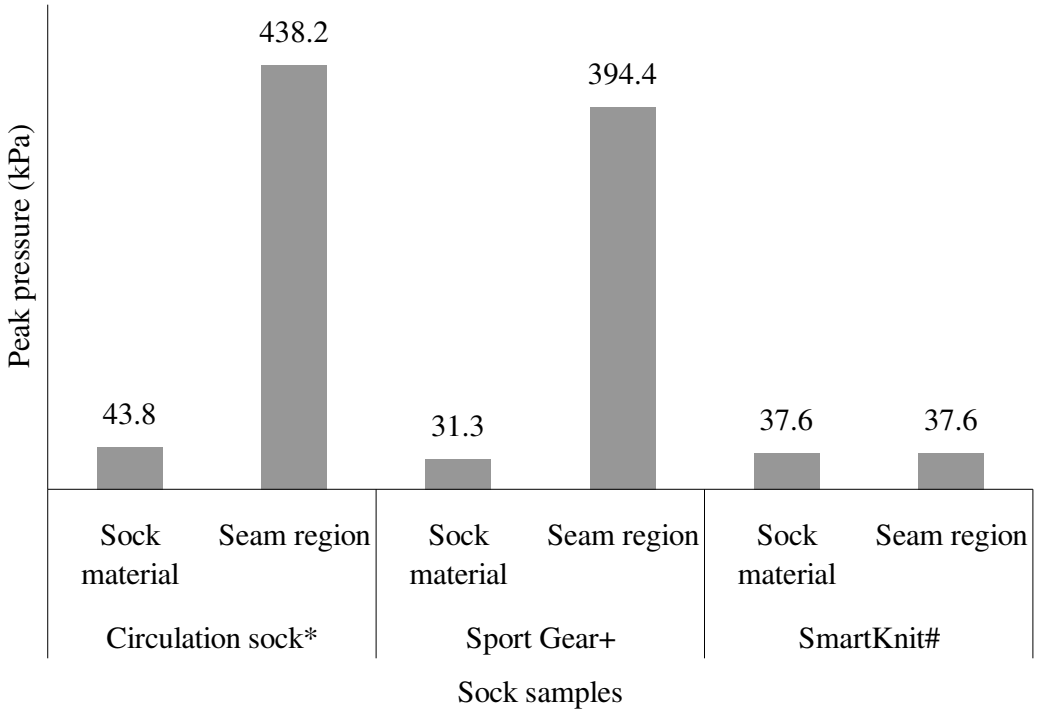


Figure 15. Three-dimensional image of the magnitude of localised pressure measured at the seamed area of the sample when the sock was under load.



*Red Robin, Melbourne Australia, +Fruit of the Loom, Mt. Airy USA, #KnitRite, Kansas USA

Figure 16. Pressure measured at the seam and sock regions of two therapeutic and one supermarket socks.

Conclusion

The results of this experiment verify that the bulk of a sewn sock seam can form a region of localised high pressure and that this pressure is of the magnitude of ten times that afforded by the sock material and a knitted seam. Even though the results provide sufficient evidence to logically suggest that the standard sock for in-shoe testing should be seam-less, the experimental design limits the general applicability of these experimental results to the foot-shoe environment due to two main factors. The first factor is the loading of the sample with a single and constant mass and, the second factor is the measurement obtained from between two rigid and non-compliant surfaces as opposed to the realistic environment being one non-compliant (shoe) and one soft or compliant surface (foot). Therefore, to more realistically determine any potential effect on pressures from a sock seam, these limitations are minimised in the following experiment.

Localised pressure and sock seams under increasing applied loads [24]

Rationale and purpose

For a sock seam to form a localised area of high pressure on the foot, it would need to be firmly trapped against the skin, and a firm shoe would generally provide the trap. The firmness of the trap provided by the shoe would be likely to vary depending on the action of the foot during different phases of the gait cycle and due to the seam being absorbed into the soft (semi-compliant) flesh of the foot when trapped against the firm (non-compliant) shoe. The previous experiment was limited in its general applicability for making inferences to the injury potential role of the sock seam on a foot within a shoe due to testing a single sustained pressure and utilising two non-compliant surfaces. Therefore, the purpose of this experiment was to explore the limitations of the previous experiment by applying incremental pressures to seam and seamless sock samples compressed between a semi-compliant and a non-compliant surface.

Method

A bench-based test was designed to address the purpose of study.

Socks were eligible for inclusion if they were marketed as therapeutic to the diabetic population. Four socks were eligable for inclusion in the study. Three socks with sewn seams (seamed socks) (*Sport Gear*, Fruit of the Loom, Mt. Airy USA; *BlisterGuard*, PTFE, New York USA & *TheraSock-Double sock system,* TheraFoot Technologies, Kansas USA) were compared against a sock with a knitted construction (seamless sock) *(SmartKnit,* Knit-Rite Inc., Kansas USA). The *Sport Gear* and *SmartKnit* socks were of similar and the thinnest fabric composition, the *BlisterGuard* were the thickest, while the *TheraSock-Double sock system* were a similar thickness and composition to *Sport Gear* and *SmartKnit* socks but had two layers sewn together. The *BlisterGuard* and *TheraSock-Double sock system* socks had the thickest seams, the *Sport Gear*

[24] This study was presented in poster format: Stacpoole-Shea, S., Walden, G., Villarreal, E., Harkless, L. & Shea, G., (2000, March) *What are the effects of incremental pressures on the pressure exerted from sock seams?* Poster session presented at The Diabetic Foot, Conference of the Australian Podiatry Council, Sydney, Australia.

sock had the thinnest seam, while the *Smart Knit* sock seam was indiscriminatable to the surrounding fabric.

Instrumentation and procedures

Pressure was measured with the F-scan™ In-sole Pressure Analysis System 4.12 as described in the previous experiment. Four sock samples were dissected as previously described and placed with a pressure sensor between a non-compliant and a semi-compliant surface associated with a mechanically driven and controlled compressed air pressure *Trublu*[25] device, and the testing apparatus and set up is shown in *Figure 17*. The semi-compliant material was 1.5 mm of PPT[26], which is described as an open cell polyurethane foam (McPoil & Cornwall, 1992). PPT was selected as it readily utilised in therapeutic footwear interventions to protect diabetic foot ulceration [McPoil, 1992 #1569]. Three trials were conducted with each sock sample under applied loads in increments of 100 kPa from 100 to 500 kPa. Each load was applied and maintained while the previous trial's data were labelled and then data collected to standardise the time that the sensor was active to minimise creep. These loads were chosen as they were the minimum increments available on the *Trublu*[27] device. Data were collected for eight seconds for each trial. The samples were placed in the device such that the inner sock and seam were directly against the pressure sensor and then the semi-compliant surface. This arrangement was intended to mimic a sock seam pressed against the foot (semi-compliant surface) within the shoe (non-compliant surface) A protocol error of 10% was accepted as a limitation of the unit of measures and study design.

Data analysis

Areas of the midfoot (baseline) and forefoot encompassing the distal sock and sock seam of each sock's image data were identified for pressure measure analysis. Peak pressure data were analysed over a standardised area with the F-scan™ 4.12 software from the midpoint from the eight seconds of data collected for each trial and exported into Excel for presentation.

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[25] Novel Incorporated, St Paul USA

[26] Professional Technology Incorporated, Deer Park USA

[27] Novel Incorporated, St Paul USA

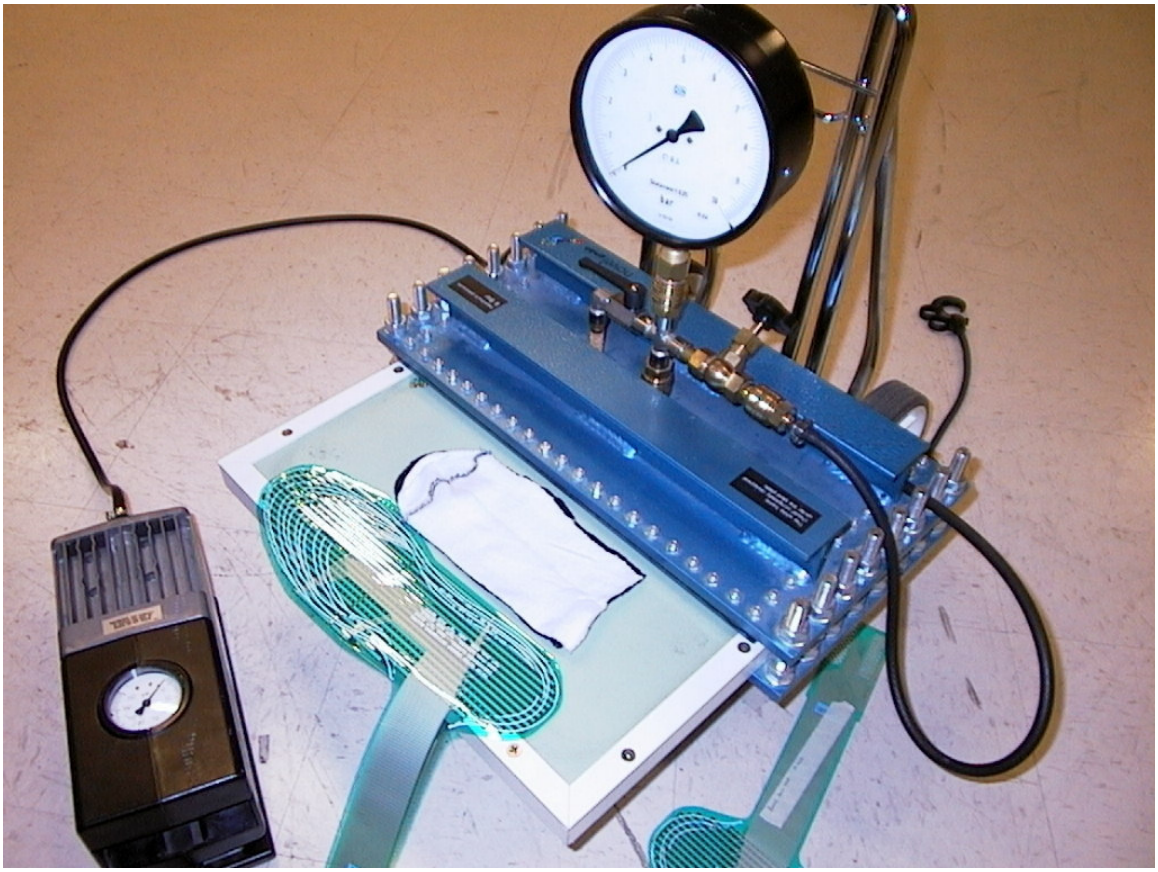
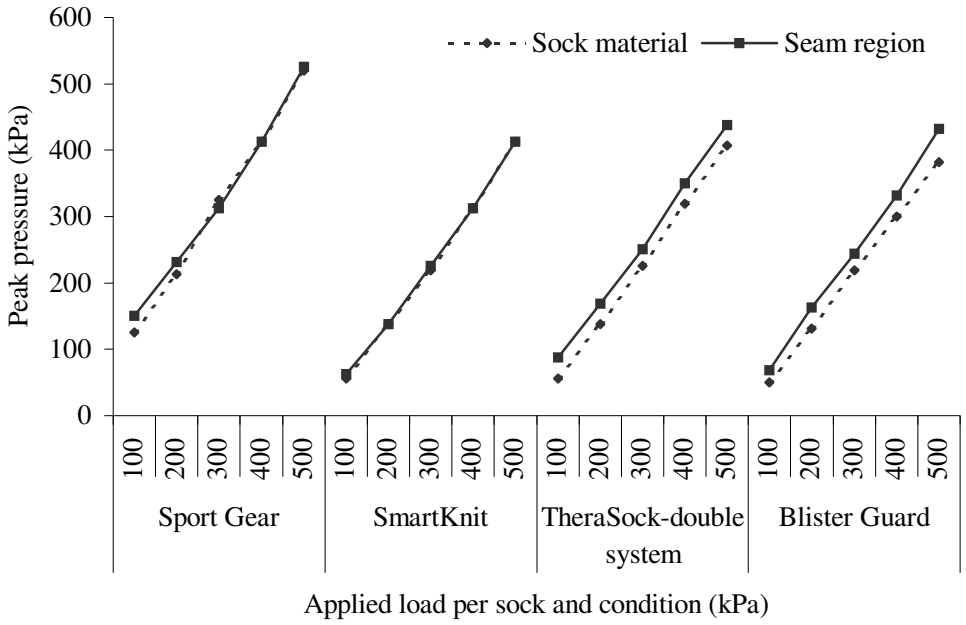


Figure 17. Testing set up utilising a mechanically driven and controlled compressed air pressure Trublu™ device, the pressure sensor insole matrix and the sock sample (the semi-compliant material is not shown in the photograph)

Results

The results are presented in *Figure 18* and it shows that the pressures measured at the seam and no-seam area increased proportionally as the applied pressure was also increased. The sock with the knitted seam, and therefore, no detectable increase in fabric bulk, showed minimal difference at the seamed and non-seamed site at each incremental rise in applied pressure. The *Sport Gear* sock that was made of the thinnest fabric showed a difference in pressure at the lowest applied pressures, but this difference dissipated at the higher pressures. Both the *TheraSock double system* sock and the *BlisterGuard* sock showed a difference between the seam and the non-seamed areas at each of the incremental pressures, with the seam area consistently showing a higher pressure.

The percent difference between the seam and no-seam areas during testing did not reach above 60% and the highest difference was found at the lowest pressure (100kPa) for the TheraSock Double system sock.



Legend: *Sport Gear*, Fruit of the Loom, Mt. Airy USA; *SmartKnit*, KnitRite, Kansas USA; *TheraSock double system*, TheraFoot Technologies, Kansas USA; *Blister Guard*, PTFE, New York USA.

Figure 18. Peak pressure as measured on each sock condition at each applied load.

Discussion

The results of this experiment at low pressures are in agreement with the previous study, except that the pressure difference between seamed and non-seamed areas in seamed socks was substantially less. The lower difference is most likely explained by the change in the experimental design that included the semi-compliant material. The semi-compliant material provided cushioning which was sufficient to accommodate the seam-bulk and the compliant material fully embedded the seam after 300kPa of applied pressure in the seamed sock with the thinnest fabric. However, the semi-compliant material was insufficient to embed the thicker seams in the thicker fabric socks (BlisterGuard and TheraSock double sock) and their seams formed an area of localised higher pressures throughout the range of pressures applied. The TheraSock double

system sock showed the densest seam (being four layers of fabric sewn together) and was the least embedded by the cushioning thus showing the highest percent difference of all sock conditions and pressures tested.

The absorption of the seam by the semi-compliant material provides insight into the potential effect that the trapping of a seam against the compliant tissue of the foot by a shoe would have. The results of this experiment raise questions to the validity of the current sock prescription and education practises for people with diabetes and further study is warranted.

Conclusion

This experiment showed that having one semi-compliant surface rather than two non-compliant surfaces reduced the severity of the pressure increase at the seam to less than 60% more than the non-seam area compared to the 1000% increase found in the previous experiment. Different applied pressures also influence the pressures measured on different seams and fabrics.

Chapter summary

The use of padded socks as a cushioning device to protect the plantar foot from high plantar pressures is unsubstantiated when the results of the thesis study are viewed in light of the uncertainty analysis results found in Chapter Three. The results of this chapter did not find evidence to agree with Research Question Two (a). However, the consequences of the practice of educating people with diabetes to wear padded socks to protect their feet may in fact potentially lead to injury if the thick sewn seam became trapped between the foot and the shoe. The results of the two experiments on sock seams, especially suggest that a sock seam trapped against a foot by a shoe (non-compliant) is more of a concern over bony prominences (non-compliant) than other more fleshy parts of the foot (semi-compliant). Therefore, until pressure threshold levels are identified at which skin integrity becomes compromised and these results can be verified, potentially feet may be being placed at risk by wearing padded (thick fabric) socks with sewn seams. Consequently, to minimize potential risk to the subjects who participate in the thesis studies, the seamless sock was selected as the standard-testing sock.

CHAPTER SIX

PROTOCOL SAFETY, VERIFICATION OF SUBJECT-CONTROLLED GAIT CONSISTENCY AND DEFINING TEMPORAL-GAIT PRESSURES IN A DIABETIC POPULATION

Rationale and purpose

This chapter reports the results of the initial investigation into in-shoe plantar pressure measurement during walking gait in adults with diabetes. The study was designed to test Research Question Two (b) and address three aims. The first aim was to test the in-shoe pressure measurement protocol for foot safety, because if the procedures were to pose a foot injury risk, and were utilised in a neuropathic population, then the subjects could potentially incur injury that could begin the sequelae towards ulceration, infection, limb amputation and even death. Foot injury risk was defined as interruption to the skin, that would take the form of blistering, abrasion or cut.

The second aim was to verify that walking gait spatial and temporal measurement variables were consistent for the population when subjects self-selected and controlled their comfortable walking gait during the in-shoe plantar pressure measurement procedures. The Pedar™ system does not contain instrumentation to verify the distance travelled during testing and therefore, the consistency of spatial and temporal gait measures is not known. Lack of verification of spatial and temporal gait measurement variables during in-shoe plantar pressure measurement is indirectly supported by the literature. Specifically, pressure measure's reliability was not affected by speed when controlled by a treadmill (Kernozek et al., 1996), variability in temporal variables was a normal component of mid-gait walking (McPoil et al., 1999), and gait velocity variation was

acceptable within ± 10% in people with diabetes and neuropathy (Cavanagh et al., 1998). However, investigation to validate the assumption that walking gait temporal and spatial variables are consistent when the subject self-selects their comfortable walking pace during in-shoe plantar pressure measurement procedures was conducted for good practice.

The third aim explored in-shoe plantar pressures beyond the absolute value convention to define the pressures measured as a function of stance time. Chapter Three Part I showed that it is the convention that in-shoe plantar pressure results are described in terms of the peak absolute value recorded during each step without regard to time. There is ample literature that concurs with the assumption that high peak pressures are associated with forefoot ulceration. However, an absolute peak pressure threshold value, above which ulceration will occur, has not been established, suggesting that measures other than the peak, may be related to ulceration occurrence (Armstrong, Peters et al., 1998).

Data presentation and description conventions from other gait analysis tools, specifically kinetic, kinematic and electromyographic methods, differ from plantar pressure analysis, in that rather than compare the absolute peak values, their results are often graphed as they relate to time. These results are co-plotted to enable comparisons to be made with reference data, which is generally from a baseline or healthy population (for example see (Craik & Dutterer, 1995; Winter, 1991)) Recently, the pattern that peak plantar pressure results as related to stance time has provided insight into pressure with neuropathy and ulceration (Maluf & Mueller, 2003). Therefore, the pattern of peak plantar pressure as it relates to stance time was defined and for cross-validation with the literature, plots of measures of the pattern of force and mean pressure were produced.

Subjects

A convenience population of eight subjects who were diagnosed with diabetes, but without peripheral neuropathy or a history of plantar forefoot ulceration volunteered to take part in the study. Potential subjects were informed about the study via a presentation about *foot health and diabetes* that was given by the author at a diabetes education session in the Dietetics Department at the Texas Diabetes Institute. Subjects who volunteered were briefly screened for inclusion at the end of the session and then an appointment time was made to confirm their eligibility. The Institutional Review Boards of the University of Texas Health Science Center and the University Health System gave approval for the study, and informed consent was obtained from all subjects prior to their participation.

Subjects were included if they were an adult with diabetes and were able to walk unassisted. Subjects were excluded if they had peripheral neuropathy as defined in Chapter Four; a history of foot ulceration, major trauma to the lower limbs or lower back, surgery to the feet, or if they had concurrent disease processes such as Parkinson's disease that limited their ability to walk consistently. All subjects who volunteered were eligible and consented to participate in the study and their positive decision was influenced by two incentives. The first incentive was that they would receive in-shoe plantar pressure assessment that was generally reserved for surgical patients and they would receive it free of charge. The second was that they would receive free of charge a pair of walking shoes.

The population of eight subjects (two men and six women), ranged in age from 43 to 60 years (mean 52, SD 6), height of 1.51 to 1.73 m (mean 1.62, SD 0.06) and mass of 65.91 to 113.64 kg (mean 94.09, SD 17.81). Body mass index (BMI) ranged from 26 to 50 (mean 36, SD 7), classifying three subjects as overweight (BMI 25-30) and five as obese (BMI>30) (Zeman, 1991).

Procedures

Data collection and processing

In-shoe plantar pressure measurement

Procedures for subject treatment, in-shoe plantar pressure measurement trial practice, data collection and processing and subject discharge that were developed in Chapter Three and those described in Chapter Four were conducted.

The subjects wore appropriately sized *SmartKnit* seamless socks and the standard *Nike* canvas shoes during testing.

External verification of spatial and temporal gait variables consistency when the subject controls for self selected natural walking

The subjects were fitted for in-shoe plantar pressure measurement and trials were practised and conducted where the subjects walked away from the data collection device over the laboratory floor beside the GaitMatt II™ (E. Q. Incorporated, Chalfont, PA) walkway for the distance allowed by the Pedar™ system umbilical data collection cord. For spatial and temporal gait

variable testing, the subject then returned to the starting point by walking over the GaitMat II™ walkway.

GaitMat II™ is a system for measuring the spatial and temporal variables of gait. It consists of a walkway with pressure sensitive switches embedded in its surface. The system recorded steps while the subject walked on the walkway. At least two left and two right steps were recorded for each subject for each trial. Five trials were conducted and by convention the first trial was not included in the analysis (Pederson & Gore, 1994). The investigator visually observed each trial and any trials that included irregular steps or a stumble were repeated. All steps recorded were included in the analysis.

The default sampling interval of five milliseconds (frequency = 200 Hz) was selected for measurement of gait variables. The variables and their measurement units were step length, stride length and support base in metres (m), and step time, swing time, stance time, single support time and double support time in milliseconds (ms), and average velocity in metres per second (ms^{-1}). The GaitMatt II™ output that defines the measurement of the spatial variables is presented in *Figure 19*. The GaitMatt II™ output that defines the measurement of the temporal variables are presented in *Figure 20* and *Figure 21*. Average velocity (ms^{-1}) was calculated by the following formula:

Velocity = (last contact distance - first contact distance) / (last contact time - first contact time)

Statistical analysis

Absolute value analyses

The peak pressure and pressure-time integral absolute values measured for each step and for each limb obtained from in-shoe plantar pressure measurement with the Pedar™ system and the spatial and temporal gait variables obtained from each trial from the GaitMat II™ system were examined for and confirmed as being normally distributed using proportion probability (P-P) plots with the proportion estimated using the Rankit formula. Descriptive statistics were calculated for the in-shoe plantar pressure measurement variables of peak pressure and pressure-time integral for the whole foot and the anatomical regions of the hallux, 1MPJ and 2-5MPJ and heel regions. Even though the not all of these variables were identified as useful for ulceration location identification in Chapter Three, they are included to allow comparison of the study results with the reported

literature. Descriptive statistics were also calculated from each trial for the spatial and temporal measurement variables of step length, stride length, support base, step time, swing time, stance time, single support time, double support time, and average velocity. The GaitMatt II™ variable means were examined for between-trial differences using a one-way analysis of variance (ANOVA) for repeated measures (3,1) function, and *post hoc* analyses were conducted using the Dunnett's T3 test. Dunnett's T3 test was chosen for *post hoc* analyses as it does not require the assumption of equal variances to be met as already discussed in Chapter Three (SPSS Incorporated, 1998).

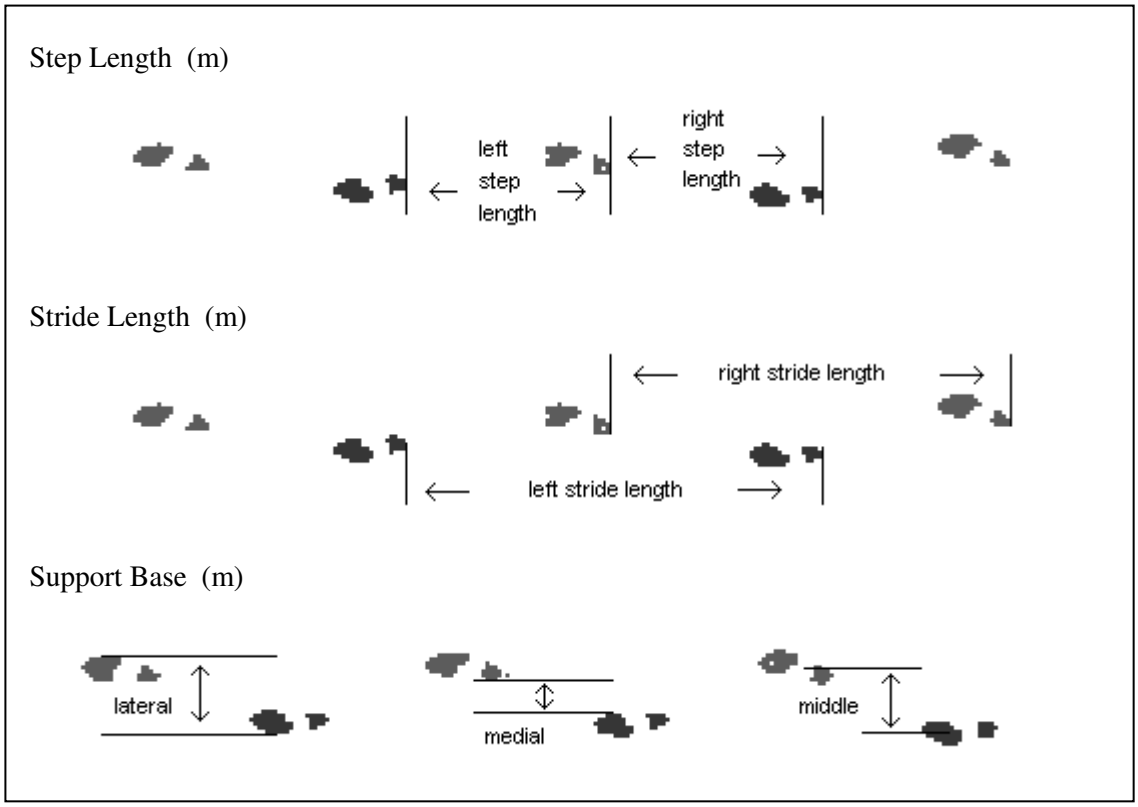


Figure 19. The definition of the calculation of the spatial variables as measured by GaitMatt II™.

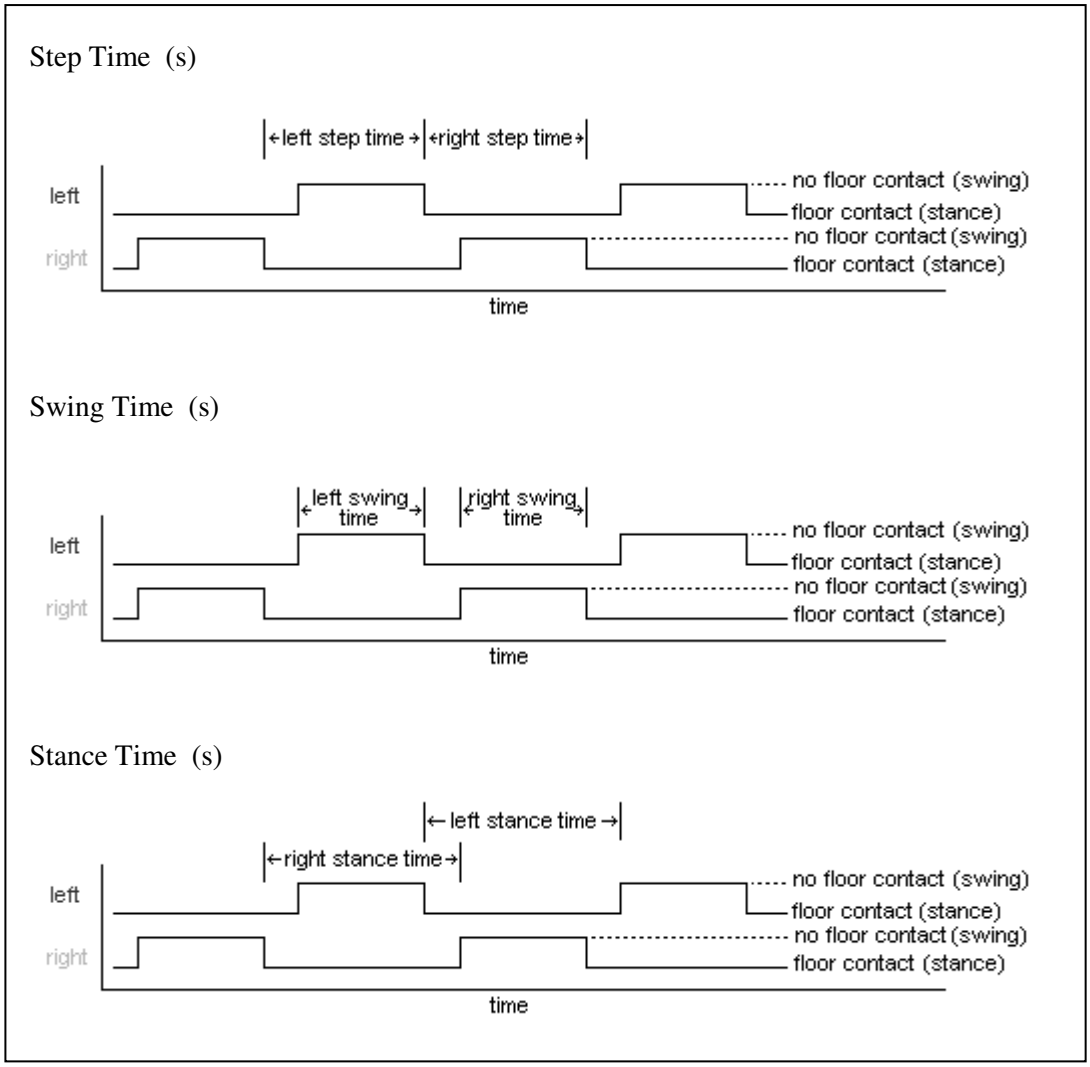


Figure 20. Definitions of the temporal variables of step, swing and stance time as measured by GaitMatt II™.

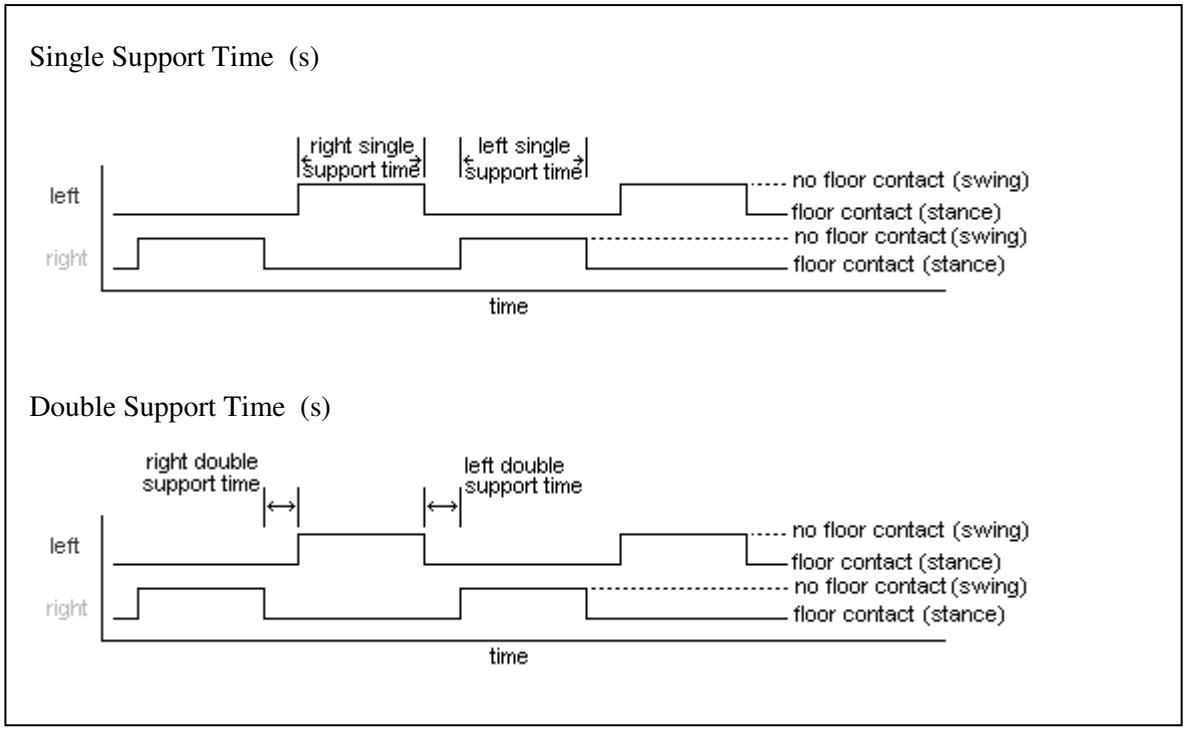


Figure 21. Definitions of the temporal variables of single and double support time as measured by GaitMatt II™.

Pressure-time analyses

The in-shoe plantar pressure absolute values measured for force, mean pressure and peak pressure at each 200 Hz data point of the percent-normalised stance phase of each step for each limb were averaged to create a representative step for graphical exploration. The average values (means) from the representative step were presented graphically bounded by their corresponding 95% confidence limits. Graphs were developed for three of the variables beginning with force to facilitate comparison with and validate the graphical result patterns of the present study with the reported literature. The graphs of the mean pressure were then produced and used to describe the influence on the result patterns from the standardised area defined for each anatomical region. Finally the graph of the peak pressure was produced to describe the patterns that reflected the area defined by an individual sensor and therefore, potentially ulceration.

Confidence limits for continuous data are generally constructed using the joining of Gaussian theory based point-to-point confidence intervals, generally calculated from the 95% confidence interval of each mean value for each time point using the formula (Portney & Watkins, 1993 p646):

$$95\%CI = \overline{X} \pm (z)SD$$

However, the point-to-point statistical methods appropriate for the analysis of less complex single point measure data are inappropriate when applied to continuous curves of gait data. These methods ignore the fact that the curve is a series of related (not independent) points and these points are being considered simultaneously (Lenoff et al., 1999). To utilise single point statistical methods for examination of continuous data presented over percentage-normalised stance phase (with 100 time points), then a Bonferroni correction to the magnitude of 100 is required (Portney & Watkins, 1993, pp 406-407). However, a Bonferroni correction of that magnitude would result in the confidence limits being so broad as to be of little interpretative value (Lenoff et al., 1999).

A method for calculation of confidence bands appropriate for continuous curves of data is the bootstrap (Lenoff et al., 1999). The bootstrap is a re-sampling with replacement procedure that is applicable for continuous, or gait curve data from which prediction and confidence bands can be constructed and these are advocated for use for evaluating gait data curves (Davison & Hinkley, 1997; Efron & Tibshirani, 1993; Lenoff et al., 1999).

To calculate confidence bands using the bootstrap method, the data were ranked and replications of the ranked data values were repeatedly generated and means calculated (Zhu, 1997). All bootstrap calculations were performed in Excel and for each calculation, 1000 iterations of sampling with replacement were performed. The results of the calculations provided a pseudo population of 1000 cases closely representing the original data set and a curve was determined for each variable where only 2.5% (25) of the graphs crossed the curve at any point (Efron & Tibshirani, 1993). As the bootstrap method is dependant on random number generation, the validity of Excel random number generation was tested. The validity of 200,000 random integers (range 1-10) that were generated were analysed by SPSS using a one-way ANOVA with *post hoc* comparison (SPSS Incorporated, 1998). The random integers were not significantly different at the $p<0.05$ level (The smallest p-value determined by any *post hoc* comparison was 0.18 (std error 10.024)).

Results

Foot injury risk from in-shoe pressure measurement procedures

There were no instances of foot injury, discomfort or symptoms of potential foot injury reported by the subjects during data collection, nor reported to the clinic nurse in the two days after the data collection. There were no signs of injury or potential injury identified by the author during the foot inspection at subject discharge.

Verification of spatial and temporal variable consistency when the subject controls for self selected natural walking

The descriptive statistic results for spatial measurement variables per trial are presented in Table 26, while the temporal measurement variables per trial are presented in Table 27. The descriptive statistic results show, and the lack of statistical significance ($p<0.05$) shown by the ANOVA and *post hoc* analyses confirm, that the walking gait of this sample population was highly consistent. For all variables, the means of each trial were consistent and did not vary greater than ±10%.

In-shoe plantar pressure measurement

Absolute value analyses

The absolute values measured for the variables of peak pressure and pressure-time integral over the whole foot and defined anatomical regions were examined descriptively for each limb and the population results are presented in Table 28.

Table 26

Results for spatial measurement variables from four trials. The 'trial number' represents all steps for all subjects (n=8) for that trial.

Variable & ANOVA significance	Trial number*	Mean	SD	Min	Max
Step length (m)	2	0.57	0.07	0.41	0.68
p=0.34	3	0.58	0.06	0.43	0.68
	4	0.59	0.06	0.43	0.68
	5	0.60	0.06	0.44	0.70
Stride length (m)	2	1.13	0.13	0.84	1.33
p=0.30	3	1.15	0.12	0.87	1.33
	4	1.17	0.12	0.90	1.37
	5	1.20	0.11	0.94	1.38
Support base (m)	2	0.26	0.05	0.15	0.34
p=0.70	3	0.27	0.04	0.18	0.33
	4	0.25	0.05	0.16	0.34
	5	0.25	0.06	0.15	0.38

*By convention, the first trial was excluded from analysis, leaving trials numbered two to five for analysis (Pederson & Gore, 1994).

Table 27

Results (n=8) for temporal measurement variables from four trials .

Variable & ANOVA significance	Trial number*	Mean	SD	Min	Max
Step time (s)	2	0.55	0.06	0.45	0.64
p=0.99	3	0.55	0.05	0.44	0.64
	4	0.55	0.06	0.44	0.66
	5	0.55	0.04	0.46	0.61
Swing time (s)	2	0.37	0.04	0.29	0.44
p=0.85	3	0.38	0.05	0.26	0.44
	4	0.38	0.06	0.27	0.46
	5	0.38	0.04	0.28	0.44
Stance time (s)	2	0.73	0.07	0.63	0.86
p=0.71	3	0.73	0.06	0.59	0.83
	4	0.71	0.07	0.61	0.83
	5	0.71	0.06	0.61	0.81
Single support time (s)	2	0.37	0.04	0.29	0.44
p=0.85	3	0.38	0.05	0.26	0.44
	4	0.38	0.06	0.27	0.46
	5	0.38	0.04	0.28	0.44
Double support time (s)	2	0.18	0.03	0.14	0.24
p=0.12	3	0.17	0.02	0.14	0.23
	4	0.16	0.02	0.12	0.20
	5	0.16	0.03	0.12	0.22
Velocity (ms^{-1})	2	1.01	0.11	0.85	1.21
p=0.08	3	1.05	0.12	0.89	1.27
	4	1.08	0.10	0.92	1.21
	5	1.10	0.12	0.92	1.27

*By convention, the first trial is excluded from analysis, leaving trials numbered two to five for analysis (Pederson & Gore, 1994).

Table 28

Results from absolute value analyses for peak pressure and pressure time integral (n=8).

Variable	Anatomical region	Mean	SD	Min	Max
Peak pressure (kPa)	Total foot	339.85	36.86	252	405
	Hallux	313.64	37.89	223	379
	1MPJ	230.26	37.52	156	302
	2-5MPJ	223.99	25.58	155	266
	Heel	207.50	18.71	164	244
Pressure-time integral	Total foot	123.40	8.52	106	143
(kPa s)	Hallux	72.10	13.08	48	100
	1MPJ	61.44	10.60	42	85
	2-5MPJ	64.76	7.29	47	80
	Heel	56.11	7.60	43	78

Pressure-time analyses

Graphs were plotted for the force, mean pressure and peak pressure over percentage-normalised stance time. The means and the 95% confidence limits derived from the point-by-point and the bootstrap methods are presented on the same graphs to illustrate the two methods. The result for peak pressure-total over percentage-normalised stance time for limb 13 was erroneous due to a processing error and was discarded leaving 15 limbs for analysis. The variability between individual limb results are presented using the force-total for all limbs in *Figure 22* and for the sample mean in *Figure 23*. The mean results calculated using the point-by-point and the bootstrap methods are very similar, leaving the plots of these curves indistinguishable and presents as a bold continuous central line, which is in fact two lines (a dashed and a continuous line) very slightly offset. For all graphs, the 95% confidence point-by-point limits are shown in the outer dashed lines and the bootstrap bands are shown in the continuous outer lines. In both *Figure 22* and *Figure 23*, the bootstrap bands are larger (and therefore, wider) than the point-by-point limits, which confirm that the bootstrap method provides a more conservative estimate of the 95% confidence limits than the point-by-point method.

The variability in the pattern of foot loading between limbs is shown in *Figure 22* and this variability is reflected in the width of the point-by-point limits and bootstrap bands plotted on the mean from each time point that is shown in *Figure 23*.

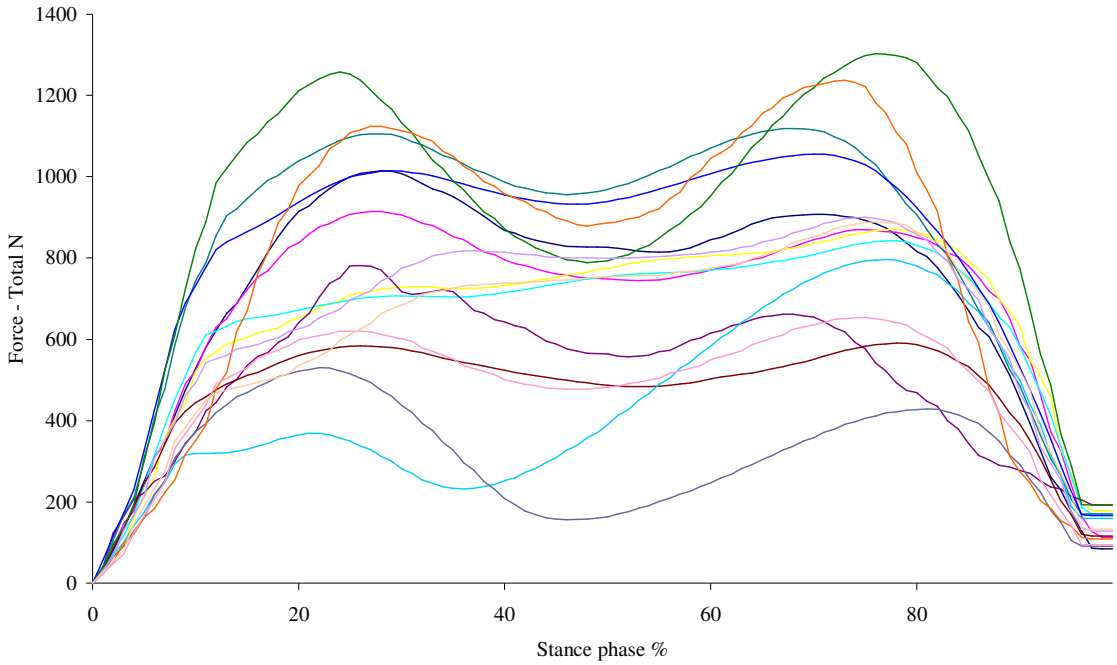


Figure 22. The 16 individual limbs (n=8) results for force over the whole foot (total) during percentage-normalised stance time shows the variability associated with individual subjects when walking.

The graph of force on the whole foot (total) over percentage-normalised stance time presented in *Figure 23* shows the double hump shape that is typically expected (Craik & Dutterer, 1995; Winter, 1991). The first hump represents the higher deceleration force that arrises from the limb impacting the ground at the end of swing phase, the following dell represents the lower force that relates mainly to body mass and gravity, while the second hump represents the higher acceleration force that arrises from the limb pushing off the ground. The 95% confidence limits and bands show that with 95% surety, the population mean will fall within approximately plus or minus 200 Newtons of the calculated mean through midstance phase, and that the limits and bands are narrower at the initiation and termination of gait than during midstance.

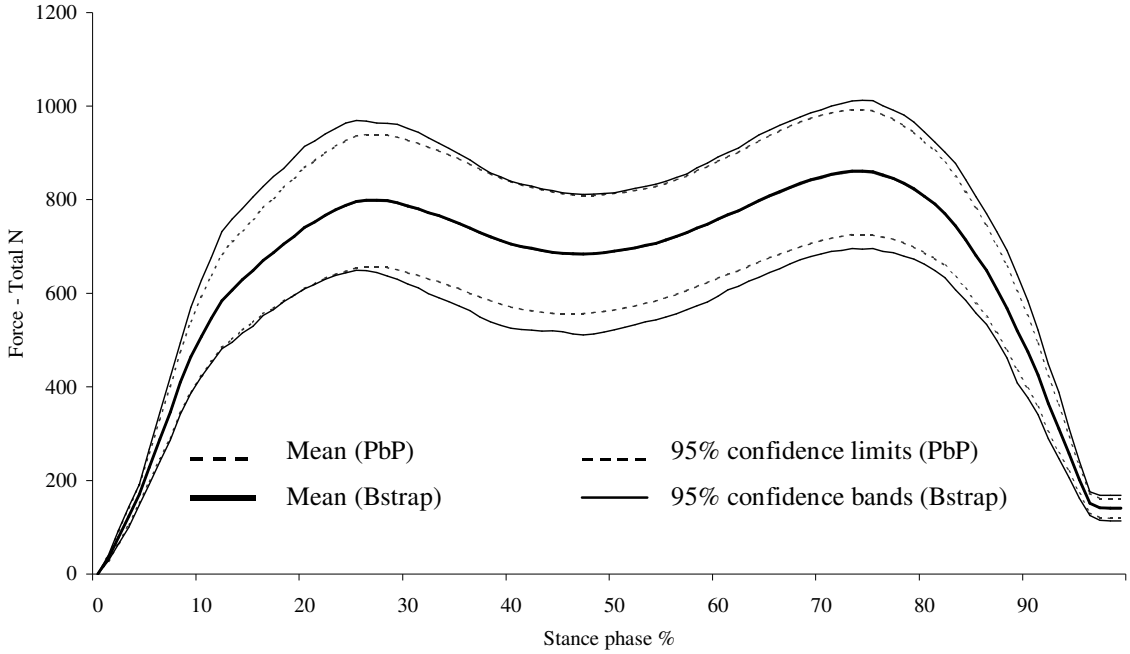


Figure 23. The means and confidence bands calculated using both the point-by-point (PbP) and bootstrap (Bstrap) methods for force over the whole foot (total) (n=8).

The force graphs over percentage-normalised stance time in Newtons for the means (PbP and Bstrap) and 95% confidence point-by-point limits and bootstrap bands for the defined anatomical regions are presented in *Figure 24*. These graphs illustrate the shapes formed from the results of the means and confidence limits for forces when measured over each anatomical region during percentage-normalised stance time. These results are presented to describe the forces that are measured over the defined anatomical regions of the plantar foot as they relate to time.

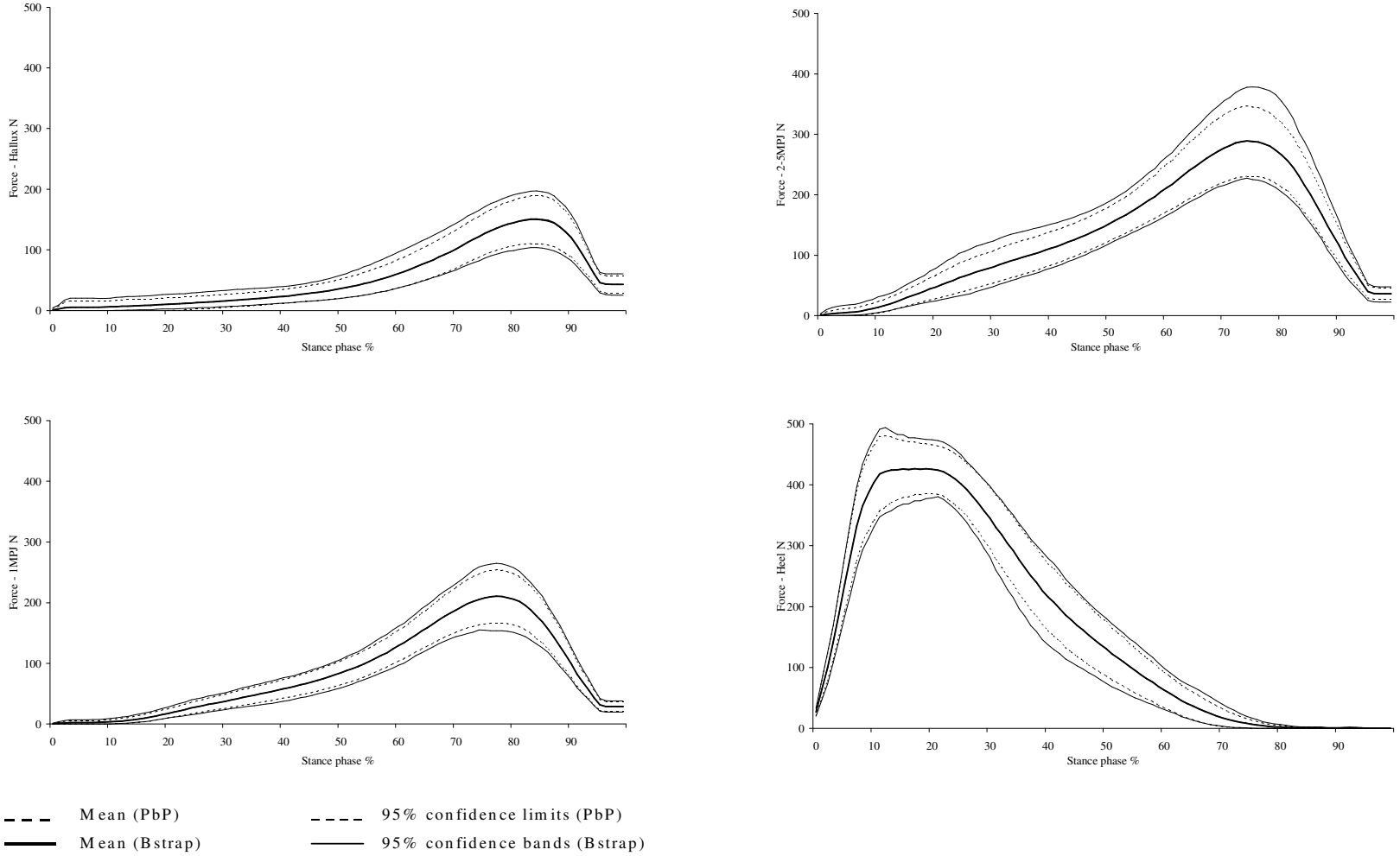


Figure 24. The means and 95% confidence point-by-point (PbP) limits and bootstrap (Bstrap) bands for force on the hallux, 1MPJ, 2-5MPJ and heel over percentage-normalised stance time (n=8).

The force on the hallux shows that even though the hallux would not be on the ground, there is a small force is measured there at the initiation of stance phase immediately after the heel contacts the ground. This small force is most likely due to force on the foot from the shoe rather than from the ground and alerts the author to the limitation of describing the specific origin of the results when using the in-shoe plantar pressure measurement tool. However, being cognisant of this limitation, the force can be seen to very gradually increase until after midstance when more body weight is transferring from the rearfoot to the forefoot. The force peaks following heel lift and then rapidly reduces as the foot leaves the ground at the termination of stance phase.

The force on the 1MPJ region shows that the pattern of force through the 1MPJ region follows a similar pattern to the hallux but peaks and begins to reduce slightly sooner as the medial forefoot accepts maximum body weight for push off and termination of stance phase occurs.

The force on the 2-5MPJ region once again follows a similar pattern to both the hallux and 1MPJ except that the load increases at a higher and more constant rate from initiation until it peaks for push off and termination of stance phase.

The force on the heel shows that the force rapidly rises after stance phase is initiated. The force peaks after ten percent of stance phase and remains loaded until 25 percent when heel lift has begun and body weight begins to transfer from solely the heel to include the forefoot. The forces gradually reduce after this time until only a small amount remains after 70 percent of stance phase, which is most likely from the shoe rather than the ground.

The following figures illustrate the shape and confidence limits for mean pressures measured on each anatomical region over percentage-normalised stance time. The mean pressure-time points relate to the force-time points mathematically by the formula:

$$Pressure = Force/Area$$

The mean pressure-time graphs for the means (PbP and Bstrap) and 95% confidence point-by-point limits and bootstrap bands for the whole foot and the defined anatomical regions over percentage-normalised stance time are presented in *Figure 25* and *Figure 26*. The defined anatomical regions are standardised for area and therefore, the mean pressure-time graphs can be directly compared to the force-time graphs. Overall, the mean pressure-time graphs can be seen to follow similar patterns, although they are flatter than the force-time patterns.

The graph of mean pressure on the whole foot (total) over percentage-normalised stance time presented in *Figure 25* shows a similar double hump shape to that of the force. The main difference is that the first hump of the mean pressure is lower than the second. This is due to the large area of the heel, and therefore, higher number of sensors that are included in the average calculation process. The dell between the humps dips lower for the mean pressure than the force due to the large sensor area (whole foot) over which the force is divided by during midstance. The 95% confidence limits and bands show that with 95% surety, the population mean will fall within approximately plus or minus 20 kPa of the calculated mean through midstance phase, and that the limits and bands are narrower at the initiation and termination of gait than during midstance.

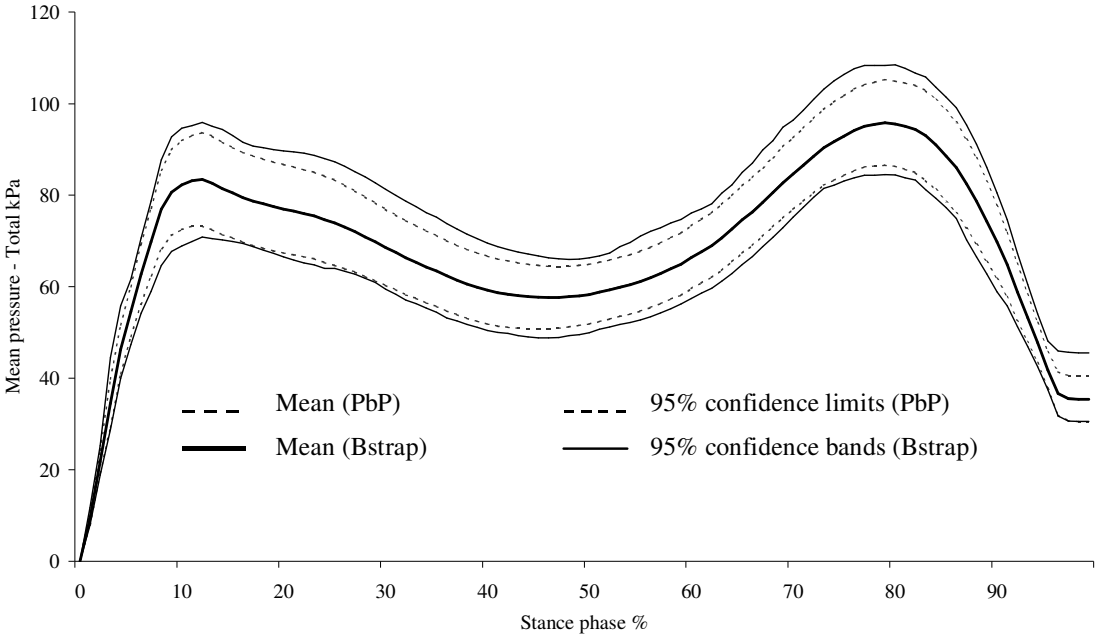


Figure 25. The means and 95% confidence point-by-point (PbP) limits and bootstrap (Bstrap) bands for mean pressure over the whole foot (total) over percentage-normalised stance time (n=8).

The mean pressure graphs presented in *Figure 26* show similar patterns to those of the force, with variations due to the large sensor area included in the average calculation process as discussed previously.

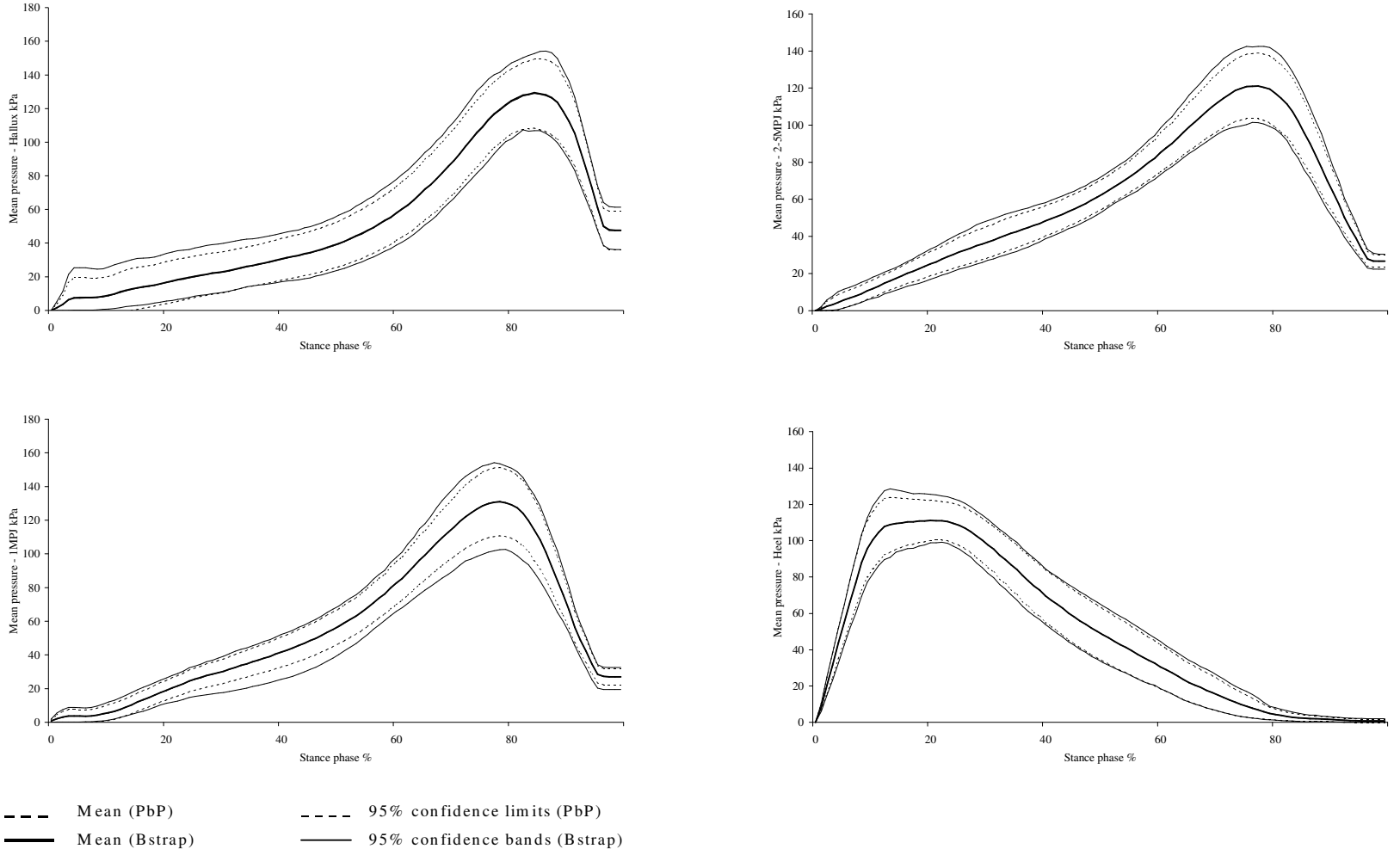


Figure 26. The means and 95% confidence point-by-point (PbP) limits and bootstrap (Bstrap) bands for mean pressure on the hallux, 1MPJ, 2-5MPJ and heel over percentage-normalised stance time (n=8).

The peak pressure graphs for the means (PbP and Bstrap) and 95% confidence point-by-point limits and bootstrap bands for the whole foot and the defined anatomical regions over percentage-normalised stance time are presented in *Figure 27* and *Figure 28*. These figures illustrate peak pressures as they relate to time and are constructed to form baseline patterns for utilisation in time-relative discussion in this and future studies of clinical populations. The peak pressure-time patterns differ from mean pressure-time patterns due to their relativity to specific sensors (sensor with the highest or peak measure) rather than being an average of several sensors. This site specificity can therefore, be utilised as baseline data to provide diagnostic insight into future studies of clinical populations with plantar foot ulcerations.

As shown earlier, once again the peak pressures over the whole foot shows the double hump pattern, as did the force and mean pressure results, except that the first hump is much lower than the second. This result reflects the lower peak pressure measured on individual sensors that are due to padded nature of the heel, which dissipates pressures over a larger area and thus more sensors. The second hump is higher relative to the first hump, due to the smaller and more prominent bony (MPJ and digits) areas over which pressure is measured. It is important to be cognisant of the fact that the pressures measured on the sensors is not different between the mean pressure and the peak pressure results, rather that the highest (peak) pressure measured by any one sensor is recorded as the measure rather than this result being tempered by the average (mean) pressure calculation process.

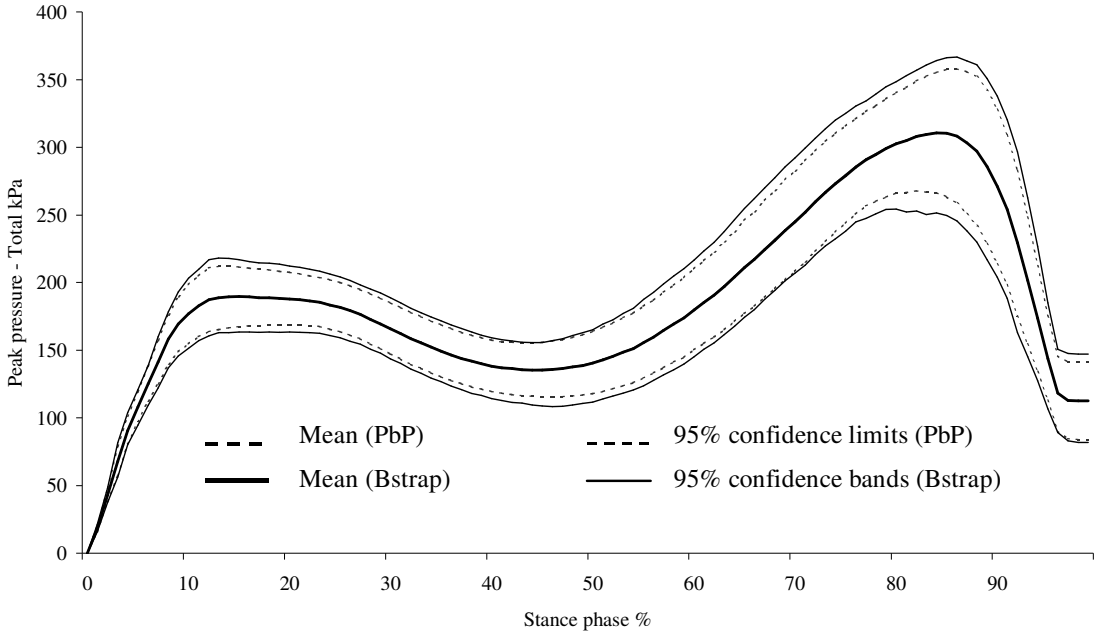


Figure 27. The means and 95% confidence point-by-point (PbP) limits and bootstrap (Bstrap) bands for peak pressure on the whole foot (total) over percentage-normalised stance time (n=8).

Once again the peak pressures on the hallux, 1MPJ, 2-5MPJ and heel follow similar patterns to the force and mean pressure, however due to their relativity to specific sensor recordings, they provide greater insight into the peak pressures actually experienced on the sites of the foot that are at risk of pressure related injury and ulceration.

The peak pressure plots presented in *Figure 28* show that there is pressure experienced on all regions of the foot throughout the whole of stance phase. The pressure on the hallux peaked at approximately 300 kPa, which is higher than the 1MPJ and 2-5MPJ that peaked at approximately 200 kPa and higher again from the heel, which peaked at approximately 175 kPa. The hallux results showed that the sample mean was within ±75 kPa with 95% surety, between 80 and 90 percent of stance phase, while the 1MPJ and 2-5MPJ means were within ±50 kPa and the heel mean was within approximately ±25 kPa.

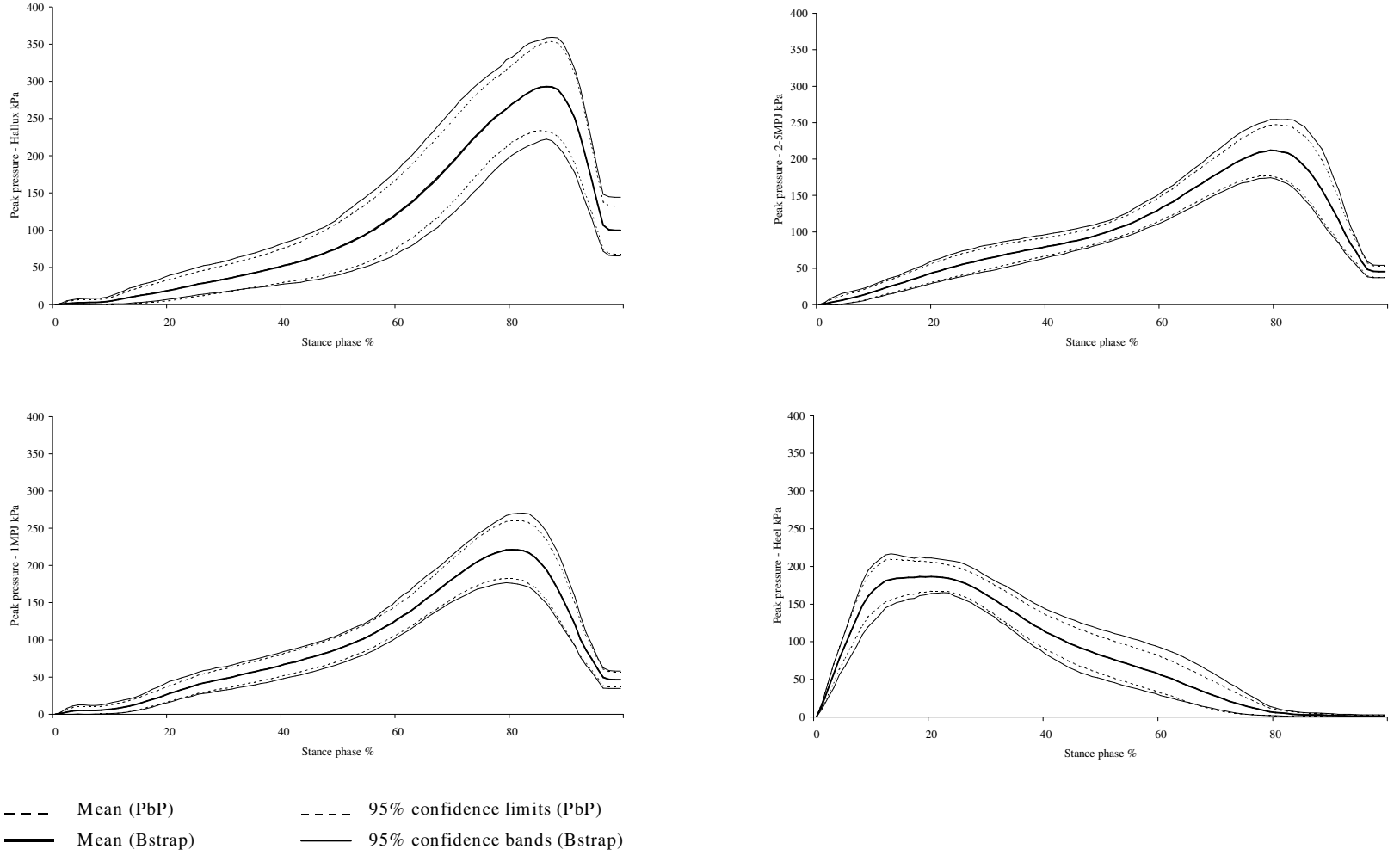


Figure 28. The means and 95% confidence point-by-point (PbP) limits and bootstrap (Bstrap) bands for mean pressure on the hallux, 1MPJ, 2-5MPJ and heel over percentage-normalised stance time (n=8).

Discussion

Protocol safety

The in-shoe plantar pressure measurement procedures as described in Chapters Three and Four was established as not posing a foot injury risk to a population of adults with diabetes. This sample was sought and tested due to their ability to self-detect both injury risk and potential. Even though shown to not pose an injury risk, these results cannot be generalised to the neuropathic population, because there may be injury risk that remains undetected and clinician test supervision is required.

Verification of spatial and temporal variable consistency when the subject controls for self selected natural walking

Gait temporal and spatial variables measured for this sample population were found to be highly consistent between trials and confirmed the assumption that gait is consistent when the subjects self-select their own comfortable pace during in-shoe plantar pressure measurement procedures. The present study population walked at the same velocity (Mean 1.06 ms^{-1}), but with a slightly smaller standard deviation (SD 0.11 ms^{-1}) during in-shoe plantar pressure measurement procedures than that reported by Muellar, Minor et al. (1994) (SD 0.19 ms^{-1}) for a diabetic population during kinematic study procedures. The present study population also walked with a stride length comparable to, but slightly less variable as reflected in the smaller standard deviation (Mean 1.16m (SD 0.12m) than that reported by Muellar, Minor et al. (Mean 1.20m (SD 0.23m)).

Based on the plus or minus ten percent velocity variation that was reported to be acceptable for the diabetic population studied by Cavanagh et al. (1998), the results from the present study procedures are acceptable. Therefore, external verification of temporal and spatial gait variables was not added to the procedures conducted for the studies to follow in this thesis.

In-shoe plantar pressure measurement

Absolute value analyses

Comparison between study reports in the literature is fraught with difficulty due to the lack of a standardised protocol, however, other than the different foot wear styles used, the population and

methods reported by Perry et al. (1995) are comparable to the present study and are therefore, utilised to cross validate the present study. Absolute value results from the present study and those reported by Perry et al. (1995) are presented for comparison in Table 29.

Table 29

Comparative mean (standard deviation) peak pressure absolute value results (kPa) from in-shoe plantar pressure analysis of adults with diabetes, but without neuropathy.

	Present study result n=8 (16 limbs: both feet data)	Perry, Ulbrecht, Derr & Cavanagh (1995) n=13 (13 limbs: right foot only data)	
Anatomical region	Canvas oxford shoe	Running shoe	Leather oxford shoe
Heel region	207.50 (18.71)	187 (24)	304 (45)
1MPJ region	230.26 (37.52)	292 (86)	392 (148)
Hallux region	313.64 (37.89)	180 (60)	274 (130)

Comparisons between the results from the two studies presented in Table 29 are made whilst being cognisant of the fact that different shoes were tested and the anatomical regions defined are not standardised. However, with these limitations in mind, the peak pressures measured on the heel region appear logical with the highest peak pressure being reported in the firm shoes (leather oxford), the lowest recorded in the padded shoes (running shoe) and the canvas oxford shoe, being soft but not padded, peak pressure measure falling between the other shoes.

The differences found between the mean results from the other two regions (1MPJ and hallux) reported by Perry et al. (1995) and the present study cannot be explained. The larger standard deviations reported by Perry et al. (1995) than the present study, potentially suggest that there are either true differences in the procedures for data collection or analysis between the studies, or that the populations are not homogeneous. Large standard deviations suggest that there is high variability within the data and the lack of a data validity checking procedure by Perry et al. (1995), as proposed in Chapter Three and utilised in the present study, would increase the variability of the data if inconsistent data were included in the final analyses. Alternatively, large standard deviations may also reflect highly skewed data, but the authors did not report testing for skewness.

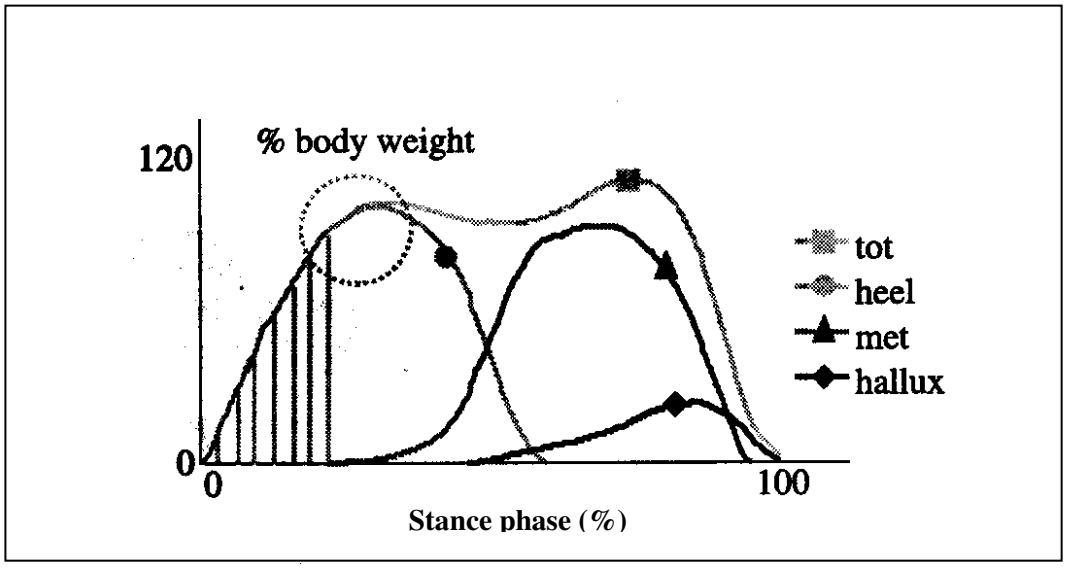
Even though there are differences between Perry et al. (1995) and the present study that remain unexplained, there are similarities within the methods and results that support cross validation. Therefore, with cross validation support for the absolute value results from the present study, the same results measured relative to time are assumed to be valid for discussion.

Pressure-time analyses

Both the means derived from the standard point-by-point and the bootstrap methods were graphed together in *Figure 23* to provide a crosscheck between the methods. Both the point-to-point and bootstrap means overlay, confirming the methods are comparable. The statistical predictive range of the 95% confidence bands (bootstrap) are wider than those derived from the point-by-point method as shown in *Figure 23* which confirms that the bootstrap method bands are more conservative (Lenoff et al., 1999). More conservative bands, translates to greater surety that the sample mean is representative of the population mean and can be used as a basis for clinical evaluation (Portney & Watkins, 1993).

To facilitate the comparison of, and therefore, cross validation of the present study results with that of Uccioli et al. (2001), their force-time graphs are reproduced in *Figure 29*. The force-time graphs from the present study follow comparable shapes to and are therefore, cross validated by those of the above authors. Both the total force results graphed by the present study and that of Uccioli et al. follow the double hump pattern that is widely accepted (Winter, 1991) and is a vector sum of the varying forces through the regional contact areas of the foot during stance phase (%).

As alluded to earlier, the classic representation of the force imparted onto the ground through the weight bearing foot during stance phase is confirmed by *Figure 29* and can be roughly described as following the shape of a stylised capital ‘M’. Therefore, the first hump formed by the plot of the mean in the graph describes the large decelerating force imparted onto the ground through the heel. The trough formed by the mean in the graph describes the smaller force imparted onto the ground as the body moves forward over the whole foot with the swinging of the other limb. The second hump, formed by the mean in the graph, describes the large acceleration force imparted onto the ground through the forefoot (1MPJ and 2-5MPJ) and ends as the hallux leaves the ground.



The dotted circle indicates the force values when other parts of the foot beyond the heel come in contact with the sensitive surface of the platform: the heel force curve shows no lack of continuity: From Uccioli, L., Caselli, A., Giacomozzi, C., Macellari, V., Giurato, L., Lardieri, L. et al, (2001) Pattern of abnormal tangential forces in the diabetic neuropathic foot. *Clinical Biomechanics, 16*, 446-454: Figure 5 p453.

Figure 29. An example of the ground reaction force under the foot of a healthy subject during percent-normalised stance phase.

The regional force-time graphs follow the patterns related to their loading during the stance phase. The heel force-time graph showed a large force as the heel contacted the ground and then the force petered off as the load transferred to the forefoot. The force-time graphs for the forefoot components also describe their action. The 2-5MPJ region showed that it initially accepted a small force while the full force continued to be born through the heel. As the 2-5MPJ accepted more force, the 1MPJ began to accept force until the hallux and toes were fully loaded with the movement of the body to over the foot. The full force of acceleration was then experienced by the forefoot, with the force petering off firstly with the 2-5MPJ region followed by the 1MPJ and finally the hallux as the foot left the ground.

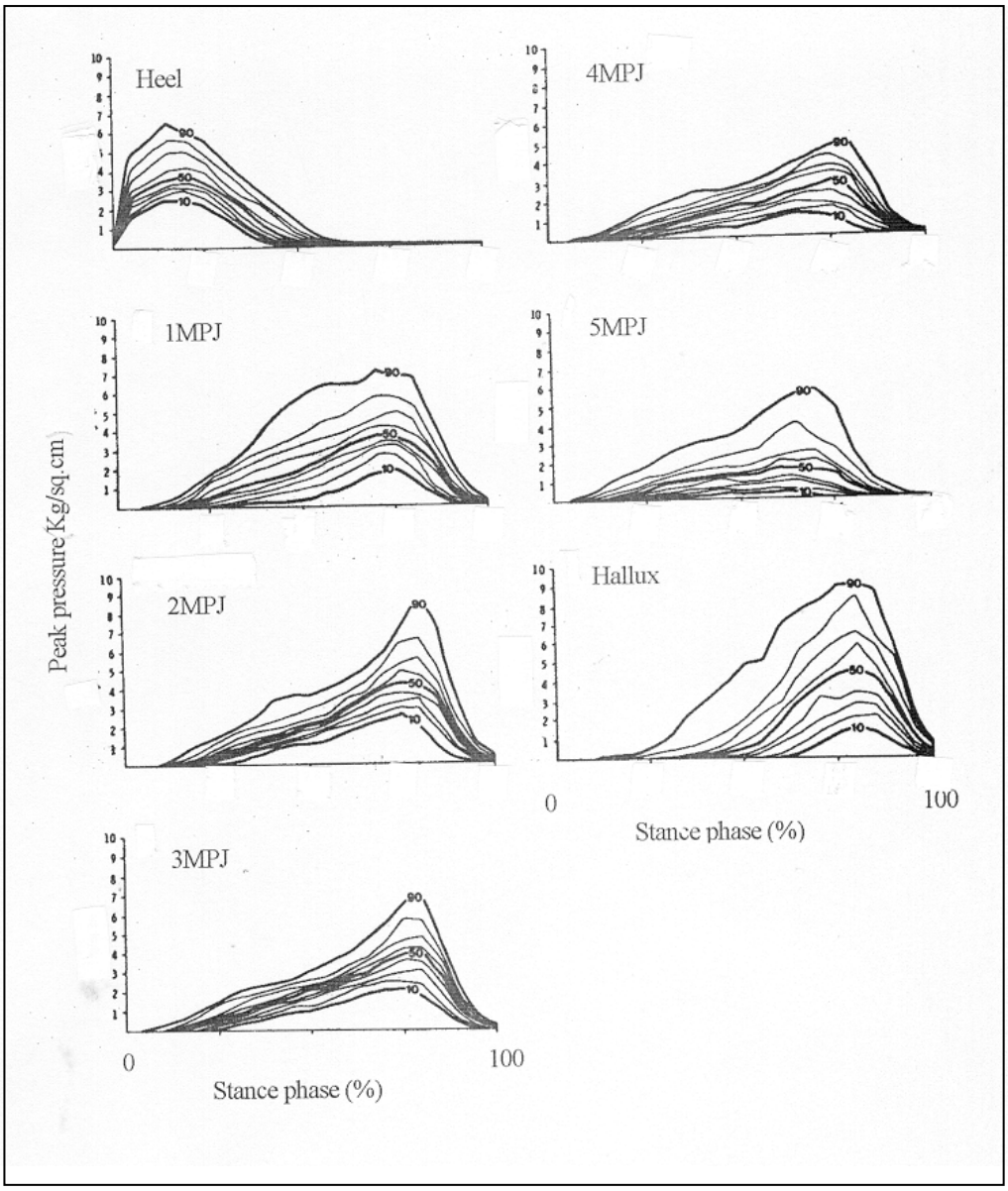
Reports of mean pressure-time graphs have not been identified, therefore, the results of mean pressure-time for the present study were produced for cross validation by their relationship to the force-time graph patterns. The mean pressure-time graph results are comparable to the results of the force-time graphs because they are calculated from the same measures. Cross validation was confirmed by the similarity of the shapes formed from the two variable graphs. However, as ulcerations are generally smaller than the defined anatomical region in which they occur, the

mean pressure over the region is not as useful for investigating ulceration than the sensor specific peak pressure results. Therefore, to provide a reference graph of a neuropathy- and ulceration-free diabetic population, peak pressures over percentage-normalised stance time for future study application to other diabetic populations, the present study's peak pressure-time graphs need cross validation.

To facilitate the comparison and cross validation of the present study with the literature, the pressure-time graphs reported by Duckworth, Betts, Franks and Burke (1982) and Quesada and Rash (2000) are reproduced in *Figure 30* and *Figure 31*, respectively. The total peak pressure-time graph patterns from both the reported studies and the present study show a lower first hump, which may be due to the structure of the large heel pad as already discussed (large area and shock/force absorbing padding) as compared to their MPJ regions and hallux (smaller areas and less padding). The instrument and method of Quesada and Rash is comparable to the present study and both the present study's 1MPJ and 2-5MPJ and the combined MPJ region peak pressure-time patterns show similar concave loading shapes.

The present study's peak pressure-time pattern from the hallux shows a later, more concave and steeper loading than that of Duckworth et al. (1982) and this observation is repeated in the present study's 1MPJ graph. The present study's peak pressure-time pattern on the heel follows this same observation except that it is in the reverse. The present study's peak pressure on the heel remains loaded until approximately 80% of stance phase as compared to approximately 60% reported by Duckworth et al. The differences in loading may be due to instrumental differences between the studies because the present study used in-shoe pressure measurement of midgait walking, while Duckworth et al. collected peak pressure data by the subject taking a single barefoot step onto a raised pressure platform.

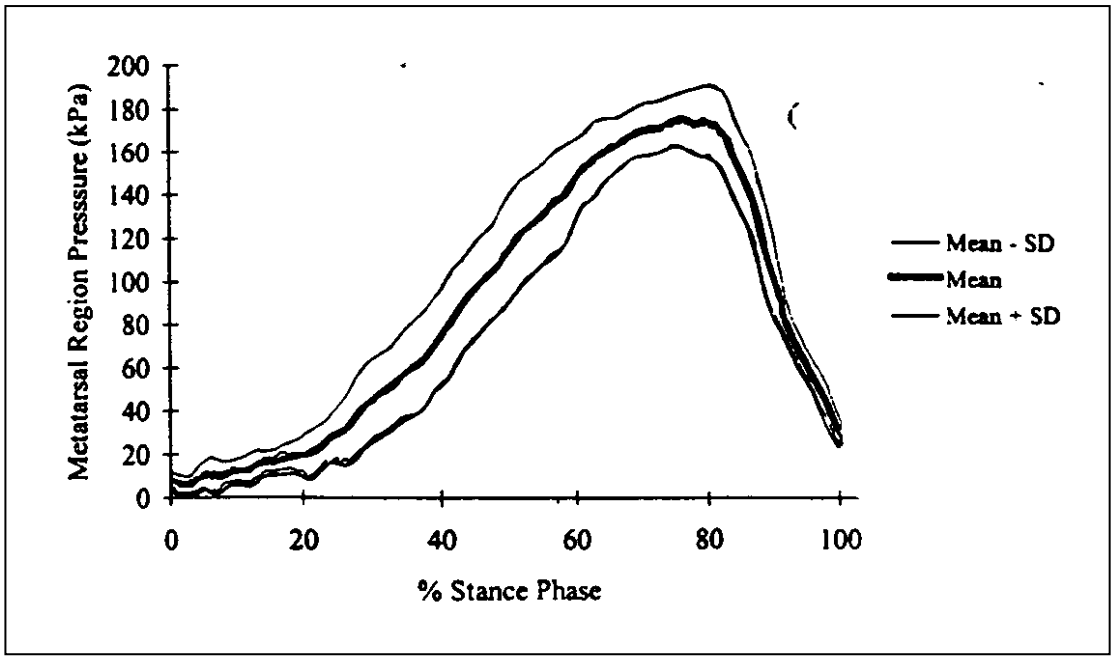
The variability of the data from the present study and that reported by Quesda and Rash (2000) are comparable and show similar limits that closely relate to the mean. The limits on the graph from these authors are one standard deviation and approximately 10 kPa, while the present study are 95% confidence limits which are at least two standard deviations and are approximately 25 kPa for the similar region. However, the variability graphed by Duckworth et al. (1982) differs from both the present study and that of Quesda and Rash and show wide percentile curves. The width of the percentiles, once again, may be due to instrumental or method differences, but may also be due to differing populations tested by their inclusion of very young children with immature gait in the population tested (ages one to 43 years old).



From Duckworth, T., Betts, R. P., Franks, C. I., & Burke, J. (1982) The measurement of pressures under the foot. *Foot & Ankle*, 3(3), 130-141: Figure 8 p137.

Figure 30. Peak pressure percentile curves obtained from 50 control measurements[28].

[28] The peak pressures are expressed in kilogram per square centimetre which are approximately one tenth of the values if expressed in kPa.



In Quesada, P. M., & Rash, G. S. (2000) Quantitative assessment of simultaneous capacitive and resistive plantar pressure measurements during walking. *Foot & Ankle International, 21*(11), 928-934: Figure 2 p929.

Figure 31. Example of mean ± standard deviation curves for a single subject's peak plantar pressure.

Conclusion

This study was conducted to address Research Question Two (b). The protocol developed for in-shoe plantar pressure analysis in Chapter Three and methods of Chapter Four were tested and found to be safe and not pose any specific foot injury risk in adults with diabetes and normal sensation. Additionally, the study verified that temporal and spatial variables of gait were consistent during in-shoe plantar pressure measurement procedures when subjects self-controlled their walking gait. The addressing of these two aims confirmed that the in-shoe plantar pressure measurement procedures developed for the thesis study were not likely to impose risk to the subjects or significantly modify their gait and were therefore, adopted for future thesis studies.

The in-shoe plantar pressure measurement results were analysed firstly using the common absolute value method and found to be comparable to the published literature within the constraints of the lack of a standard protocol, methods and standard footwear. The results were further explored graphically and relative to time using the data point-to-data point and the continuous data bootstrap methods. Patterns formed by graphing the mean results from both methods were so similar in that the method means overlayed. Additionally, the method means of

the total force results showed patterns that were similar to and therefore, cross-validated by those in the literature. The bootstrap method was found to be comparable to, but slightly more conservative than the standard point-to-point method and graphs of force, mean pressure and peak pressure at defined anatomical regions of the foot were produced. The peak pressure results, as they related to time graphs, provided information especially relevant to showing the pattern of pressure on an anatomical region and specific sensors more so than the absolute value results. A change in the patterns rather than a change in the absolute measured value of peak pressure over an anatomical region or specific sensor could hypothetically provide clinically useful insight into the gait-related aetiology of pressure related injury and ulceration in the population of people with diabetes, neuropathy and ulceration. Therefore, further exploration of this results-presentation method in a clinical population is required and will be conducted in the following chapter.

CHAPTER SEVEN

THE EFFECT OF NEUROPATHY AND ULCERATION ON IN-SHOE PLANTAR PRESSURE MEASURES IN A DIABETIC POPULATION

Rationale and purpose

The previous chapter demonstrated that pressure-time graphs of in-shoe plantar pressure measure variables form patterns that are comparable to the literature. A graph of peak pressure on the forefoot over stance time reportedly differs between diabetic sub-populations with and without neuropathy and a history of forefoot ulceration (Maluf & Mueller, 2003). However, potential differences between peak pressure-time graphs for defined anatomical regions of the plantar foot in diabetic sub-populations with and without neuropathy are unknown. Additionally, potential differences between these graphs for diabetic and neuropathic sub-populations with ulcerations on either the hallux or 1MPJ are also unknown. Knowledge of if, where and how peak pressure-time graphs differ with neuropathy and differ between hallux and 1MPJ ulcerations will be useful to assess and design interventions to encourage ulceration healing and eventually be an aid to prevent ulceration occurrence.

Therefore, the purpose of the present study was two fold. First, the present study will investigate potential differences between in-shoe plantar pressures when neuropathy is present by comparing diabetic sub-populations with and without neuropathy. Secondly, the present study will address Research Question Three (a) and investigate potential differences in in-shoe plantar pressures when ulceration is present on either the hallux or the 1MPJ and by comparisons of the same, but not ulcerated regions in the diabetic sub-population without neuropathy or ulceration. For all analyses, investigation into potential differences will be conducted using the common absolute

method that will allow comparisons to be made with the reported literature, but also the usefulness of analysing peak pressure as a function of stance time will be conducted.

Subjects

The academic staff, residents and fellows of the Podiatry Service in the Department of Orthopedics at the University of Texas Health Science Center were enlisted to identify subjects for this and the following shoe out-sole study. A PowerPoint™ assisted presentation was made at the weekly education forum to describe the background and aims of both this and the shoe out-sole study, and the inclusion and exclusion criteria for subject selection. All patients who attended the "At-risk Diabetic Foot Clinic" at the Texas Diabetes Institute in late 1998 and until mid-1999 were screened for inclusion. The Texas Diabetes Institute High-risk Diabetic Foot Clinic is a teaching clinic of the University of Texas Health Science Center, Department of Orthopedics, and Podiatry Residency Program and is staffed by Podiatry residents under the supervision of academic staff. Patients generally attend this clinic due to their lack of health insurance and low socio-economic status, which limits their access to other health care facilities. Subjects who met the inclusion criteria were identified to the author who confirmed their eligibility prior to inviting them to participate in the study. The Institutional Review Boards of the University of Texas Health Science Center and the University Health System gave approval for the study, and informed consent was obtained from all subjects prior to their participation.

Subjects were included if they met the criteria for one of two groups. The first population was that described previously in Chapter Six, and the volunteers were adults with diabetes, but without peripheral neuropathy nor plantar forefoot ulceration. The second population criteria required that the volunteer be an adult with diabetes, peripheral neuropathy, plantar forefoot ulceration either to the plantar hallux or the plantar 1MPJ and were able to walk unassisted. Subjects were excluded if they had a history of major trauma to the feet, legs or lower back, surgery to the feet, or if they had concurrent disease processes such as Parkinson's disease that limited their ability to walk consistently. The exclusion of subjects that had had surgery to their feet severely limited the number of suitable subjects. This was because podiatric surgical residents who could provide the patients with ready access to subsidised surgery staffed the clinic. All invited subjects consented to participate in the study and their positive decision was influenced by the incentive that they would receive free of charge in-shoe plantar pressure assessment that was normally reserved for surgical assessment.

Twenty-eight subjects were identified who met the inclusion criteria for the 'ulcerated group'. There were 19 men and nine women in the study population. The population were aged between 32 and 64 years (mean 52.04, SD 8.75), weighed between 63.64-136.36 kg (mean 86.67, SD 15.27), height was between 1.52-1.90 m (mean 1.71, SD 0.10) and body mass index (BMI) ranged from 19.78 to 41.38 (mean 29.03, SD 4.84). Eleven subjects were classified as overweight (BMI 25-30) and another eleven were classified as obese (BMI>30) (Zeman, 1991). The population were diagnosed with Type 2 diabetes for between six months and 37 years (mean 11.48 years, SD 9.34). Sixteen subjects managed the hyperglycaemia component of their diabetes with oral hypoglycaemic medication (tablets), ten subjects used insulin injections, while one subject was taking both tablets and insulin injections and another did not require hypoglycaemic medication due to a successful pancreas transplant. The demographic results for the population per ulceration site are presented in Table 30.

Table 30

Sub-population demographic results.

Ulceration site	Age (years)	Weight (kg)	Height (m)	BMI	Years DM (years)
None	52 (43-60)	94.09 (65.91-113.64)	1.62 (1.51-1.73)	36 (26-50)	Not recorded
Hallux	48 (32-62)	83.66 (63.64-134.09)	1.74 (1.52-1.98)	28 (20-38)	10 (0.5-37)
1MPJ	56 (45-64)	87.85 (68.18-104.54)	1.70 (1.55-1.86)	31 (23-41)	14 (1-30)

Procedures

All subjects underwent the protocol that was developed in Chapter Three, the methods described in Chapter Four and tested for safety in Chapter Six. The subjects wore appropriately sized SmartKnit seamless socks (KnitRite, Kansas, USA) as previously described in Chapter Five. The shoes worn for baseline data collection were Nike canvas shoes (Nike, Beaverton, Oregon, USA) as previously described and used for data collection in Chapter Six.

Data analyses

Data analysis was conducted as previously described in chapters three, four and six.

Data from the two populations were categorised into sub-population groups based on neuropathy and ulceration, status and location, and presented in Table 31.

Table 31

Sub-population categorisation process.

Diabetic	Neuropathic	Ulceration	Sub-population category	Abbreviation
Yes	No	No	Non-neuropathic-no ulceration	NoN NoU
Yes	Yes	No	Neuropathic-no ulceration	N NoU
Yes	Yes	Yes – Hallux	Neuropathic-hallux ulceration	N HalluxU
Yes	Yes	Yes – 1MPJ	Neuropathic-1MPJ ulceration	N 1MPJU

Statistical analyses

Absolute value analyses

Absolute value analyses were conducted as this is the current results presentation method and these results will enable the present study results to be compared to those in the literature. Both the absolute value results for peak pressures and pressure-time integrals per anatomical region will be analysed as these variables were found in Chapter Three have a statistically significant relationship to ulceration location.

All absolute value analyses were performed using SPSS Release 8 for Windows. Results were examined for and confirmed as being normally distributed using proportion probability (P-P) plots with the proportion estimated using the Rankit formula. The variable means of sub-populations were compared using the one-way analysis of variance for repeated measures (ANOVA) function, and *post hoc* analyses were conducted using the Dunnett's T3 test. Dunnett's T3 test was chosen for *post hoc* analyses as it does not require the assumption of equality of variances to be met as already described in Chapter Three (SPSS Incorporated, 1998).

Pressure measures as they relate to stance time

The results of peak pressure over percent-normalised stance time were plotted, along with the respective 95% confidence bands. These plots describe the pattern of pressure and are expected to provide clinically useful insight into the aetiology of pressure-related injury and ulceration in the clinical population with diabetes, neuropathy and ulceration.

Peak pressure-time analyses were performed using Excel 2000 for Windows. Bootstrap means and 95% confidence bands were calculated and graphed as previously described in Chapter Six.

Results

Absolute values analyses

At the time of data collection, two subjects were found to have developed both a hallux and 1MPJ ulceration on one foot and these limbs were excluded from future analyses, leaving 54 limbs in the neuropathic and ulcerated population. The descriptive statistics for the variables of peak pressure and pressure-time integral per each anatomical region and each ulceration sub-population are presented in Table 32.

Table 32

Descriptive analysis of absolute value results per variable (a. peak pressure and b. pressure-time integral) and anatomical region and sub-population.

a) Peak pressure absolute value results

Variable	Anatomical region	Ulceration sub-population*	Mean	SD	Min	Max
Peak pressure (kPa)	Total foot	N-1MPJU	417.1	99.0	304.3	578.7
		N-HalluxU	361.5	88.8	220.0	576.7
		N-NoU	369.5	96.1	210.0	543.0
		NoN-NoU	339.9	73.0	203.7	466.0
	Hallux	N-1MPJU	247.8	127.6	69.3	513.3
		N-HalluxU	289.3	109.5	98.0	460.0
		N-NoU	246.6	120.6	83.8	496.0
		NoN-NoU	313.6	105.6	119.7	466.0
	1MPJ	N-1MPJU	374.2	113.3	220.7	578.7
		N-HalluxU	274.7	119.2	131.3	576.7
		N-NoU	296.8	113.1	54.0	543.0
		NoN-NoU	230.3	74.8	116.3	352.3
	2-5MPJ	N-1MPJU	292.8	105.3	122.7	531.3
		N-HalluxU	243.5	64.5	146.7	374.3
		N-NoU	281.9	74.2	135.3	443.3
		NoN-NoU	224.0	66.4	118.7	363.3
	Heel	N-1MPJU	246.9	47.0	186.7	326.7
		N-HalluxU	214.4	68.4	71.4	292.7
		N-NoU	239.8	70.7	123.8	429.3
		NoN-NoU	207.5	38.5	160.3	273.3

*Sub-population groups are: n=11 for N-1MPJU, n=17 for N-HalluxU, n=26 for N-NoU and n=16 for NoN-NoU.

Table 32 *continued*

b) Pressure-time integral absolute value results.

Variable	Anatomical region	Ulceration sub-population*	Mean	SD	Min	Max
Pressure-time integral (kPa s)	Total foot	N-1MPJU	160.1	42.1	109.7	252.8
		N-HalluxU	136.4	33.1	77.0	221.9
		N-NoU	152.3	48.7	65.8	294.0
		NoN-NoU	123.4	26.0	76.7	156.4
	Hallux	N-1MPJU	57.3	22.6	10.3	94.2
		N-HalluxU	70.2	27.6	24.8	111.7
		N-NoU	62.8	25.8	24.1	125.0
		NoN-NoU	72.1	35.4	15.1	132.1
	1MPJ	N-1MPJU	107.4	48.7	48.6	189.3
		N-HalluxU	79.2	39.0	43.6	197.6
		N-NoU	95.7	42.8	9.5	189.8
		NoN-NoU	61.4	22.8	20.2	98.9
	2-5MPJ	N-1MPJU	85.6	33.1	18.8	137.8
		N-HalluxU	72.6	29.4	22.6	131.4
		N-NoU	9.27	3.13	2.98	15.62
		NoN-NoU	6.48	2.01	3.42	9.58
	Heel	N-1MPJU	7.75	3.45	4.65	16.88
		N-HalluxU	6.31	2.17	0.71	10.45
		N-NoU	7.92	3.52	2.06	18.97
		NoN-NoU	5.61	1.77	2.91	8.70

*Sub-population groups are: n=11 for N-1MPJU, n=17 for N-HalluxU, n=26 for N-NoU and n=16 for NoN-NoU.

The ANOVA results from comparing the variable means of peak pressure and pressure-time integral per anatomical region grouped by ulceration sub-population are presented in Table 33. There were significant differences between means of the ulceration sub-populations for the 1MPJ and 2-5MPJ anatomical regions for both peak pressure and pressure-time integral. The means of the ulceration sub-populations for pressure-time integral for the anatomical regions of total foot and the heel approached significance at the $p<0.05$ level (0.06 and 0.05, respectively).

Table 33

ANOVA table showing significant differences (p<0.05) between means of absolute values per variable and anatomical region grouped by ulceration sub-population.

Variable	Anatomical region	Groups	Sum of squares	Degrees freedom	Mean square	F	Sig.
Peak pressure (kPa)	1MPJ	Between	1399.95	3	466.65	4.06	0.01
		Within	7595.40	66	115.08		
		Total	8995.35	69			
	2-5MPJ	Between	495.90	3	165.30	2.86	0.04
		Within	3813.89	66	57.79		
		Total	4309.79	69			
Pressure-time Integral (kPa s)	1MPJ	Between	178.59	3	59.53	3.86	0.01
		Within	1017.08	66	15.41		
		Total	1195.67	69			
	2-5MPJ	Between	92.08	3	30.70	3.67	0.02
		Within	552.37	66	8.37		
		Total	644.45	69			

The results of the *post hoc* analyses that showed significant differences (p<0.05) between ulceration sub-populations are presented in Table 34. These results show that there were significant differences between peak pressures on the 1MPJ region when 1MPJ ulceration and neuropathy was present (N-1MPJU) compared to when neither neuropathy nor ulceration are present (NoN-NoU). There were also significant differences between pressure-time integral results on the 1MPJ, 2-5MPJ and heel regions between neuropathy and neuropathy-free (NoN-NoU and N-NoU sub-populations).

Table 34

Post hoc analyses that showed significant differences (p<0.05) between ulceration (ulcer) sub-populations (I and J) per variable and anatomical region.

Dependent Variable	Anatomical region	Ulcer Sub-pop (I)	Ulcer Sub-pop (J)	Mean Dif. (I-J)	Std. Error	Sig.	95% CI Lower Limit	95% CI Upper Limit
Peak pressure (kPa)	1MPJ	N-1MPJU	NoN-NoU	14.39	4.20	0.01	2.83	25.95
Pressure-time	1MPJ	N-NoU	NoN-NoU	3.42	1.25	0.01	0.62	6.23
integral	2-5MPJ	N-NoU	NoN-NoU	2.80	0.92	0.01	0.61	4.98
(kPa s)	Heel	N-NoU	NoN-NoU	2.31	0.92	0.04	0.04	4.58

The pressure-time graphs for the four ulceration sub-populations are divided into two sections. The first section presents the effect of neuropathy on pressure-time patterns. Comparisons are made between the sub-populations: neuropathic and ulceration-free and non-neuropathic and ulceration free. The second section presents the effect of ulceration position on pressure-time patterns. Comparisons are made between the sub-populations: neuropathic with 1MPJ and neuropathic with hallux ulceration.

The effect of neuropathy: Neuropathic and ulceration-free sub-population compared to non-neuropathic and ulceration-free sub-population

The graphical results of peak pressures from the sub-populations with and without neuropathy and without ulceration (NoN NoU and N NoU) are presented per anatomical region in *Figure 32* through to *Figure 36*. The graphical results from these sub-populations describe differences in peak pressure (kPa) that occurred during stance phase with and without neuropathy.

The graph in *Figure 32* shows that when neuropathic, the peak pressure over the whole foot (Total kPa) has a more gentle rise, followed by less unloading during midstance and a ten percent earlier and slightly lower peak when compared to the non-neuropathic sub-population. The respective lower and upper confidence bands (bootstrap) of the sub-populations differ between approximately 70 and 95 percent of stance phase.

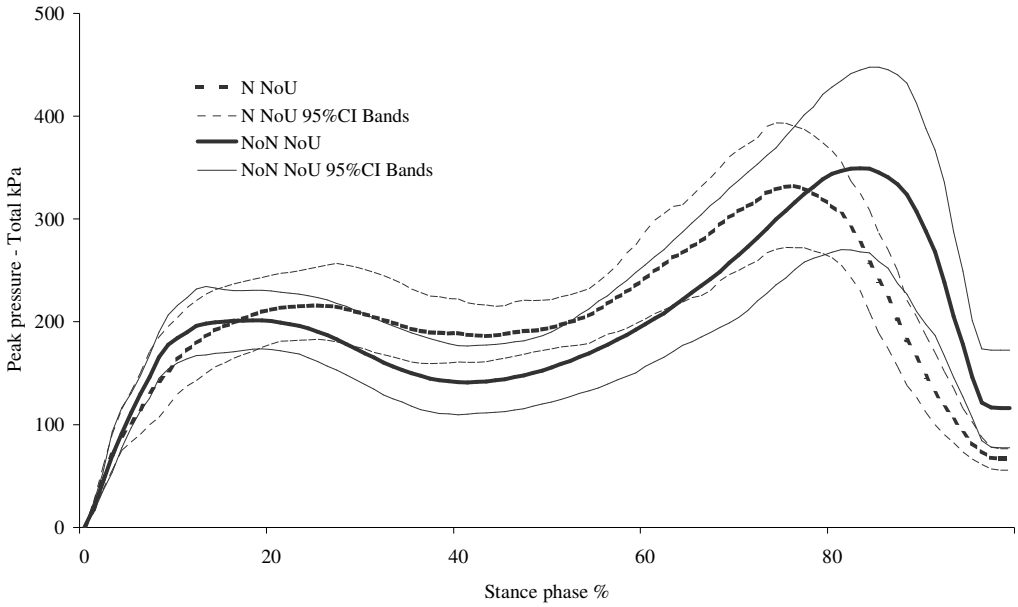


Figure 32. The means and 95% confidence bands (Bstrap) for peak pressure over the whole foot (total) per sub-population.

The graph in *Figure 33* shows that when neuropathic, the peak pressure on the hallux peaks approximately 10% earlier in stance phase at approximately 15 kPa less than the non-neuropathic sub-population. The respective lower and upper confidence bands (Bstrap) of the sub-populations differ between approximately 80 and 95%of stance phase.

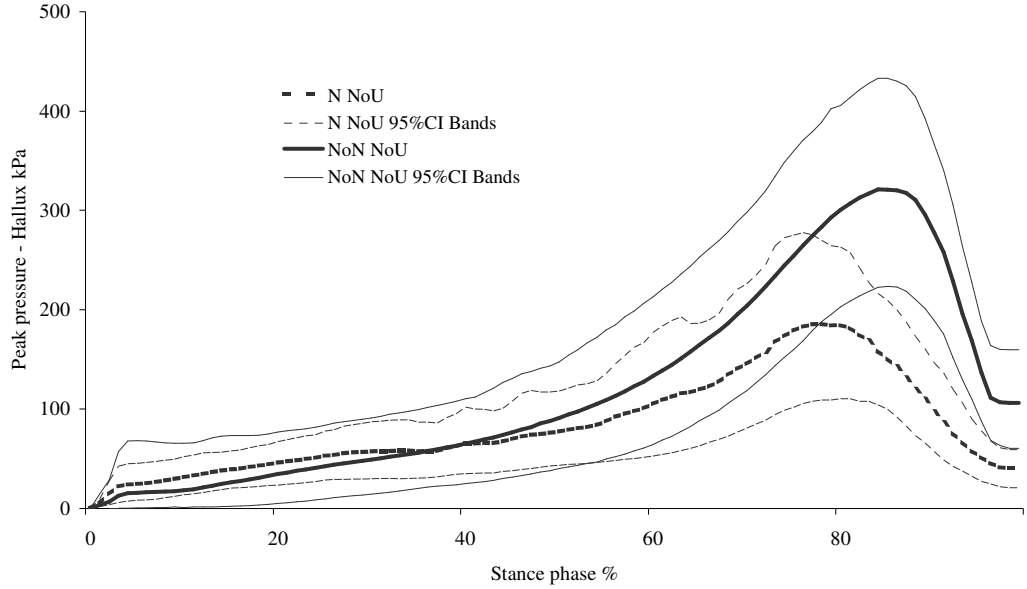


Figure 33. The means and 95% confidence bands (Bstrap) for peak pressure-Hallux per sub-population.

The graph in *Figure 34* shows that when neuropathic, the peak pressure on the 1MPJ is consistently approximately five kPa higher and peaks slightly earlier at 75% of stance phase when compared to the neuropathy-free sub-population. The respective lower and upper confidence bands (Bstrap) of the sub-populations clearly differ in the first 20% and then are aligned on a parallel path from 20% until 60% of stance phase.

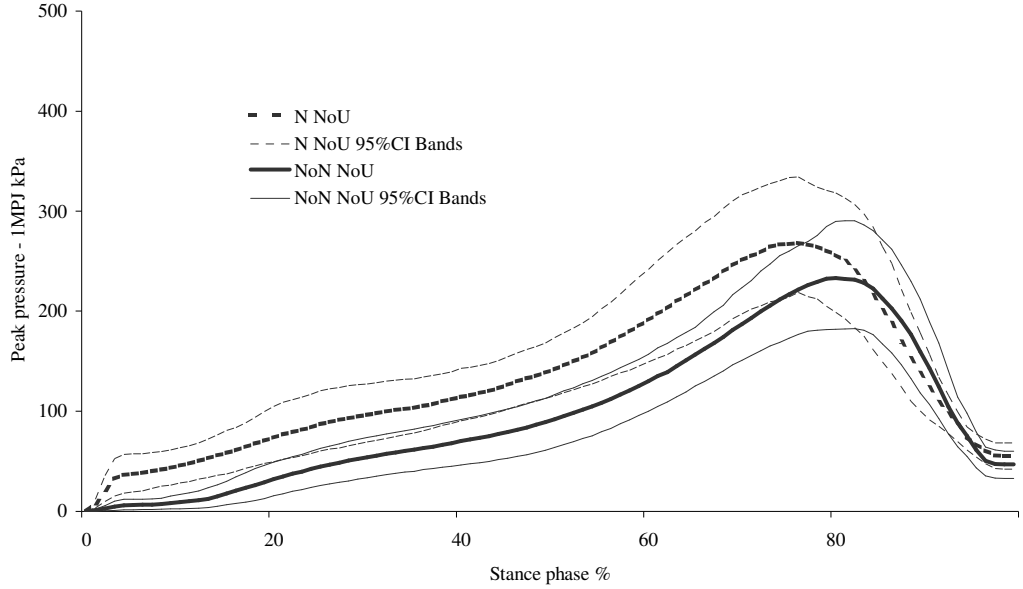


Figure 34. The means and 95% confidence bands (Bstrap) for peak pressure-1MPJ per sub-population.

The graph in *Figure 35* shows that when neuropathic, the peak pressure on the 2-5MPJ is higher initially and then consistently five kPa higher from 20% of stance phase until it peaks at approximately 10% earlier in stance phase than the neuropathy-free sub-population. The respective lower and upper confidence bands (Bstrap) of the sub-populations overlap throughout stance phase suggesting that the peak pressures in kPa do not differ between the sub-populations.

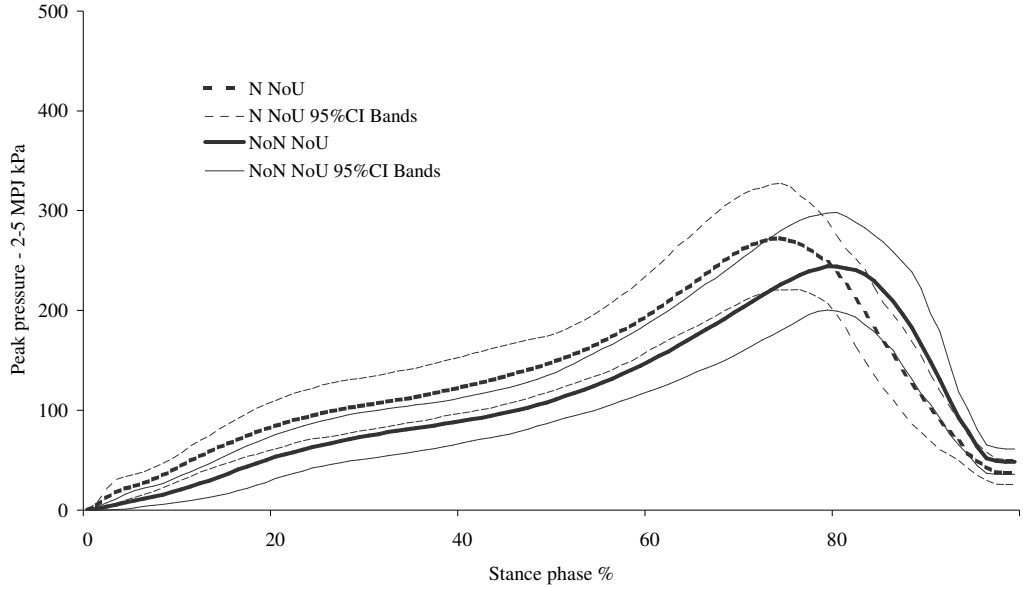


Figure 35. The means and 95% confidence bands (Bstrap) for peak pressure-2-5MPJper sub-population.

The graph in *Figure 36* shows that when neuropathic, the peak pressure on the heel rises at the beginning of stance phase at a slightly lower rate and peaks approximately 5% after the neuropathy-free sub-population. The mean peak pressure is approximately ten kPa higher from approximately 40% to the end of stance phase. The 95% confidence bands (Bstrap) aligned from 80%, and then clearly differed in the final 5% of stance phase.

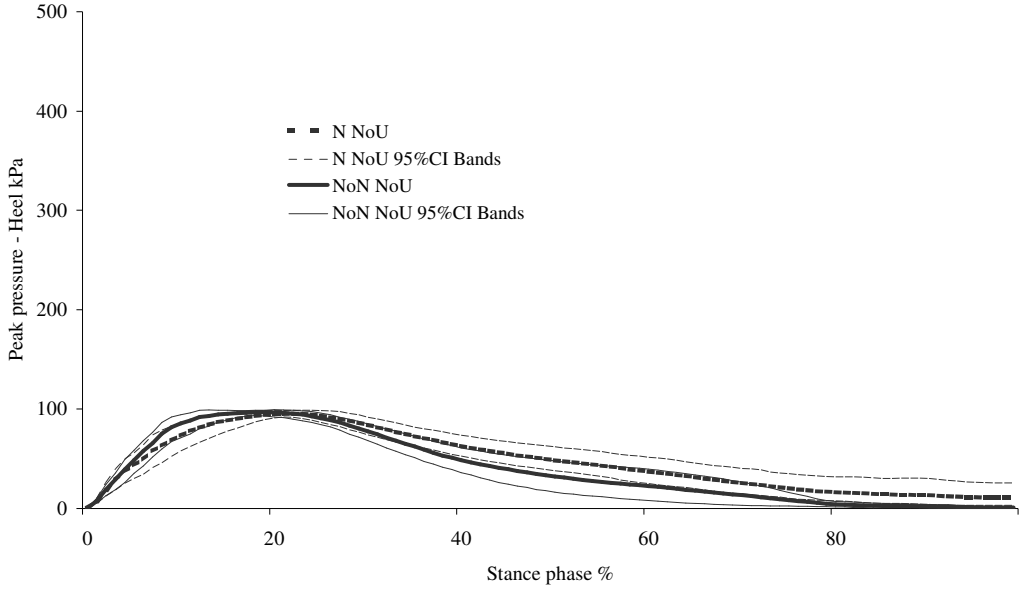


Figure 36. The means and 95% confidence bands (Bstrap) for peak pressure-heel per sub-population.

The effect of neuropathy and ulceration: Hallux or 1MPJ ulceration with neuropathy and neuropathy sub-populations compared to ulceration-free sub-population

The graphical results of peak pressures from the sub-populations that are non-neuropathic and with out ulceration, neuropathic with ulceration-1MPJ and ulceration-Hallux during stance time per anatomical region are presented in *Figure 37* through to *Figure 41*. The graphs from these sub-populations describe differences in the pattern of peak pressures that occurred during stance phase on hallux or 1MPJ ulcerations when compared to each other and the ulceration and neuropathy-free sub-population.

The graph in *Figure 37* shows that with ulceration, the peak pressure over the whole foot (Total) was slightly elevated during the middle, 20 to 70%, of stance phase when compared to the ulceration and neuropathy-free sub-population. During this time, the hallux ulceration group were very slightly, but consistently higher than the 1MPJ ulceration group. Hallux ulceration peaked approximately 5% earlier but lower than 1MPJ ulceration and the ulceration and neuropathy-free sub-populations. The 95% confidence bands (Bstrap) overlapped throughout stance phase suggesting that peak pressures over the whole foot (Total) were not different between the three sub-populations.

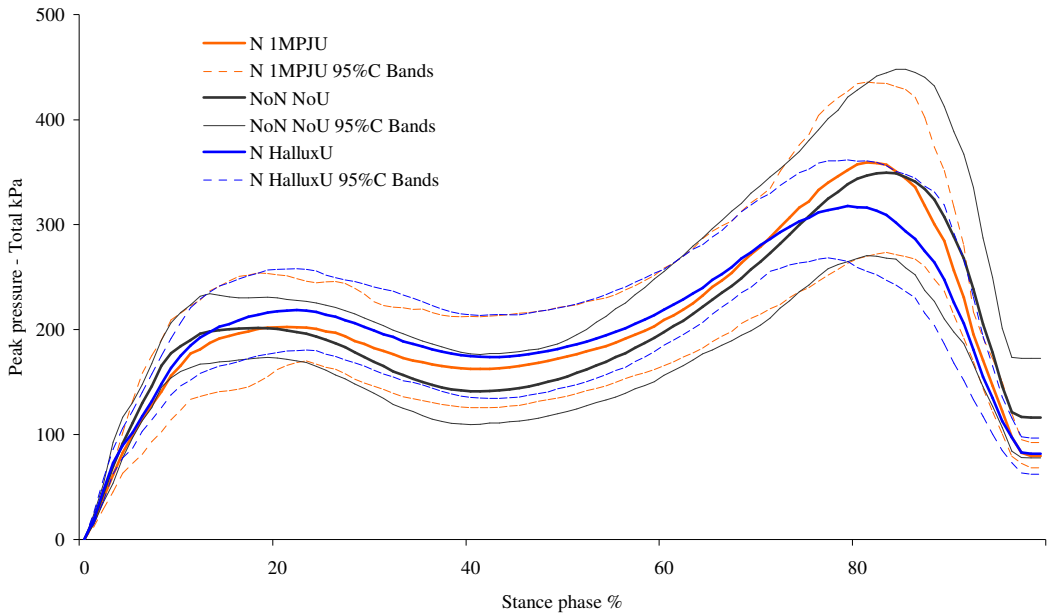


Figure 37. The means and 95% confidence bands (Bstrap) for peak pressure-Total foot per sub-population.

The graph in *Figure 38* shows that during the first 65% of stance phase, that the peak pressure on the hallux is consistently lower with 1MPJ ulceration than with Hallux ulceration or when neuropathy and ulceration-free. From approximately 70% of stance phase, during push off, 1MPJ ulcerations peaked ten kPa lower, and hallux ulcerations peaked approximately seven kPa lower than when neuropathy and ulceration-free. The hallux ulceration lower 95% confidence band (Bstrap) was lower than the other sub-populations through out stance phase suggesting that the lower range peak pressures over the hallux were different between the three sub-populations.

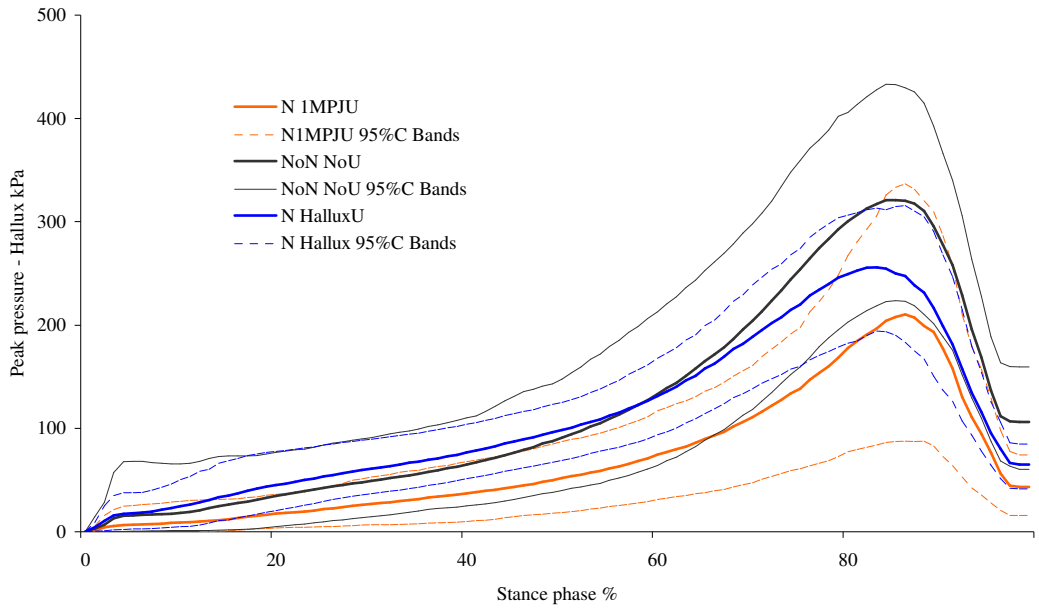


Figure 38. The means and 95% confidence bands (Bstrap) for peak pressure-Hallux per sub-population.

The graph in *Figure 39* shows that the peak pressure on the 1MPJ is slightly, but consistently higher when ulceration is present. During push off, with 1MPJ ulceration the pressure peaked slightly higher and earlier, whereas with hallux ulceration the pressure peaked at the same time as, but ten kPa higher than when neuropathy and ulceration-free. The 95% confidence bands (Bstrap) overlapped and were of comparable widths throughout stance phase suggesting that the peak pressures over the 1MPJ were not distinctly different between the three sub-populations.

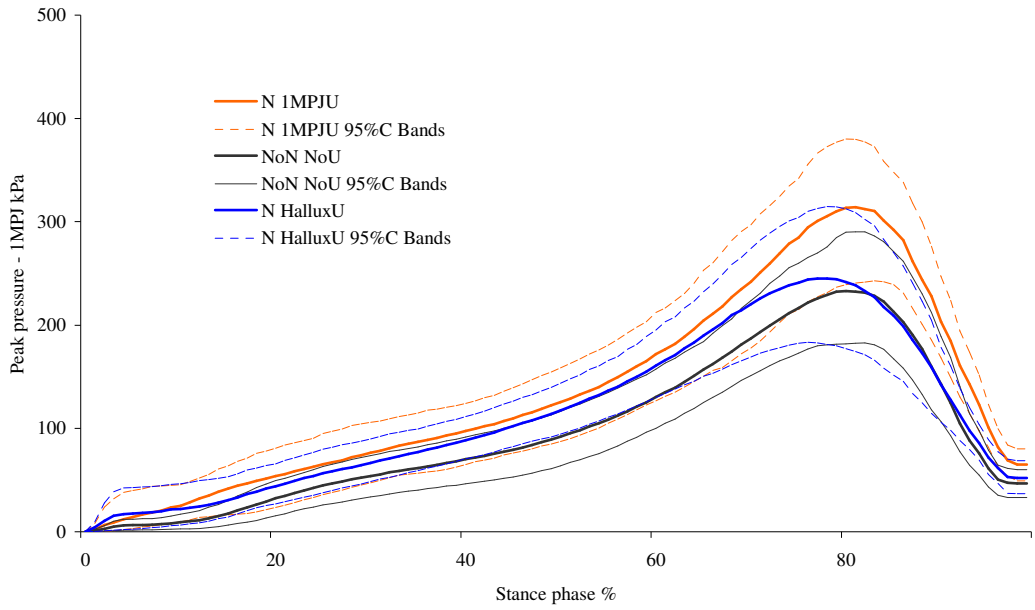


Figure 39. The means and 95% confidence bands (Bstrap) for peak pressure-1MPJ per sub-population.

The graph in *Figure 40* shows that with ulceration, that the peak pressure on the 2-5MPJ shows that the relationships between sub-populations for peak pressure on the 2-5MPJ closely resemble those of the peak pressure on the 1MPJ. Once again, during push off, 1MPJ ulceration and neuropathy and ulceration-free sub-populations are very similar, wheras hallux-ulceration is elevated, approximately five kPa, when compared to the other two sub-populations. The 95% confidence bands (Bstrap) are similar to those of the 1MPJ and overlapped and were of comparable widths through out stance phase suggesting that the peak pressures over the 2-5MPJ were not distinctly different between the three sub-populations.

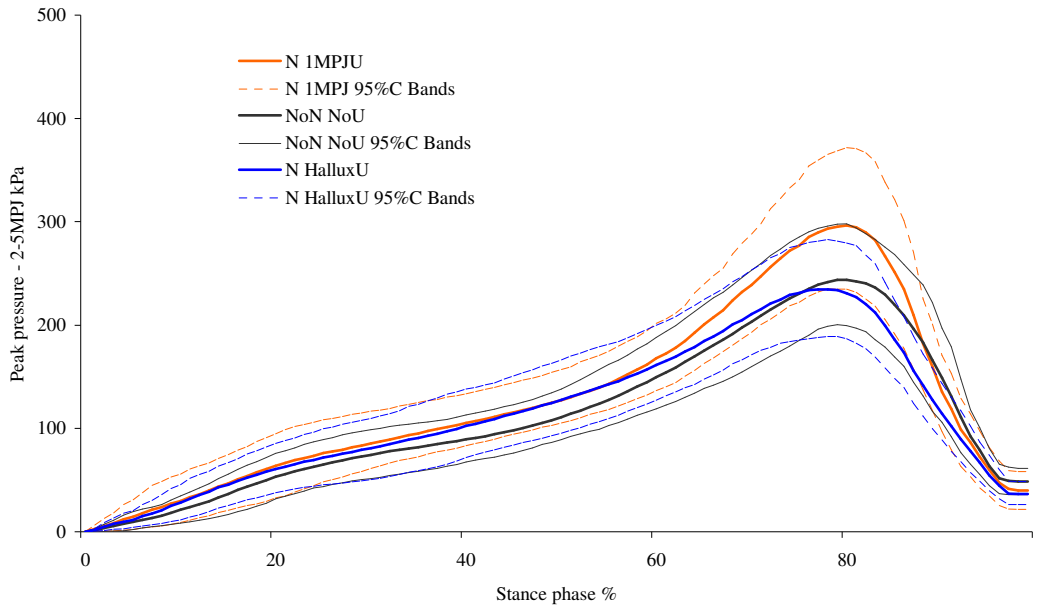


Figure 40. The means and 95% confidence bands (Bstrap) for peak pressure-2-5MPJ per sub-population.

The graph in *Figure 41* shows that the peak pressure over the heel is elevated approximately 20 kPa from 40 to 70 percent of stance phase with ulceration when compared to when neuropathy and ulceration-free. The lower limits of the 95% confidence bands from the ulceration sub-populations are also elevated above the mean for the neuropathy and ulceration-free from 40 to 70 percent of stance phase, suggesting a trend to load the heel more during this time, but as the other bands overlap the sub-populations were not distinctly different.

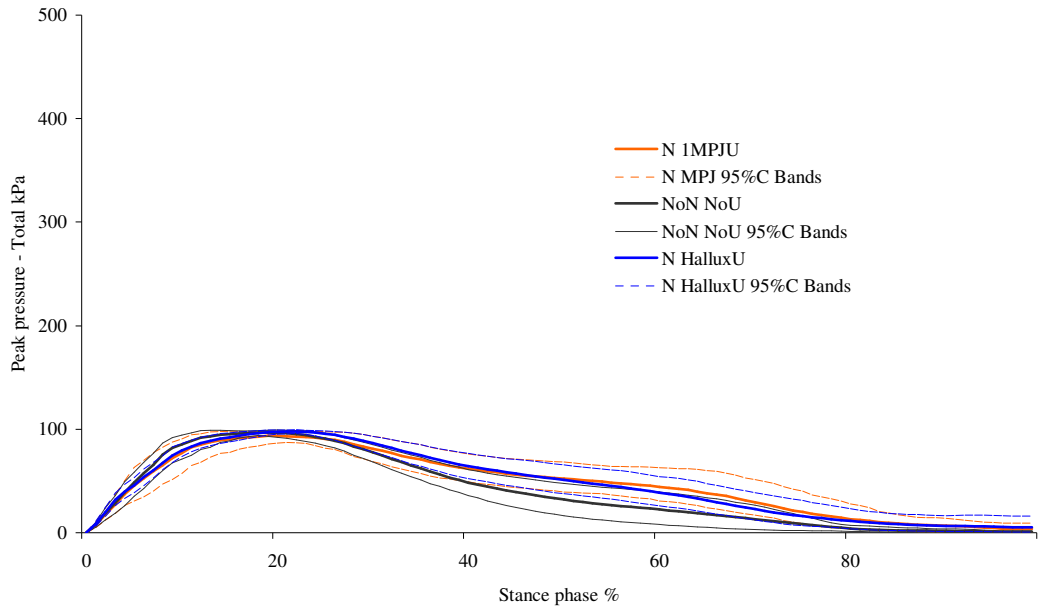


Figure 41. The means and 95% confidence bands (Bstrap) for peak pressure-heel per sub-population.

Discussion

Absolute values analyses

Even though significant differences were found between the means of the sub-populations the actual differences were small and were less than the measurable accuracy established for the device in Chapter Three. Therefore, actual differences between the sup-populations are so small to not be of any clinical usefulness.

In Chapter Five, the study results for the population with diabetes but without neuropathy or ulceration (NoN NoU sub-population) were discussed with comparable study results reported by Perry et al. (1995). Once again, comparable results for discussion of the present study sub-population with diabetes and neuropathy, but without ulceration (N NoU) and that reported by Perry et al. (1995) together with that reported by Maluf and Mueller (2003) are presented in Table 35. The following comparisons are made whilst being cognisant of the limitations of making comparisons without a standardised protocol, methods, footwear and anatomical region definitions, as discussed previously in Chapter Five.

The results from the present study are higher than the running shoe results and lower than the leather oxford shoe results reported by Perry et al. (1995), but the highest forefoot region of the

present study is very similar to the forefoot peak result reported by Maluf and Mueller (2003). The differences between the present study results and Perry et al. are plausible due to the logical differences expected between a cushioned sole running shoe (lower peak pressures), firm sole leather oxford shoe (higher peak pressures) and the present study's minimally-cushioned flexible soled shoe (moderate peak pressures). Other than the peak pressure result from the leather oxford shoe on the heel region that was higher, all other results from Perry et al. and all results from Maluf and Mueller are contained within plus or minus one standard deviation of the present study's results; providing cross validation and confirmation that the present study results are from a comparable population to these other studies. This comparison between study results obtained from using different shoes aptly shows the importance of the strict adherence to standardisation of footwear discussed in Chapter Three, and without standardisation, valid comparisons and conclusions cannot be drawn.

Table 35

Comparative mean (standard deviation) results of peak pressure absolute value measures (kPa) from in-shoe plantar pressure analysis of adults with diabetes and neuropathy, but without ulceration (N-NoU) (N/R = not reported).

		Present study*	Maluf & Mueller (2003)**	Perry, Ulbrecht, Derr & Cavanagh (1995)***	
Variable	Anatomical region	Canvas oxford shoe	Subject's own shoes with/without custom inserts	Running shoe	Leather oxford shoe
Peak pressure (kPa)	Heel	239.8 (70.7)	N/R	186 (24)	324 (65)
	2-5MPJ	281.9 (74.2)	Forefoot combined	N/R	N/R
	1MPJ	296.8 (113.1)	307 (99)	236 (55)	306 (80)
	Hallux	246.6 (120.6)		191 (60)	325 (172)
Pressure-time integral (kPa s)	2-5MPJ	9.27 (3.13)	Forefoot combined	N/R	N/R
	1MPJ	95.7 (42.8)	94 (23)	N/R	N/R
	Hallux	62.8 (25.8)		N/R	N/R

* n=26 limbs: both feet data (ulceration-none-contralateral sub-population)
** n = 10 subjects: number of limbs used was not reported
*** n=13 limbs: right foot only data

To provide results to cross validate and discuss the present study results from the sub-populations with diabetes, neuropathy and ulceration (NHalluxU and N1MPJU), the results reported by Maluf and Mueller (2003) are presented in Table 36. The present study's peak pressure results from the highest peak forefoot region for both sub-populations are much higher than that reported by Maluf and Mueller (2003). A potential explanation for this difference is due to the subjects in Maluf and Mueller wearing their own custom therapeutic shoes with custom inserts compared to the present study subjects who wore standardised shoes without inserts during testing. It is logical and expected that measures of peak pressures would be lower when custom therapeutic shoes and inserts are worn as this footwear is prescribed with the aim to reduce localised areas of high pressure (Litzelman et al., 1997). However, due to the extent of the differences between the studies, the present study results for these sub-populations cannot be cross validated with Maluf and Mueller.

The pressure-time integral result from the forefoot reported by Maluf and Mueller (2003) is similar to the present study result measured on hallux ulceration but higher than on 1MPJ ulceration. The lack of reporting of the actual forefoot ulceration locations, in addition to the wearing of therapeutic footwear by Maluf and Mueller as already discussed, prevents accurate explanation of the differences between the studies. However, the present study's pressure-time integral results are within one standard deviation of Maluf and Mueller, confirming the study results as being from a comparable population.

The ANOVA results presented in Table 33 confirm the results from the archival analysis in Chapter Three and show that the peak pressures and pressure-time integral measures on the 1MPJ and 2-5MPJ are significantly different between ulceration locations.

The *post hoc* results presented in Table 34 did not find that pressure measures could differentiate between ulcerations located on the hallux and 1MPJ, but instead found that there were significant differences between the neuropathic with 1MPJ ulceration (N1MPJU) and neuropathy and ulceration-free (NoNNoU); and neuropathic (NNoU) and non-neuropathic with out ulceration (NoNNoU) sub-populations. These results show that pressure measures are different between these stages of diabetes, and therefore, warrant further exploration for potential clinical screening tool development. Of note is with there being significant differences between measures of peak pressures and pressure-time integral, these results also confirm the opinion of Cavanagh, Ulbrecht and Caputo (2001) that time is a factor in the relationship between ulceration and peak pressures.

Table 36

Comparative mean (standard deviation) results of peak pressure absolute value measures (kPa) from in-shoe plantar pressure analysis of adults with diabetes, neuropathy and ulceration (N-HalluxU or 1MPJU sub-populations).

		Present study*		Maluf & Mueller (2003)**
Variable	Anatomical region	Hallux ulceration	1MPJ ulceration	Forefoot ulceration
Peak pressure (kPa)	2-5MPJ	243.5 (64.5)	292.8 (105.3)	Forefoot combined 189 (99)
	1MPJ	274.7 (119.2)	374.2 (113.3)	
	Hallux	289.3 (109.5)	247.8 (127.6)	
Pressure-time integral (kPa s)	2-5MPJ	72.6 (29.4)	85.6 (33.1)	Forefoot combined 81 (36)
	1MPJ	79.2 (39.0)	107.4 (48.7)	
	Hallux	70.2 (27.6)	57.3 (22.6)	

* n=26 limbs: both feet data (N-Hallux U or 1MPJU sub-populations)
** n = 10 subjects: number of limbs used was not reported

The present study results are supported by Caselli, Pham, Giurini, Armstrong and Veves (2002), albeit the studies differ in their methodology: barefoot stepping over a pressure plate versus in-shoe procedures. The present study results show that there were significant differences between the 1MPJ and 2-5MPJ, and the heel in the ulceration-free sub-populations with and without neuropathy (NoNNoU and NNoU). This is comparable to that of Caselli et al. who reported that there was a higher forefoot to heel peak pressure ratio in severe neuropathy when compared to moderate, mild or no neuropathy. Once again, the present study's result showing differences in pressure-time integral measures suggests that if time is a factor in the severity stages of diabetes, and there is a forefoot to heel ratio change shown by Caselli et al., then further investigation is indicated to explore any functional changes to the foot structure or gait that could explain ulceration occurrence and risk.

Links between absolute values analyses and pressure-time comparisons

The peak pressure (kPa) on the 1MPJ over stance time graph for hallux and 1MPJ ulcerations and neuropathy and ulceration-free sub-populations presented in *Figure 39* agrees with the absolute value analysis presented in Table 34. The peak pressure-time graph shows that 1MPJ ulceration

peaks at least ten kPa higher than the neuropathy and ulceration-free sub-populations, whereas the *post hoc* analysis shows that there is a mean difference of 14.39 kPa between these sub-populations. However, even though there is a distinct difference between the means on the pressure-time graph at 80% of stance phase, the 95% confidence bands of these means overlap which suggests that the sub-populations are not distinctly different and arise from the same population. This finding is a useful example of where statistically significant differences between the absolute value mean results may not be as clinically useful as graphical comparisons of the peak pressure-time means and 95% confidence bands (Portney & Watkins, 1993).

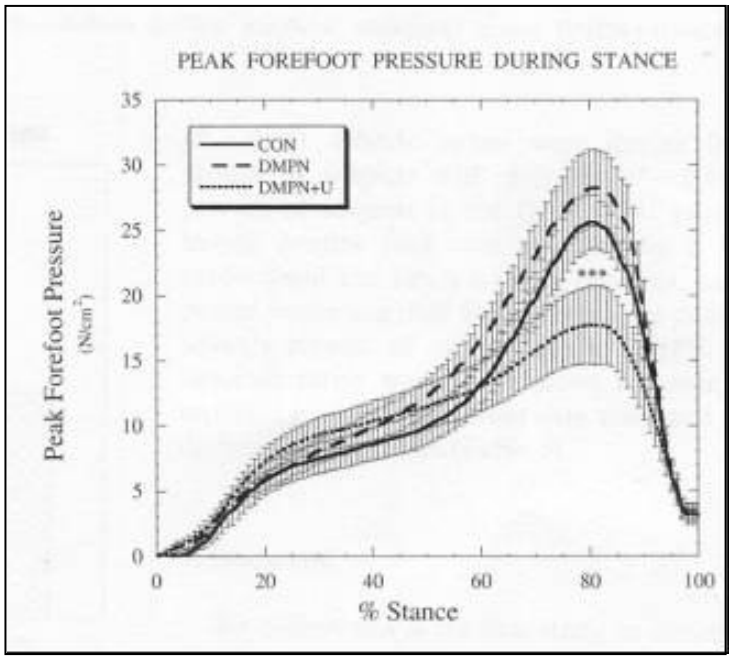
Pressure-time comparisons

Comparing the pressure-time graphs between the ulceration-free neuropathic and non-neuropathic sub-populations, the results over the whole foot (total) suggest that with neuropathy the timing of the pattern of pressure varies and the gentle lead in to an earlier peak in the neuropathic sub-population results suggests a prolonged double limb support phase. In order for the slopes to be gentle, the other limb must still be carrying body weight. Also, for the forefoot to peak earlier, then the other limb must be ready to accept body weight. It may be hypothesised that if both feet continue to maintain acceptance of body weight, then they may experience pressure, even at low levels from a prolonged period each step. Prolonged even low-level pressure may be detrimental to the tissues due to resulting tissue ischaemia and hypoxia (Sanders et al., 1995). Further investigation utilising instrumentation that can provide bilateral gait timing is suggested to determine any role that bilateral foot function and timing has in potential injury or injury risk to the neuropathic foot.

The graphical results suggest that there is a more shuffling gait when neuropathic. This is evident from the hallux graph that shows an earlier but less pressure peak during push off, which suggests a more flat-footed and less propulsive push off phase. The 1MPJ and 2-5MPJ graphs show that the forefoot accepts load and peaks sooner and higher when neuropathic. This would be expected if body weight was passively moving forward over the foot and the pressures are a result of compression into the ground rather than during transfer into the digits at toe off phase.

Alternatively, the higher peak pressures on the 1MPJ and lower peak pressures on the hallux graphs could also suggest that the foot was abducted from the direction of progression with neuropathy, therefore, negating the loading of the hallux at toe off to some extent. The extent that the gait is a shuffle, abducted and/or double limb stance time prolonged could readily be quantified using a gait-timing mat, suggesting that potentially, first line screening for gait changes for foot injury risk identification could be conducted with inexpensive gait analysis devices.

The study results presented in *Figure 34* agree with the figure reported by Maluf and Muellar (2003), which is reproduced in *Figure 42*. Both graphs show that, although not significantly different, peak pressures on the 1MPJ are slightly higher (about five kPa) when comparing non-neuropathic and neuropathic ulceration-free populations. The study results, however, do not agree with Maluf and Muellar that peak pressures are significantly lower on the 1MPJ when there is ulceration on the forefoot. On the contrary, the study results presented in *Figure 39* show peak pressures on the 1MPJ to be higher, when ulceration is present on the forefoot, than without neuropathy or ulceration.



CON = Control (non-diabetic) population (n=10),
DMPN = Diabetic and neuropathic (without ulceration (n=10)),
DMPN + U = Diabetic, neuropathic and recurrent ulceration (n=10)

In Maluf, K. S., & Mueller, M. J. (2003), Comparison of physical activity and cumulative plantar tissue stress among subjects with and without diabetes mellitus and a history of recurrent plantar ulcers. *Clinical Biomechanics, 18*, 567-575

Figure 42. Peak pressure in the forefoot region plotted as a function of time during stance phase (group mean and SE).

Comparisons of pressure-time graphs

The major limitation in the absolute value analyses has been the lack of insight that they provide to look further to modify or change the peak pressures to provide optimal foot protection and nor do they show how the pressure experienced by the foot has varied from a normal or safe level. The pressure-time graphs have the potential, when based on a larger sample size, to show the range of pressure patterns that the normal foot experiences. Although there are few definite differences found between sub-populations seen in the pressure-time graphs from the present study, the graphs show that during the stance phase some variations in the pattern of pressure through the anatomical region occur. The variation in pressures between sub-populations in the present study is supported by the work of Uccioli et al. (2001), who showed that the direction of tangential forces varied with neuropathy and ulceration. With knowledge that kinetic variations do occur and the additional knowledge of when they occur, further investigation could provide links to be made with established kinematic functions of the foot, limb and body, and specific multi-functional therapeutic interventions be designed and tested.

The effect of neuropathy: Neuropathic and ulceration-free sub-population compared to non-neuropathic and ulceration-free sub-population

Comparing the pressure-time graphs between the ulceration-free neuropathic and non-neuropathic sub-populations, the results over the whole foot (total) suggest that with neuropathy the timing of the pattern of pressure varies and the gentle lead in to an earlier peak in the neuropathic sub-population results suggests a prolonged double limb support phase. In order for the slopes to be gentle, the other limb must still be carrying body weight. Also, for the forefoot to peak earlier, then the other limb must be ready to accept body weight. It may be hypothesised that if both feet continue to maintain acceptance of body weight, then they may experience pressure, even at low levels from a prolonged period each step. Prolonged even low-level pressure may be detrimental to the tissues due to resulting tissue ischaemia and hypoxia (Sanders et al., 1995). Further investigation utilising instrumentation that can provide bilateral gait timing is suggested to determine any role that bilateral foot function and timing has in potential injury or injury risk to the neuropathic foot.

The present study results from the defined anatomical area graphs suggest that there is a more shuffling gait when neuropathic. This is evident from the hallux graph that shows an earlier but lower pressure peak during push off, which suggests a more flat-footed and less propulsive push off phase. The 1MPJ and 2-5MPJ graphs show that the forefoot accepts load and peaks sooner and

higher when neuropathic. This would be expected if body weight was passively moving forward over the foot and the pressures are a result of compression into the ground rather than during transfer into the digits at toe off phase.

Alternatively, the higher peak pressures on the 1MPJ and lower peak pressures on the hallux graphs could also suggest that the foot was abducted from the direction of progression with neuropathy, therefore, negating the loading of the hallux at toe off to some extent. The extent that the gait is a shuffle, abducted and/or double limb stance time prolonged could readily be quantified using a gait-timing mat, suggesting that potentially, first line screening for gait changes for foot injury risk identification could be conducted with inexpensive gait analysis devices.

The effect of neuropathy and ulceration: Hallux or 1MPJ ulceration with neuropathy and neuropathy sub-populations compared to ulceration-free sub-population

The results from the present study show that there is a different relationship with peak pressure between hallux and 1MPJ ulcerations. This is particularly notable in the pressure-time graphs of the hallux and 1MPJ anatomical regions. Specifically, when there is ulceration on the hallux, then hallux pressures are somewhat higher than the other sub-populations throughout stance. However, when there is ulceration on the 1MPJ, then 1MPJ pressures are similar to the other sub-populations until the later of stance phase when they peak higher, but remain lower than the pressures from the hallux ulceration sub-population. These graphs supports earlier discussions, that further investigation utilising kinematic instrumentation is suggested to explore potential functional links that may exist between pressure and foot, limb and body actions.

Conclusion

This chapter has cross validated the results of the present study to the literature, and has demonstrated that the method of utilising pressure-time graphs provides greater insight into and confirms that there are differences and similarities between sub-populations with and without neuropathy, and ulcerations on the 1MPJ and hallux than does the absolute value method. What remains unknown and is the overall aim of this thesis and the focus of the next and final investigation, is whether the intervention with shoe therapy, namely rocker-soled shoe modifications to therapeutic shoes, have positive protective effects on existing ulceration and what is the ideal rocker-sole modification design.

CHAPTER EIGHT

THE EFFICACY OF THERAPEUTIC FOOTWEAR WITH AND WITHOUT ROCKER-SOLE MODIFICATIONS TO PROTECT ULCERATION

Background

Therapeutic shoes with rocker-sole modifications are routinely prescribed (see Chapter Two, p 34) with the aim to protect the ulceration from adverse plantar pressures so that healing can occur. Of concern is that experimental evidence from the study of people with ulceration is lacking and the efficacy to which these modifications provide protection to ulceration is unknown. Consequently, shoe design features, devices and techniques for shoe modification and shoe prescription are based on conflicting opinions (Litzelman et al., 1997), are *ad hoc* and remain largely an art (Ulbrecht et al., 1994). Of concern, is that without experimental evidence to support this intervention's efficacy, these therapeutic footwear may be included in the footwear-related pivotal events that were implicated as leading onto half of the eventual limb amputations reported in people with diabetes (Reiber, 1994; Reiber et al., 2002).

Rocker-sole shoes are designed using various fore sole angles placed at various anteroposterior pivot positions relative to the distal metatarsophalangeal joints line. Based on an extensive review of the literature, Schaff and Cavanagh (1990) reported that there was no consensus of opinion concerning the angle of the rocker-sole and the anteroposterior position of the rocker. Experimentally, the techniques used to construct rocker-sole modifications have not been standardised for the angle or placement of the pivot point (Nawoczenski et al., 1988).

Purpose

The purpose of the present study is to address research questions three (b) and four. That is, the purpose is to define the peak pressures experienced on the plantar foot when walking in a therapeutic shoe when compared to an athletic shoe, and to determine the efficacy of commonly prescribed rocker-soled shoe modifications of different angles and pivot point positions to protect ulceration on the hallux and 1MPJ during walking.

To this end the study has three aims:

1. To define the effect on walking pressures under hallux and 1MPJ ulceration when wearing therapeutic shoes compared to athletic shoes,

2. To define the effect that adding various rocker-sole modifications to therapeutic shoes has on walking pressures measured under hallux or 1MPJ ulceration, and

3. To determine the most beneficial shoe or rocker-sole modification that is useful to protect hallux or 1MPJ ulceration from walking pressures.

Subjects

The academic staff, residents and fellows of the Podiatry Service in the Department of Orthopedics at the University of Texas Health Science Center were enlisted to identify subjects for the study. A PowerPoint™ assisted presentation was made at the weekly education forum to describe the background and aims of the study, and the inclusion and exclusion criteria for subject selection. All patients that attended the "At-risk Diabetic Foot Clinic" at the Texas Diabetes Institute in late 1998 and until mid-1999 were screened for inclusion. The Texas Diabetes Institute High-risk Diabetic Foot Clinic is a teaching clinic of the University of Texas Health Science Center, Department of Orthopedics, and Podiatry Residency Program and is staffed by Podiatry residents under the supervision of academic staff. Patients generally attend this clinic due to their lack of health insurance and low socio-economic status, which limits their access to other health care facilities. Subjects who met the inclusion criteria were identified to the author who confirmed their eligibility prior to inviting them to participate in the study. The Institutional Review Boards of the University of Texas Health Science Center and the University Health System gave approval for the study, and informed consent was obtained from all subjects prior to their participation.

Subjects were included if they were an adult with diabetes, peripheral neuropathy, plantar forefoot ulceration either to the plantar hallux or the plantar first metatarsophalangeal joint and were able to walk unassisted. Subjects were excluded if they were unable to walk consistently and unassisted. Specifically they were excluded if they had a history of major trauma to the feet, legs or lower back, surgery to the feet, or if they had concurrent disease processes such as Parkinson's disease. The exclusion of subjects that had had surgery to their feet severely limited the number of suitable subjects. This was because podiatric surgical residents who could provide the patients with ready access to subsidised surgery staffed the clinic. All invited subjects consented to participate in the study and their positive decision was influenced by two incentives. The first incentive was that they would receive free of charge in-shoe plantar pressure assessment that was normally reserved for surgical assessment. The second was that they would receive free of charge the footwear with rocker-sole modification ($US 600 dollars per pair) that was assessed to be most beneficial to protect the ulceration on their foot.

Thirty-three subjects were identified that met the inclusion criteria and many of these subjects participated in the previous study. There were 23 men and ten women in the study population. The population were aged between 32 and 64 years (mean 52.39, SD 8.33), weighed between 63.64-136.36 kg (mean 87.71, SD 16.94), height was between 1.52-1.98 m (mean 1.72, SD 0.11) and body mass index (BMI) ranged from 19.78 to 41.38. Fourteen subjects were classified as overweight (BMI 25-30) and twelve were classified as obese (BMI>30) (Zeman, 1991). The population were diagnosed with Type 2 diabetes for between six months and 30 years (mean 11.83, SD 9.14). Nineteen subjects managed the hyperglycaemia component of their diabetes with oral hypoglycaemic medication (tablets), 12 subjects used insulin injections, while one subject was taking both tablets and insulin injections and another did not require hypoglycaemic medication due to a successful pancreas transplant. Thirty subjects had ulceration on one foot (19 subjects had plantar hallux ulceration and 11 subjects had plantar 1MPJ ulceration) while four subjects had a plantar ulceration on both feet (hallux ulceration on one foot and 1MPJ on the other foot).

Procedures

All subjects underwent the protocol developed in Chapter Three and tested in Chapter Six and the methods described in Chapter Four. The subjects wore appropriately sized SmartKnit socks (KnitRite, Kansas, USA) as described in Chapter Five. The shoes worn for baseline data collection were the Nike canvas shoes (Nike, Beaverton, Oregon, USA) as described in Chapter Six.

The therapeutic shoes worn for testing were Sequoia Therapeutic shoes (San Antonio Shoes, San Antonio, Texas, USA). Their style is the oxford design with specific additional features for accommodating the needs of diabetic foot therapies. These features include a firm and supportive leather shoe vamp with a soft nylon and Lycra dorsal section designed to minimise dorsal pressure on clawed or retracted toes. Other features include extra depth throughout the shoe and removable insoles for accommodation and replacement with customised insoles or therapeutic devices and a non-textured EVA (ethyl vinyl acetate) sole suitable for outsole additions (for example: rocker-soles, metatarsal bars and leg lengthen components).

The therapeutic rocker-sole modifications tested were of differing take-off angles and pivot point positions. The rocker-sole angles and positions to be tested were selected based on consultation with Certified Pedorthotists at the Texas Diabetes Institute and a review of the literature. The rocker take-off angles tested were 15, 20 and 25 degrees and are presented in *Figure 43*. The pivot point position for these rocker angles was determined from the line made between (level with) the most distal points of the first and fifth metatarsophalangeal joints (1-5MPJ line) measured from standardised anterior-posterior weight bearing radiographs that were obtained from the subject's medical file. The rocker take-off positions tested were one centimetre proximal to, distal to and level with the 1-5 MPJ line. The rocker take-off positions formed 20 degrees fore-outsole angle to the rear-outsole. Five rocker-soled shoe conditions were tested because the '20 degree rocker' and the 'level with the 1-5 MPJ line position outsole' were the same shoe. All footwear were modified by the same Certified Pedorthotist at the Texas Diabetes Institute.

Figure 43. Therapeutic shoes with rocker-sole modifications of 15, 20 and 25 degree fore-outsole angle with pivot point at the 1-5 MPJ line (top to bottom respectively).

Seven shoe conditions were tested in random order and they were labelled as follows;

- athletic (Nike canvas athletic shoe),
- therapeutic (Sequoia shoe unmodified),
- 15 degree rocker (therapeutic shoe with 15 degree fore-outsole angle level with the 1-5 MPJ line),
- 20 degree rocker (therapeutic shoe with 20 degree fore-outsole angle level with the 1-5 MPJ line),
- 25 degree rocker (therapeutic shoe with 25 degree fore-outsole angle level with the 1-5 MPJ line),
- distal rocker (therapeutic shoe with 20 degree fore-outsole angle 1 cm distal to the 1-5 MPJ line), and
- proximal rocker (therapeutic shoe with 20 degree fore-outsole angle 1 cm proximal to the 1-5 MPJ line).

All shoes were new at the beginning of testing. However, the athletic shoes were reused between subjects, while a separate set of new therapeutic shoes, appropriately sized with rocker modifications were individually modified for each subject. The therapeutic shoes were unable to be reused due to the specific and individual nature of the modifications made for each individual. Insoles other than the standard shoe inlay were not placed in the shoes during testing due to the inability to separate the effects of rocker-sole modification design from those due to insole composition on results obtained (Schaff & Cavanagh, 1990). Testing overtime was not conducted due to the lack of evidence to ensure that during testing the ulceration would not be at risk of further pressure-related injury.

At the conclusion of testing the subjects retained the SmartKnit socks worn during testing, while, after data analyses were completed, the therapeutic shoes/with rocker-sole modification that measured the lowest peak pressure on the subject's ulceration was gifted to each subject. All other therapeutic shoes/with rocker-sole modification were made available for issue to suitable patients who attended the Texas Diabetes Institute High-risk Diabetic Foot Clinic, San Antonio, Texas USA.

Data analyses

Data were analysed, as developed and described in chapters three, four and six.

Statistical analyses

Absolute value analyses

All analyses were performed using SPSS Release 8 for Windows. All data were examined for and confirmed as being normally distributed using Proportion probability (P-P) plots with the proportion estimated using the Rankit formula. One way repeated measures analysis of variance (ANOVA) function was utilised to screen the pressure and pressure-time integral variables per anatomical regions across ulceration locations and shoes for variables of statistical significance. A p-value of less than or equal to 0.05 was selected for screening for statistically significant variables and *post hoc* analyses using Dunnett's T3 (SPSS Incorporated, 1998) were performed.

Pressure measures as they relate to stance time

All analyses were performed using Excel 2000 for Windows. Bootstrap means and 95% confidence bands were plotted as described in Chapter Five.

Results

The results are presented in two sections. The first section presents the results from the hallux ulceration sub-population, and the second section presents the results from the 1MPJ ulceration sub-population. Within each section the results are presented; first, comparing the athletic shoe to the therapeutic shoe, and second, comparing the therapeutic shoe to the therapeutic shoe with rocker-sole shoe modifications.

The effect on hallux ulceration peak pressures with change of footwear

Box plots showing the hallux sub-population median absolute value results and distribution of step-to-step variation in peak pressure (kPa) and pressure-time integral (kPa s) for the hallux anatomical region (ulceration) are presented in *Figure 44* (for an explanation of the box-plot function and presentation see Chapter Three Part II(a)). Within each plot, the effects of shoe type and rocker-sole modification design are shown. Box plots are a useful means to provide a subjective impression of the effects of shoe type and intervention design (Cavanagh et al., 1998). It is apparent from these plots that the median results and step-to-step variability in peak pressure and pressure-time integral appears to be broadly similar on hallux ulceration across all shoes tested.

Overall, the ulceration bore a median peak pressure of approximately 300 kPa and pressure-time integral of approximately 80 kPa s during walking. There was wide variation in the peak pressure (less than 100 kPa to nearly 600 kPa) and pressure-time integral (nearly zero to less than 200 kPa s) for all shoes.

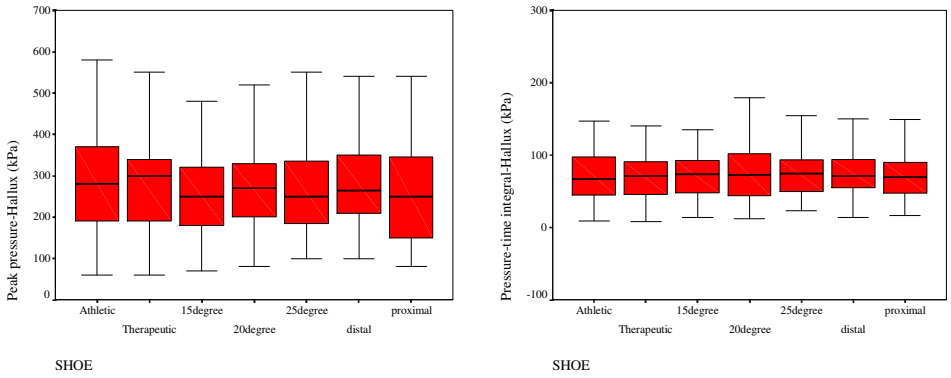


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Figure 44. Box plots showing the median and distribution of the step-to-step variation as described by the peak pressure (kPa) and pressure-time integral (kPa s) absolute value results on the hallux ulceration for the hallux ulceration sub-population per shoe.

Hallux ulceration: Athletic shoe versus therapeutic shoe

Absolute value analyses

The descriptive statistic results for the absolute value analyses are presented for the hallux ulceration sub-population in Table 37.

Table 37

Results for hallux ulceration sub-population per shoe (n=15 hallux ulcerations).

Variable	Anatomical region	Shoe type	Mean	SD	Min	Max
Peak pressure (kPa)	total	Athletic	355.68	67.07	220.00	466.00
		Therapeutic	378.05	65.09	279.00	504.67
	hallux	Athletic	301.87	109.85	98.00	460.00
		Therapeutic	286.83	95.10	72.00	417.33
	1MPJ	Athletic	258.89	95.73	131.33	398.57
		Therapeutic	268.12	129.41	80.00	504.67
	2-5MPJ	Athletic	243.23	58.05	164.00	374.29
		Therapeutic	193.93	60.11	93.00	292.00
	heel	Athletic	211.09	69.67	71.43	292.67
		Therapeutic	275.21	106.74	100.67	436.67
Pressure time-integral (kPa s)	total	Athletic	132.45	25.74	77.04	169.61
		Therapeutic	144.50	32.13	75.27	201.31
	hallux	Athletic	74.27	26.75	24.84	111.71
		Therapeutic	73.69	26.01	14.00	105.12
	1MPJ	Athletic	73.67	24.75	43.63	126.64
		Therapeutic	71.19	31.35	20.94	137.61
	2-5MPJ	Athletic	74.99	28.12	43.11	131.37
		Therapeutic	56.89	20.43	26.57	93.76
	heel	Athletic	63.90	23.00	7.06	104.49
		Therapeutic	80.41	34.25	15.93	175.96

In the hallux ulceration sub-population, the athletic shoe had a lower peak pressure over the whole foot (total) (23 kPa lower) and the heel (64 kPa lower) when compared to the therapeutic shoe. The peak pressures were similar between the shoes on the hallux and the 1MPJ (within 15 kPa). Whereas the peak pressures on the 2-5MPJ in the therapeutic shoe were lower (50 kPa lower) than the athletic shoe. The pressure-time integral was similar (within 18 kPa s) and not clinically different between shoes over the whole foot (total), hallux, 1MPJ, 2-5MPJ and heel regions.

The ANOVA results that showed significant differences between shoes at the $p \leq 0.05$ level are presented for the hallux ulceration sub-population in Table 38. There were significant differences

between shoes on only the 2-5MPJ region. Statistical significance was just outside the $p < 0.05$ level for the pressure-time integral on the 2-5MPJ for the hallux ulceration sub-population.

Table 38

The ANOVA results significant at p≤0.05 for the hallux ulceration sub-population per shoe group (Athletic versus Therapeutic shoes).

Variable	Anatomical region	Groups	Sum of Squares	Degrees of freedom	Mean Square	F	Sig.
Peak pressure (kPa)	2-5MPJ	Between	182.23	1	1822.28	5.22	0.03
		Within	977.55	28	349.13		
		total	1159.78	29			
Pressure time integral (kPa s)	2-5MPJ	Between	24.56	1	245.58	4.07	0.05
		Within	169.13	28	60.40		
		total	193.69	29			

Pressure-time comparisons

The graphical results of peak pressures measured from the hallux ulceration sub-population are presented for the whole foot (total) in *Figure 45*, the hallux region in *Figure 46* and the 2-5MPJ region in *Figure 47*. The other regional graphs are presented in Appendix E as they are ancillary to and not of direct relevance to the research question. These graphical results describe differences in peak pressure that occurred during stance phase with the athletic and therapeutic shoe when ulceration was present on the hallux.

The graphical results of the peak pressure over the whole foot (*Figure 45*) shows that peak pressures are approximately ten kPa higher in the therapeutic shoe compared to the athletic shoe during the forefoot loading phase, from ten to 40 percent, of stance phase in the hallux ulceration sub-population.

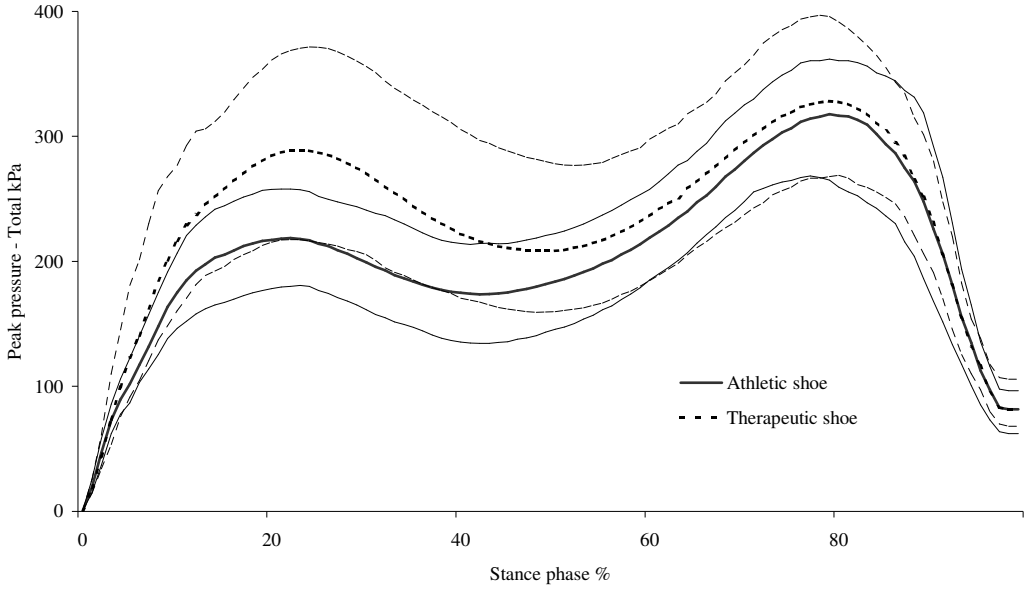


Figure 45. The means and 95% confidence bands (Bstrap) (the outer lines) for peak pressure-total for the hallux ulceration sub-population per shoe type.

The graphical results of the peak pressure on the hallux (*Figure 46*) show that peak pressures are only slightly higher in the therapeutic compared to the athletic shoe from heel lift through to push off phase, 55 to 90 percent, of stance phase in the hallux ulceration sub-population.

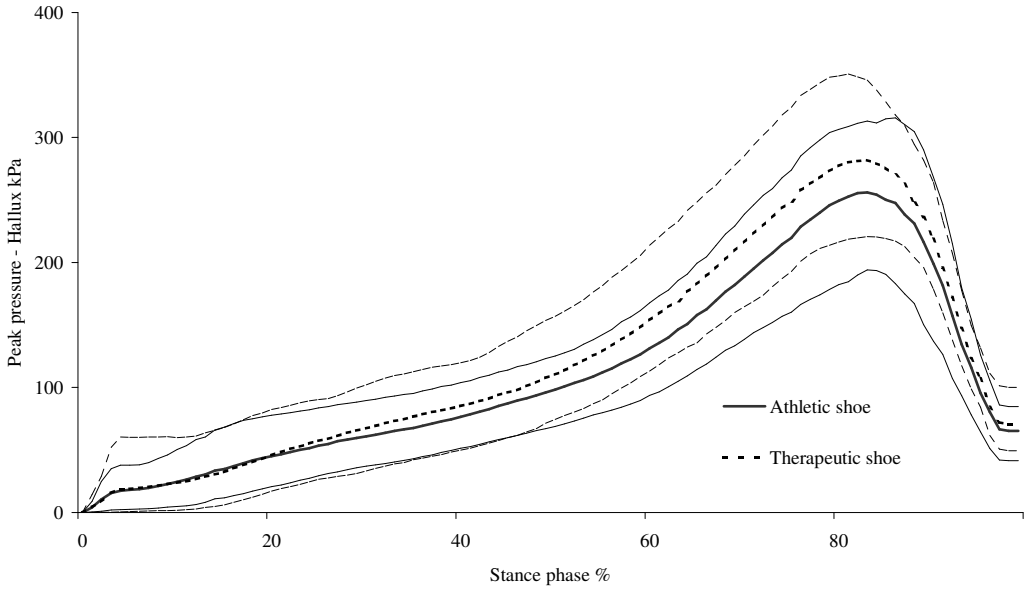


Figure 46. The means and 95% confidence bands (Bstrap) (the outer lines) for peak pressure-hallux for the hallux ulceration sub-population per shoe type.

The graphical results for peak pressure on the 2-5MPJ region (*Figure 47*) show that the peak pressures are higher in the athletic compared to the therapeutic shoe during midstance through to toe off phases, 45 to 100 percent of stance phase, for the hallux ulceration sub-population. The athletic shoe was significantly higher than the therapeutic shoe when hallux ulceration was present ($p = 0.03$) and the peak pressure on the 2-5MPJ peaked, and this occurred at approximately 80 percent of stance phase. The athletic shoe was also significantly higher than the therapeutic shoe ($p = 0.05$) for the pressure-time integral of the 2-5MPJ region when hallux ulceration was present.

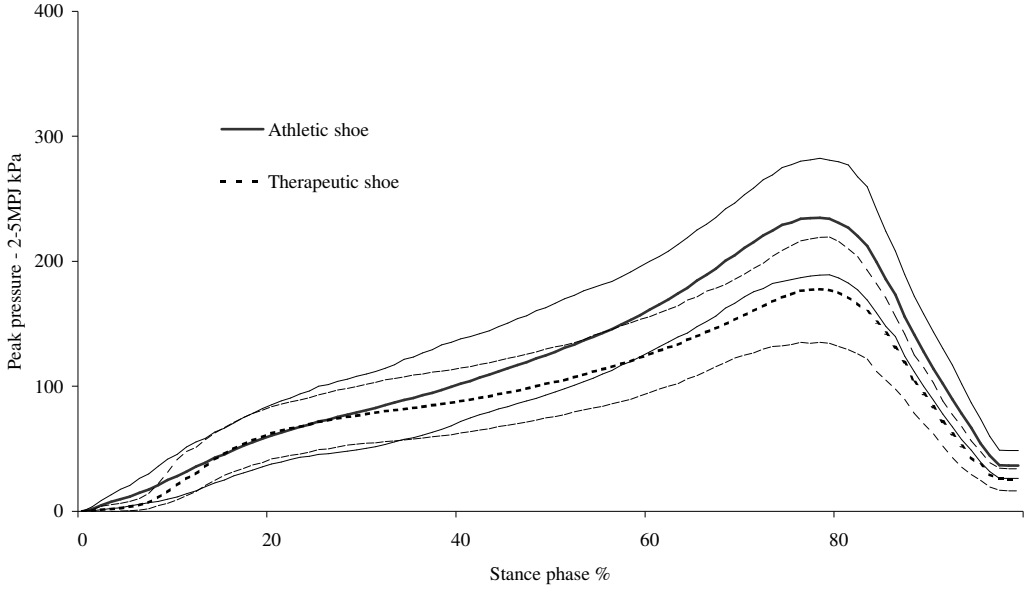


Figure 47. The means and 95% confidence bands (Bstrap) (the outer lines) for peak pressure-2-5MPJ for the hallux ulceration sub-population per shoe type.

Hallux ulceration: Therapeutic shoe versus therapeutic shoe with rocker-sole angle and pivot position modifications

Absolute value analyses

The descriptive statistic results for the absolute value analyses are presented for the hallux ulceration sub-population in Table 39 and Table 40.

In the hallux ulceration sub-population, the peak pressure was slightly lower in the rocker-sole modifications over the whole foot (total), hallux and the 2-5MPJ regions when compared to the therapeutic shoe. However, the differences were small and were less than the measurable accuracy established for the device in Chapter Three. All shoes had similar peak pressures on the 1MPJ and heel regions. All shoes had similar pressure-time integrals in all anatomical regions.

Table 39

Results for hallux ulcerations per shoe (n=15) for peak pressure and pressure-time integral as measured over the whole foot (Total).

Variable	Shoe type	Mean	SD	Min	Max
Peak pressure-Total	Therapeutic	378.05	65.09	279.00	504.67
(kPa)	15 degree rocker	358.71	74.09	237.33	525.71
	20 degree rocker	370.81	104.00	237.33	622.86
	25 degree rocker	359.83	102.32	217.33	509.33
	Distal rocker	369.70	85.40	225.33	542.00
	Proximal rocker	369.93	89.39	230.00	540.00
Pressure time-integral-Total	Therapeutic	144.50	32.13	75.27	201.31
(kPa s)	15 degree rocker	140.70	36.47	77.83	211.11
	20 degree rocker	146.04	37.86	75.73	204.49
	25 degree rocker	140.11	39.28	59.08	196.33
	Distal rocker	143.76	36.86	70.76	204.91
	Proximal rocker	147.72	34.63	94.24	210.44

Table 40

Results for hallux ulcerations per shoe (n=15) per variable a) peak pressure and b) pressure-time integral.

a) Peak pressure (kPa)					
Anatomical region	Shoe type	Mean	SD	Min	Max
Hallux	Therapeutic	286.83	95.10	72.00	417.33
	15 degree rocker	262.45	92.55	97.14	414.00
	20 degree rocker	277.91	101.63	106.00	533.33
	25 degree rocker	274.98	105.05	129.29	500.00
	Distal rocker	281.94	97.58	116.67	444.67
	Proximal rocker	272.65	110.47	128.67	448.67
1MPJ	Therapeutic	268.12	129.41	80.00	504.67
	15 degree rocker	270.43	123.49	100.00	525.00
	20 degree rocker	265.33	147.49	84.29	622.86
	25 degree rocker	256.90	131.89	93.57	498.00
	Distal rocker	271.39	134.73	88.67	542.00
	Proximal rocker	275.62	133.84	80.00	537.33
2-5MPJ	Therapeutic	193.93	60.11	93.00	292.00
	15 degree rocker	169.42	73.76	62.00	302.00
	20 degree rocker	156.94	64.46	59.33	270.00
	25 degree rocker	163.93	73.82	74.67	272.67
	Distal rocker	169.65	68.19	64.67	284.67
	Proximal rocker	177.86	66.51	67.69	274.00
Heel	Therapeutic	275.21	106.74	100.67	436.67
	15 degree rocker	256.29	103.18	114.67	439.33
	20 degree rocker	253.58	94.22	112.00	436.67
	25 degree rocker	255.18	103.10	100.67	489.33
	Distal rocker	257.39	99.89	110.67	442.00
	Proximal rocker	267.33	105.14	109.33	448.00

Table 40 continued

b) Pressure-time integral (kPa s)					
Anatomical region	Shoe type	Mean	SD	Min	Max
Hallux	Therapeutic	73.69	26.01	14.00	105.12
	15 degree rocker	73.35	29.74	21.16	115.05
	20 degree rocker	82.44	41.73	22.77	164.51
	25 degree rocker	76.24	26.86	31.30	126.09
	Distal rocker	76.14	27.36	29.93	121.21
	Proximal rocker	74.74	27.86	24.89	112.00
1MPJ	Therapeutic	71.19	31.35	20.94	137.61
	15 degree rocker	73.11	29.09	33.01	123.79
	20 degree rocker	71.29	33.02	34.39	134.22
	25 degree rocker	72.14	34.87	30.67	151.28
	Distal rocker	72.73	33.43	28.16	139.49
	Proximal rocker	78.06	34.10	19.97	137.88
2-5MPJ	Therapeutic	56.89	20.43	26.57	93.76
	15 degree rocker	58.14	38.66	15.67	178.25
	20 degree rocker	55.13	37.90	18.16	172.69
	25 degree rocker	56.89	34.21	21.35	152.84
	Distal rocker	58.86	33.65	18.96	153.09
	Proximal rocker	60.60	32.56	27.76	157.56
Heel	Therapeutic	80.41	34.25	15.93	175.96
	15 degree rocker	75.79	33.19	17.92	167.56
	20 degree rocker	74.94	27.47	20.07	145.09
	25 degree rocker	77.22	27.90	16.13	129.99
	Distal rocker	75.99	29.70	18.95	159.23
	Proximal rocker	83.18	32.37	27.73	175.09

In the hallux ulceration sub-population, the peak pressures are slightly lower in the rocker-soled modifications compared to the therapeutic shoe over the whole foot (total), hallux, 2-5MPJ and heel regions. However, the differences were small and were less than the measurable accuracy established for the device in Chapter Three. The pressure-time integral was similar in all shoes for all anatomical regions.

In the hallux ulceration sub-population, there were no significant differences found from the ANOVA and *post hoc* analyses($p < 0.05$) in any of the rocker-soled shoe modifications when compared to the therapeutic shoes.

Pressure-time comparisons

The graphical results of peak pressures measured from the hallux ulceration sub-population are presented for the whole foot (total) in *Figure 48* and the hallux region in *Figure 49*. The other regional graphs are presented in Appendix F as they are ancillary to and not of direct relevance to the research question. These graphical results describe differences in peak pressure that occurred during stance phase with the therapeutic shoe with and without the rocker-sole modifications when ulceration was present on the hallux.

The graphical results of the peak pressure over the whole foot (*Figure 48*) shows that peak pressures are slightly higher in the therapeutic shoe compared to the same shoe with rocker-sole modifications until 80% of stance phase in the hallux ulceration sub-population. Other than the 15 degree rocker-sole modification that shows a slightly lower peak pressure over the whole foot after 80% of stance phase, there are no distinct differences between rocker-sole modifications in the hallux ulceration sub-population.

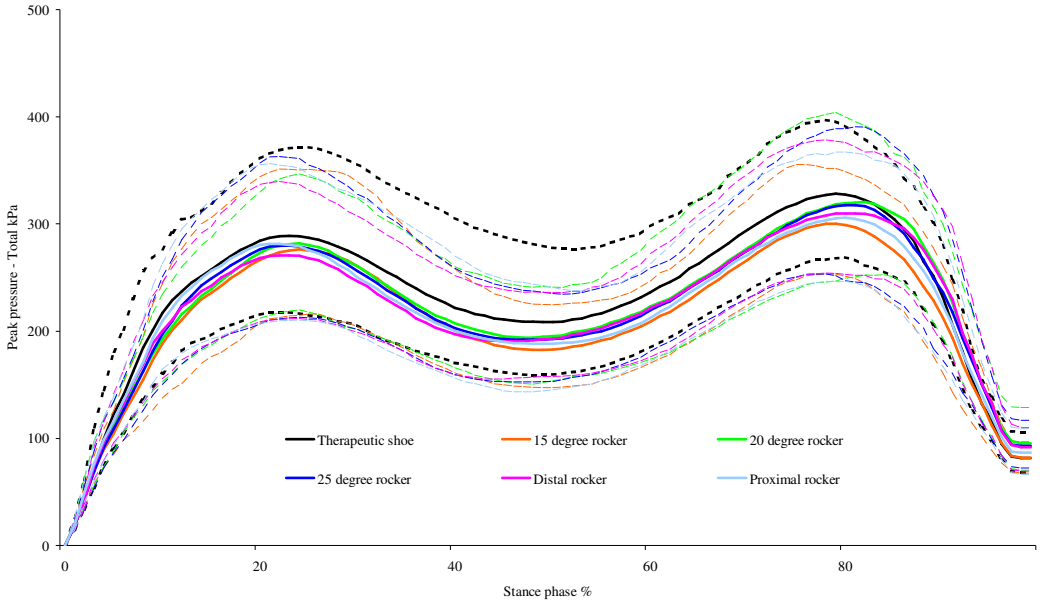


Figure 48. The means and 95% confidence bands (Bstrap) (the outer dashed lines) for peak pressure-total for the hallux ulceration sub-population per shoe type.

The graphical results of the peak pressure on the hallux (*Figure 49*) shows that peak pressures were slightly higher in the therapeutic shoe compared to the same shoe with rocker-sole modifications until 90% of stance phase in the hallux ulceration sub-population. Other than the 15 degree and proximal rocker-sole modifications that shows a slightly lower peak pressure on the hallux after 80% of stance phase, there are no distinct differences between rocker-sole modifications in the hallux ulceration sub-population.

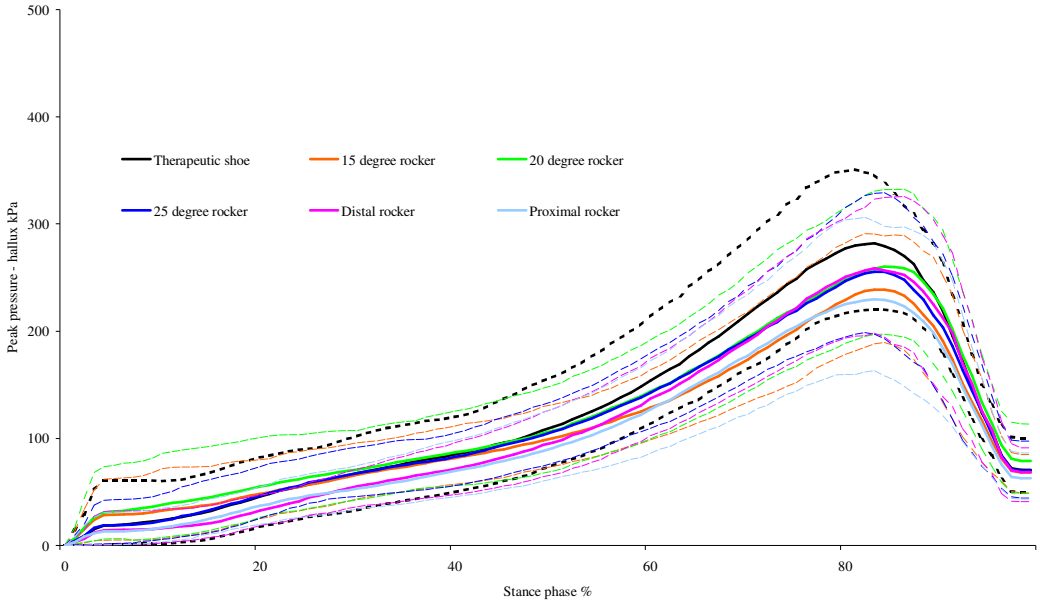


Figure 49. The means and 95% confidence bands (Bstrap) (the outer dashed lines) for peak pressure-hallux for the hallux ulceration sub-population per shoe type.

The effect on 1MPJ ulceration pressures with change of footwear

Box plots showing the 1MPJ ulceration sub-population median absolute value results and distribution of step-to-step variation in peak pressure (kPa) and pressure-time integral (kPa s) for the 1MPJ anatomical region (ulceration) are presented in *Figure 50* (for an explanation of the box-plot function and presentation see Chapter Three Part II(a)). Within each plot, the effects of shoe type and rocker-sole modification design are shown. As discussed earlier, box plots are a useful means to provide a subjective impression of the effects of shoe type and intervention design (Cavanagh et al., 1998). It is apparent from these plots that the median results and step-to-step variability in peak pressure and pressure-time integral appears to be broadly similar on 1MPJ ulceration across all shoes tested.

Overall, the ulceration bore a median peak pressure of less than 400 kPa and pressure-time integral of approximately 100 kPa s during walking. There was wide variation in the peak pressure (150kPa to 650kPa) and pressure-time integral (zero to more than 200 kPa s: excluding outliers) for all shoes.

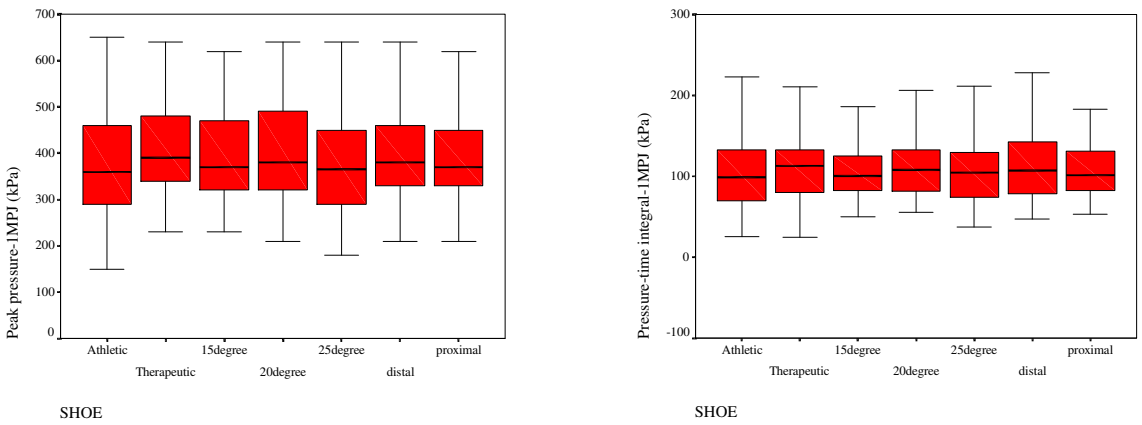


Figure 50. Box plots showing the median and distribution of the step-to-step variation as described by the peak pressure (kPa) and pressure-time integral (kPa s) absolute value results on the 1MPJ ulceration for the 1MPJ ulceration sub-population per shoe.

1MPJ ulceration: Athletic shoe versus therapeutic shoe

Absolute value analyses

The descriptive statistic results for the absolute value analyses are presented for the 1MPJ ulceration sub-population in Table 41.

In the 1MPJ ulceration sub-population, the peak pressures on the 1MPJ and the heel were lower (-41 kPa and –30 kPa respectively) in the athletic shoe compared to the therapeutic shoe. The peak pressures were similar between the shoes over the whole foot (total) and hallux. Whereas the peak pressure was lower (-81 kPa) in the therapeutic shoe on the 2-5MPJ region. The pressure-time integral on the 2-5MPJ was lower (-21 kPas) in the therapeutic shoes compared to the athletic shoes, whereas the pressure-time integral was similar (within 14 kPas) between shoes over the whole foot (total), hallux, 1MPJ and heel regions.

The ANOVA results that showed significant differences between shoes are presented for the 1MPJ ulceration sub-population in Table 42. There were significant differences in peak pressure and pressure-time integral between shoes on only the 2-5MPJ region for the 1MPJ ulceration sub-population.

Table 41

Results for 1MPJ ulceration sub-population per shoe (n=9 1MPJ ulcerations).

Variable	Anatomical region	Shoe type	Mean	SD	Min	Max
Peak pressure (kPa)	total	Athletic	409.07	88.77	304.29	559.33
		Therapeutic	405.58	53.82	332.00	489.33
	hallux	Athletic	246.40	139.98	69.33	513.33
		Therapeutic	236.94	104.12	56.43	340.67
	1MPJ	Athletic	358.69	99.80	220.71	527.33
		Therapeutic	399.68	58.75	326.67	489.33
	2-5MPJ	Athletic	303.14	96.74	202.67	531.33
		Therapeutic	222.93	57.93	105.71	286.00
	heel	Athletic	250.31	45.95	191.33	320.63
		Therapeutic	280.57	37.99	215.00	330.67
Pressure time-integral (kPa s)	total	Athletic	160.04	44.26	109.73	250.84
		Therapeutic	172.60	52.46	111.76	288.76
	hallux	Athletic	56.97	24.09	10.33	94.24
		Therapeutic	62.43	31.17	9.68	110.19
	1MPJ	Athletic	111.51	49.96	48.59	190.91
		Therapeutic	120.23	42.95	75.37	220.03
	2-5MPJ	Athletic	87.33	21.63	62.27	125.44
		Therapeutic	66.75	17.70	39.90	98.71
	heel	Athletic	81.03	35.93	50.63	165.94
		Therapeutic	95.95	37.86	47.01	171.35

Table 42

The ANOVA results significant at p≤0.05 for the 1MPJ ulceration sub-population per shoe group (Athletic versus Therapeutic shoes).

Variable	Anatomical region	Groups	Sum of Squares	Degrees of freedom	Mean Square	F	Sig.
Peak pressure (kPa)	2-5MPJ	Between	289.57	1	2895.71	4.55	0.05
		Within	1017.18	16	635.74		
		total	1306.75	17			
Pressure time-Integral (kPa s)	2-5MPJ	Between	19.06	1	190.59	4.88	0.04
		Within	62.50	16	39.06		
		total	193.69	29			

Pressure-time comparisons

The graphical results of peak pressures measured from the 1MPJ ulceration sub-population are presented in kPa for the whole foot (total) in *Figure 51*, the 1MPJ region in *Figure 52* and the 2-5MPJ region in *Figure 53*, while the other regions are presented in Appendix G. These graphical results describe differences in peak pressure that occurred during stance phase with the athletic and therapeutic shoe when ulceration was present on the 1MPJ.

The graphical results of the peak pressure over the whole foot (*Figure 51*) shows that peak pressures are at least 50 kPa higher in the therapeutic shoe compared to the athletic shoe from forefoot loading though to heel lift phases, from 20 to 80 percent, of stance phase in the 1MPJ ulceration sub-population.

The graphical results of the peak pressure on the 1MPJ (*Figure 52*) show that peak pressures are less than ten percent higher in the therapeutic compared to the athletic shoe from heel lift through to push off phase, 40 to 90 percent, of stance phase in the 1MPJ ulceration sub-population.

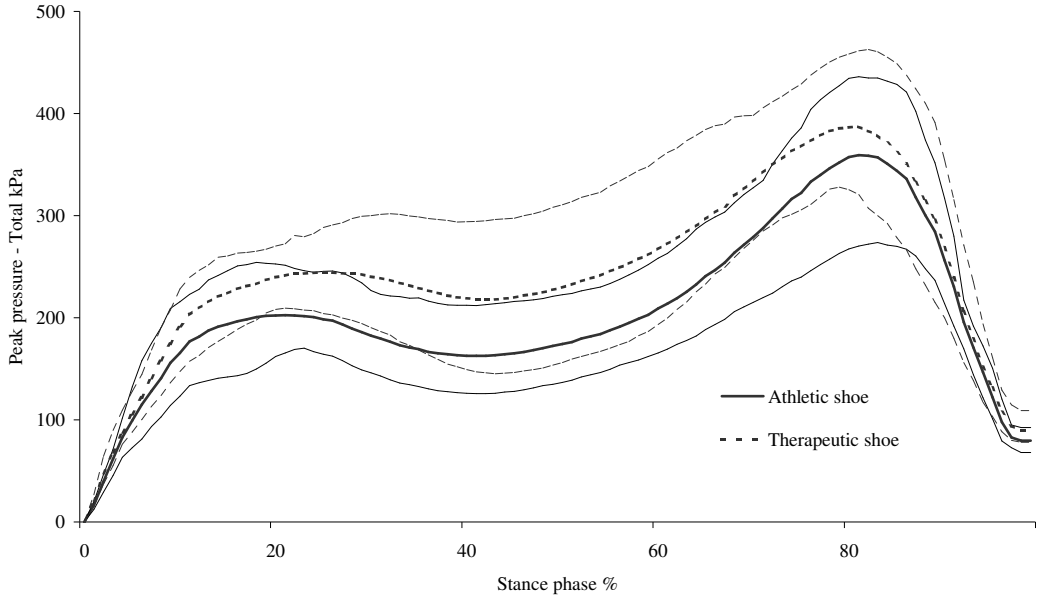


Figure 51. The means and 95% confidence bands (Bstrap) (the outer lines) for peak pressure-total for the 1MPJ ulceration sub-population per shoe type.

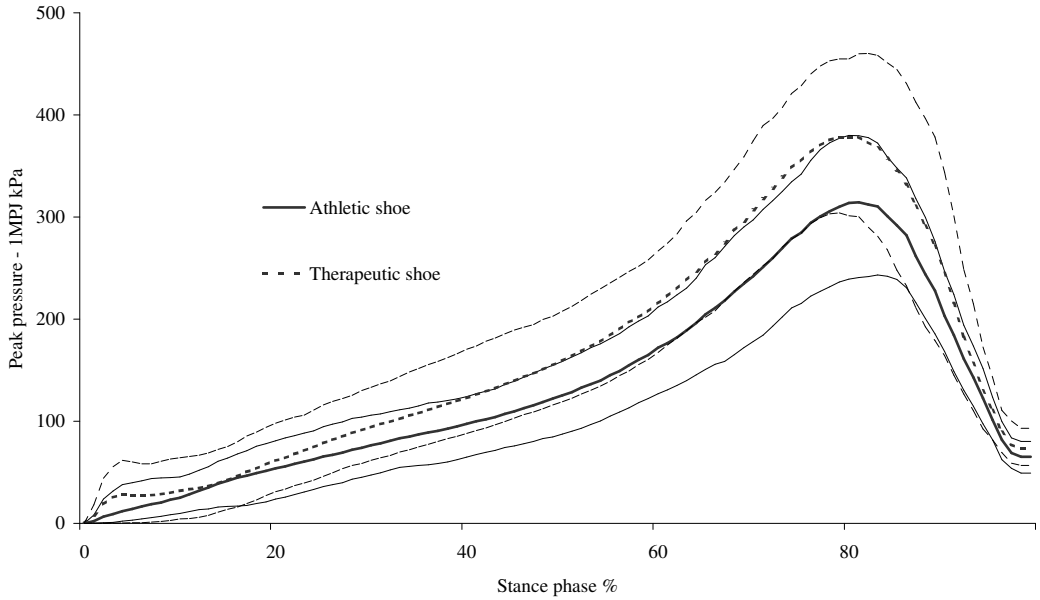


Figure 52. The means and 95% confidence bands (Bstrap) (the outer lines) for peak pressure-1MPJ for the 1MPJ ulceration sub-population per shoe type.

The graphical results for peak pressure on the 2-5MPJ region (*Figure 53*) show that the peak pressures are higher in the athletic compared to the therapeutic shoe from after midstance through to toe off phases, 60 to 90 percent, of stance phase for the 1MPJ ulceration sub-population. The athletic shoe was significantly higher than the therapeutic shoe when 1MPJ ulceration was present ($p = 0.05$) and the peak pressure on the 2-5MPJ peaked, and this occurred at approximately 80 percent of stance phase. The athletic shoe was also significantly higher than the therapeutic shoe ($p = 0.04$) for the pressure-time integral on the 2-5MPJ region when 1MPJ ulceration was present.

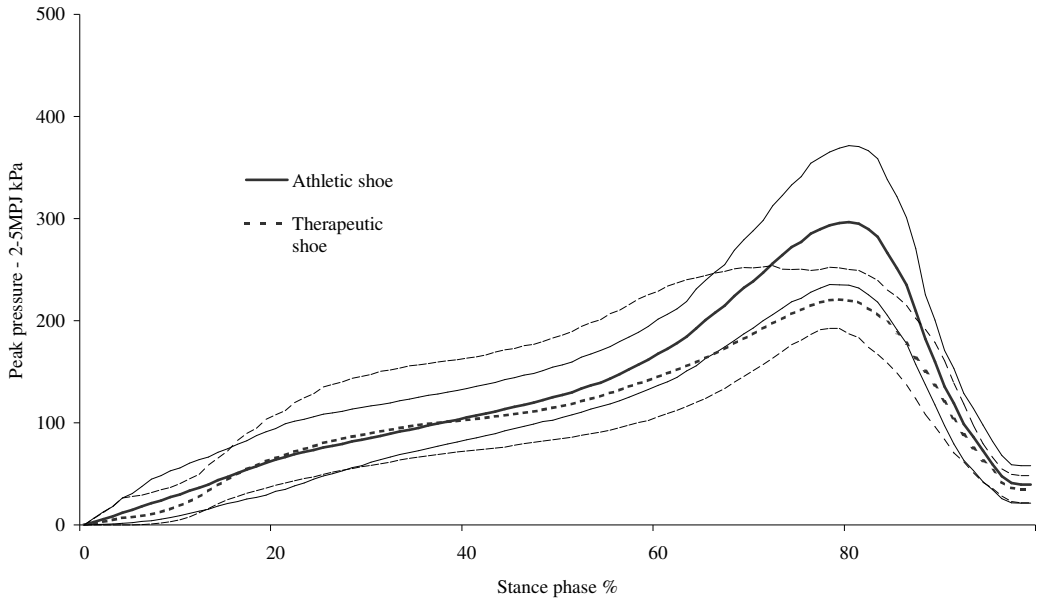


Figure 53. The means and 95% confidence bands (Bstrap) (the outer lines) for peak pressure-2-5MPJ for the 1MPJ ulceration sub-population per shoe type.

1MPJ ulceration: Therapeutic shoe versus therapeutic shoe with rocker-sole angle and pivot position modifications

Absolute value analyses

The descriptive statistic results for the absolute value analyses are presented for the 1MPJ ulceration sub-population in Table 43 and Table 44.

Table 43

Results for !MPJ ulcerations per shoe (n=9) for peak pressure and pressure-time integral as measured over the whole foot (Total).

Variable	Shoe type	Mean	SD	Min	Max
Peak pressure-Total (kPa)	Therapeutic	405.58	53.82	332.00	489.33
	15 degree rocker	387.74	74.23	294.00	528.00
	20 degree rocker	398.95	77.22	296.15	540.00
	25 degree rocker	374.06	75.30	288.00	524.67
	Distal rocker	404.78	66.37	303.57	546.00
	Proximal rocker	397.09	66.29	322.67	514.00
Pressure time-integral- Total (kPa s)	Therapeutic	172.60	52.46	111.76	288.76
	15 degree rocker	166.82	44.66	100.95	246.76
	20 degree rocker	170.54	51.18	119.14	279.58
	25 degree rocker	163.79	40.62	117.37	250.75
	Distal rocker	173.87	42.72	118.32	253.71
	Proximal rocker	169.81	49.40	122.73	289.33

Table 44

Results for 1MPJ ulcerations per shoe (n=9) per variable a) peak pressure and b) pressure-time integral.

a) Peak pressure (kPa)					
Anatomical region	Shoe type	Mean	SD	Min	Max
Hallux	Therapeutic	236.94	104.12	56.43	340.67
	15 degree rocker	223.74	95.24	64.67	328.00
	20 degree rocker	222.03	94.98	70.67	326.00
	25 degree rocker	222.03	97.39	48.67	331.43
	Distal rocker	210.93	90.54	82.00	317.33
	Proximal rocker	217.41	96.06	66.67	342.22
1MPJ	Therapeutic	399.68	58.75	326.67	489.33
	15 degree rocker	382.70	76.30	294.00	528.00
	20 degree rocker	386.41	82.02	283.08	540.00
	25 degree rocker	360.32	83.92	267.86	523.33
	Distal rocker	394.75	70.62	299.29	546.00
	Proximal rocker	374.27	71.02	281.33	514.00
2-5MPJ	Therapeutic	222.93	57.93	105.71	286.00
	15 degree rocker	201.20	42.72	144.62	279.33
	20 degree rocker	200.77	58.16	126.00	317.33
	25 degree rocker	202.55	47.31	128.46	280.00
	Distal rocker	192.03	41.46	138.67	265.71
	Proximal rocker	200.08	61.42	120.00	325.00
Heel	Therapeutic	280.57	37.99	215.00	330.67
	15 degree rocker	278.51	45.45	208.67	330.67
	20 degree rocker	300.50	53.50	204.00	384.00
	25 degree rocker	287.36	35.29	236.00	335.33
	Distal rocker	301.13	64.70	215.38	416.67
	Proximal rocker	310.41	75.69	212.00	465.00

Table 44 *continued*

b) Pressure-time integral (kPa s)					
Anatomical region	Shoe type	Mean	SD	Min	Max
Hallux	Therapeutic	62.43	31.17	9.68	110.19
	15 degree rocker	59.13	25.99	12.96	89.31
	20 degree rocker	65.72	30.40	13.47	101.77
	25 degree rocker	64.85	32.31	15.92	107.57
	Distal rocker	60.55	33.85	13.71	112.44
	Proximal rocker	59.02	28.30	11.97	103.82
1MPJ	Therapeutic	120.23	42.95	75.37	220.03
	15 degree rocker	112.01	36.64	73.09	173.59
	20 degree rocker	118.87	46.54	73.00	201.45
	25 degree rocker	107.63	30.92	66.41	151.68
	Distal rocker	118.87	36.65	78.20	176.65
	Proximal rocker	109.85	39.88	68.43	207.28
2-5MPJ	Therapeutic	66.75	17.70	39.90	98.71
	15 degree rocker	65.14	17.80	48.66	100.57
	20 degree rocker	62.84	12.66	41.57	80.28
	25 degree rocker	64.38	15.94	38.97	98.65
	Distal rocker	63.09	19.43	47.20	109.71
	Proximal rocker	63.46	13.82	37.64	80.83
Heel	Therapeutic	95.95	37.86	47.01	171.35
	15 degree rocker	88.54	38.60	30.12	164.26
	20 degree rocker	95.31	37.90	48.43	175.23
	25 degree rocker	96.89	37.17	56.64	178.81
	Distal rocker	102.95	41.02	45.76	168.51
	Proximal rocker	99.94	40.04	56.81	182.57

There were no significant differences in peak pressure and pressure-time integral from the ANOVA and *post hoc* analyses measured under the 1MPJ ulcerations in any of the rocker-soled shoe modifications when compared to the therapeutic shoes.

Pressure-time comparisons

The graphical results of peak pressures measured from the 1MPJ ulceration sub-population are presented for the whole foot (total) in *Figure 54* and the 1MPJ region in *Figure 55*, whereas the other regions are presented in Appendix H. These graphical results describe differences in peak pressure that occurred during stance phase with the therapeutic shoe with and without the rocker-sole modifications when ulceration was present on the 1MPJ.

The graphical results of the peak pressure over the whole foot (*Figure 54*) shows that peak pressures are slightly higher in the therapeutic shoe compared to the same shoe with rocker-sole modifications from 40% of stance phase in the 1MPJ ulceration sub-population. The upper confidence band is different for the therapeutic shoe compared to the rocker-sole modifications in that it does not reduce during the midstance phase, but continues to gradually raise until it peaks after 85% of stance phase. There are no distinct differences between rocker-sole modifications for peak pressure over the whole foot (total) for the 1MPJ ulceration sub-population.

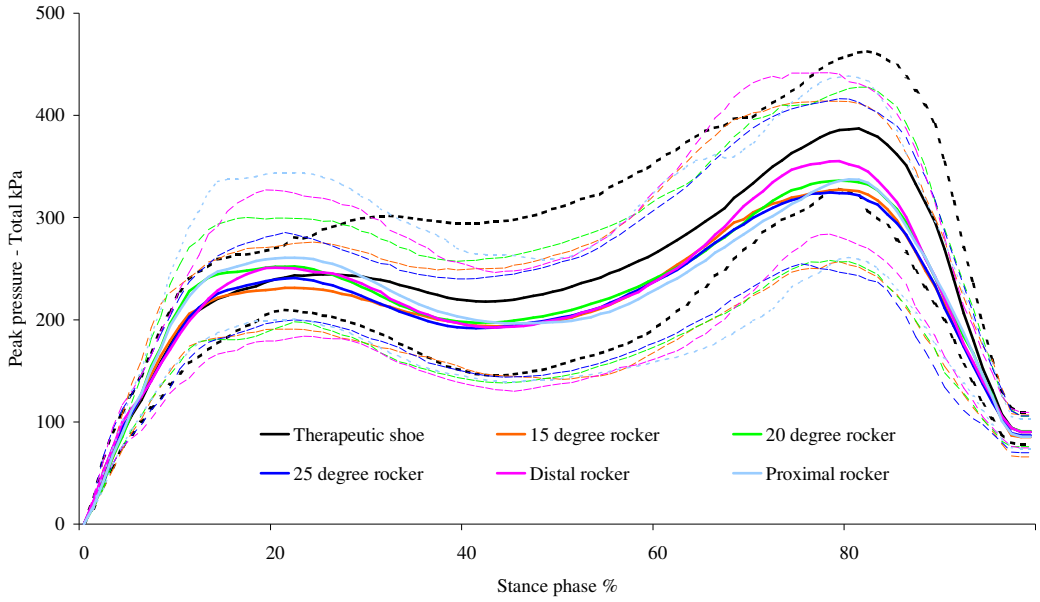


Figure 54. The means and 95% confidence bands (Bstrap) (the outer dashed lines) for peak pressure-total for the 1MPJ ulceration sub-population per shoe type.

The graphical results of the peak pressure on the 1MPJ (*Figure 55*) shows that peak pressures were slightly higher in the therapeutic shoe compared to the same shoe with rocker-sole modifications from 40% percent of stance phase in the 1MPJ ulceration sub-population. There are no distinct differences between rocker-sole modifications for peak pressure over the whole foot (total) for the 1MPJ ulceration sub-population.

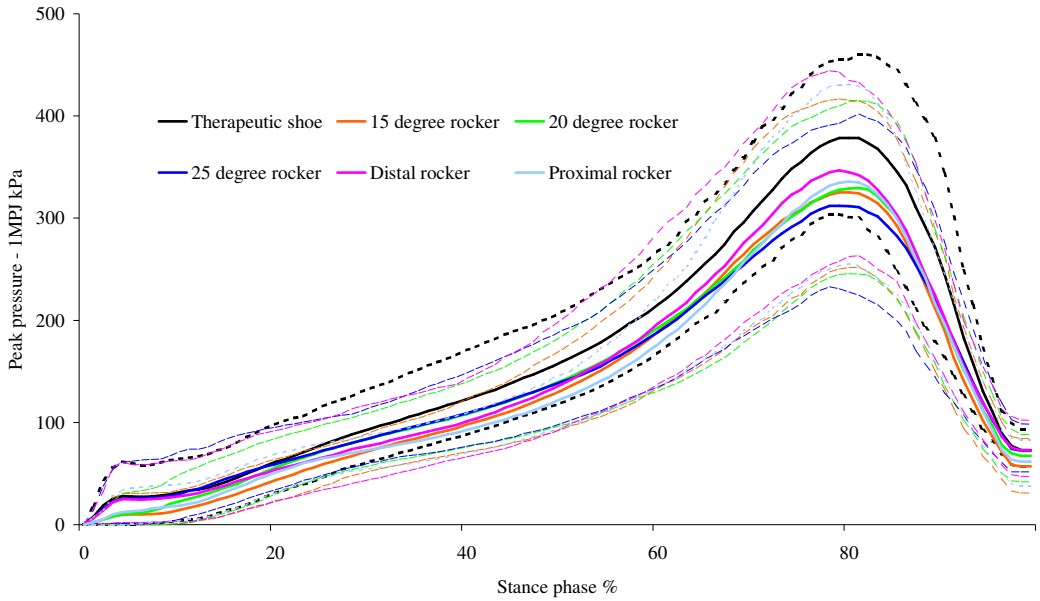


Figure 55. The means and 95% confidence bands (Bstrap) (the outer dashed lines) for peak pressure-1MPJ kPa for the 1MPJ ulceration sub-population per shoe type.

In light of the non-result gained from the ulceration sub-populations, analyses into selection of the shoe with the maximum benefit for protection from walking pressures for hallux and 1MPJ ulceration, a sample of individual subjects' results were examined and are presented in *Figure 56* to *Figure 59*. These individual subjects' results were selected as they demonstrated differences between shoes in the absolute value analyses. With differences evident in the absolute value analyses, the potential further insight gained from the pressure-time patterns can be theorised. Once again box plots are a useful means to provide a subjective impression on the effects of shoe type and intervention design. Within each plot, the effects on each individual subject's limb with ulceration of shoe type and rocker-sole modification design are shown. The figures show the

different information that is obtained from analysis of the absolute values compared to the pressure-time graphs. For the individual limb results analysed, confidence bands could not be calculated due to the export limitations of the Pedar™ system. However, it is apparent from the box plots that the effect on ulceration from different shoe types and rocker-sole modifications is specific to individual limbs. Importantly, these plots confirm the sub-population analyses and show that there is not one rocker-sole modification design that provides maximum protective benefit to either ulceration groups when walking.

The box plots in *Figure 56* show that for Subject 29, that wearing the Athletic shoe afforded the maximal protective benefit to their 1MPJ ulceration when walking. The shoe with the maximum protective benefit is defined by the lowest peak pressure and lowest pressure-time interval absolute value results. The peak pressure-stance time plots provide more information and show that both the Athletic shoe and the Therapeutic shoe with the 25 degree rocker-sole modification afforded similar low maximum peak pressures at the toe-off phase of stance phase. However, the 25 degree rocker-sole modification effected an earlier maximum peak during toe off. It remains unknown if changing of the timing, in addition to, or lowering of the peak pressure alone, that may be most useful in ulceration protection.

The box plots show and the peak pressure-time plots presented in *Figure 57* confirm that for Subject 28, neither the athletic shoe nor the unmodified therapeutic shoe were useful for protecting their 1MPJ ulceration from high pressures during walking. For this subject, the therapeutic shoes with both the 20 and the 25 degree rocker-sole modifications showed comparable protection to the ulceration from high peak pressures. However, it is apparent from both the box plots and the pressure-time plots that relocating the rocker-pivot point had an effect on the timing of the peak pressures experienced on the ulceration when walking in these shoes. Consequentially, this subject's results confirm that rocker-sole pivot position placement is an essential factor for effective clinical intervention and ulceration protection, but once again the importance of the timing of the maximum peak pressure for achieving maximum ulceration protection remains unknown.

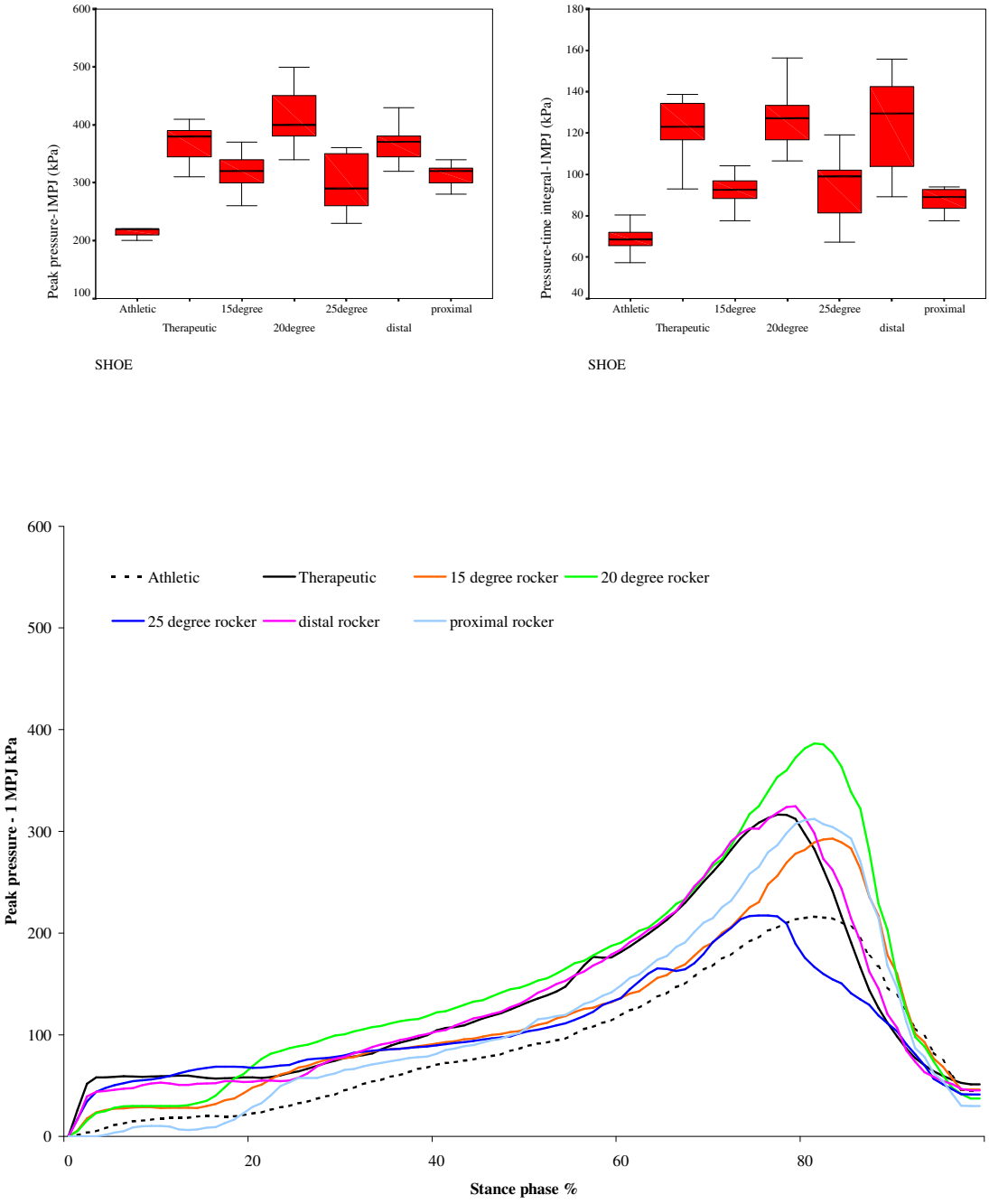


Figure 56. Peak pressure and pressure-time integral absolute value box plots of individual steps and peak pressure-time per percentage-normalised stance time plot mean results for Subject 29 measured on their 1MPJ ulceration per shoe.

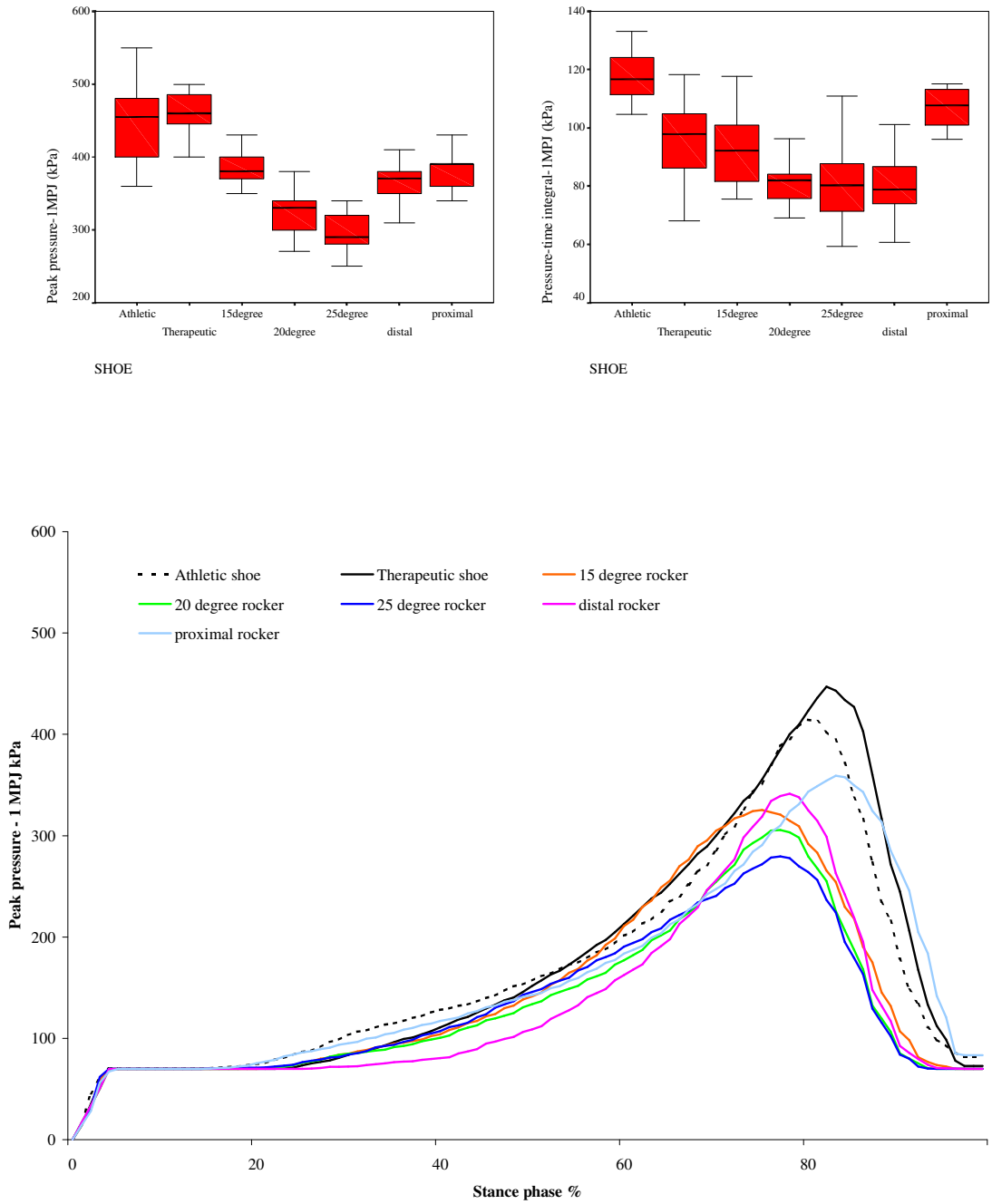


Figure 57. Peak pressure and pressure-time integral absolute value box plots of individual steps and peak pressure-time per percentage-normalised stance time plot mean results for Subject 28 measured on their 1MPJ ulceration per shoe.

The box plots show and the peak pressure-time plots presented in *Figure 58* confirm that for Subject 2 the unmodified therapeutic shoe provided the maximum protective benefit on their hallux ulceration from high pressure during walking. Importantly, this subject's results confirm that the correct placement of the rocker-sole pivot point is critical and if poorly placed, and in this case too far distal from the metatarsophalangeal joint line, may be detrimental to ulceration protection. Of most interest, are the very low peak pressure results on this subject's ulceration compared to the other individual cases. Such a low peak pressure result may suggest that little force or effort goes into the push- or toe-off phase of gait and suggests a shuffling style of gait.

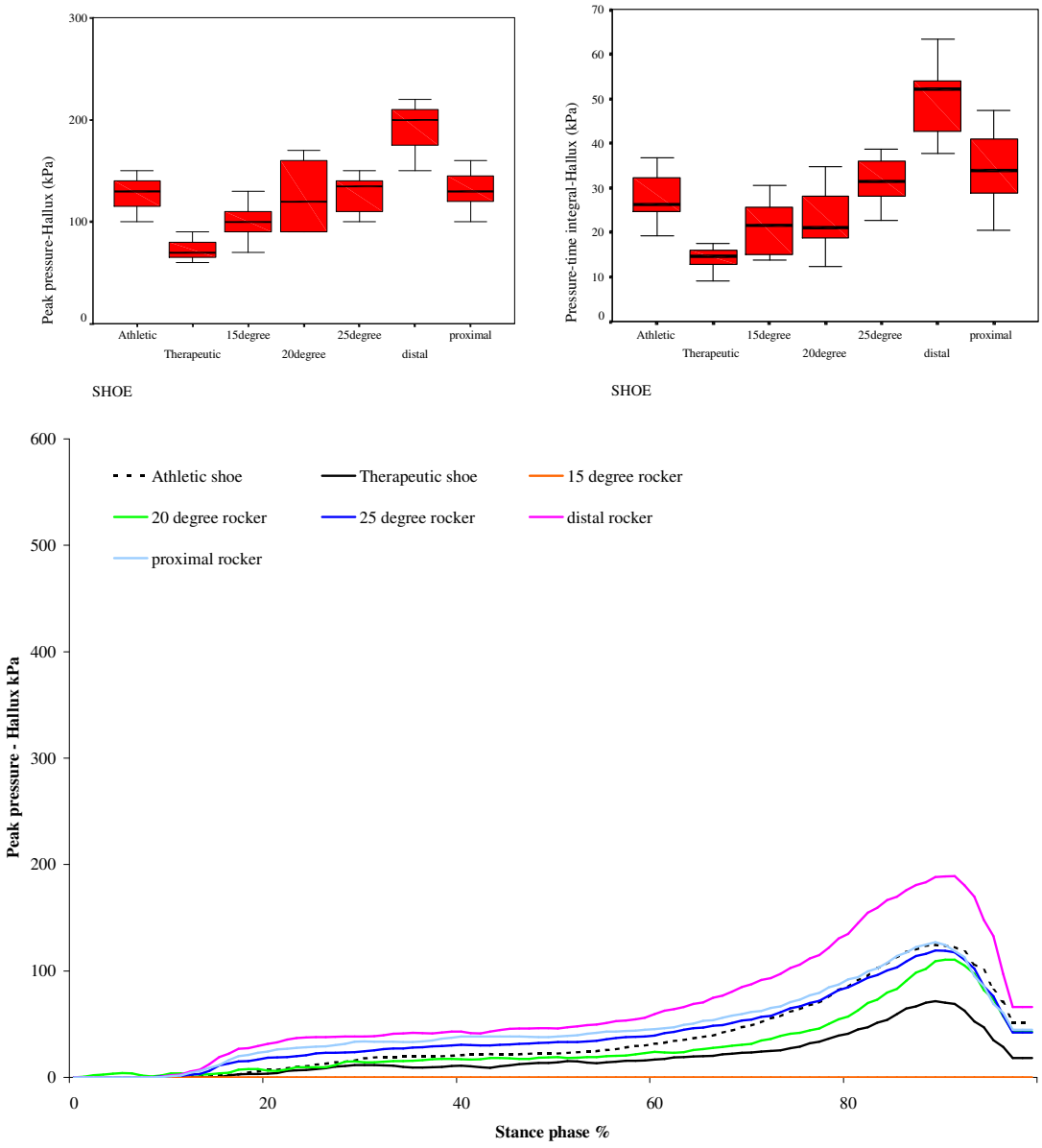


Figure 58. Peak pressure and pressure-time integral absolute value box plots of individual steps and peak pressure-time per percentage-normalised stance time plot mean results for Subject 2 measured on their hallux ulceration per shoe (The pressure-time plot for the 15 degree rocker-sole modification is unavailable for this subject due to a processing error).

The distinct differences between the athletic shoes and the therapeutic shoes, specifically that with the 15 degree rocker-sole modification shown for Subject 15 in Figure 59 appears to support the assumption that a rigid soled shoe, that does not bend at the metatarsophalangeal joint is useful for ulceration protection.

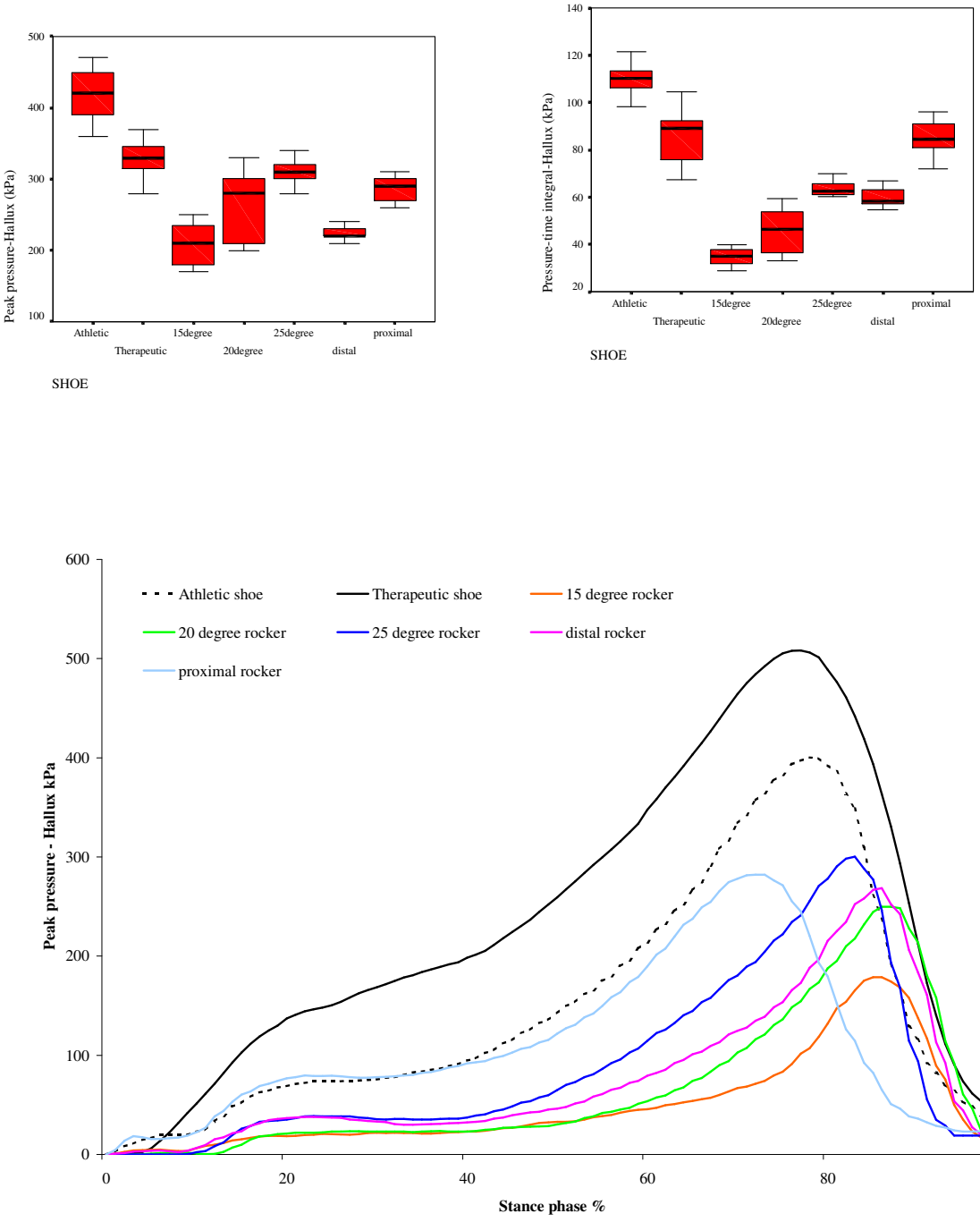


Figure 59. Peak pressure and pressure-time integral absolute value box plots of individual steps and peak pressure-time per percentage-normalised stance time plot mean results for Subject 15 measured on their Hallux ulceration per shoe.

Discussion

Athletic shoe versus therapeutic shoe

The descriptive statistic results suggest, and the ANOVA results confirm, that there were significant differences in peak pressure or pressure-time integral per ulceration between the athletic and the therapeutic shoes for the 2-5MPJ region. These differences at the 2-5MPJ regions in both ulceration sub-populations suggest that a functional change occurs in ulcerated feet when walking in the athletic versus the therapeutic shoe. The graphs of the peak pressure on the 2-5MPJ over stance time provide insight into the time those differences between the shoes occurred. With this knowledge, the likely actions of the foot, limb and body during walking could be correlated. The change in the function during walking in the different shoes could then be hypothesised and investigated using three-dimensional gait analysis tools.

In the graph of the peak pressure on the 2-5MPJ region for the hallux ulceration sub-population, it can be seen that the peak pressures begin to differ between the shoes from 30% of stance phase. From this time, the forefoot is on the ground and begins to accept body weight in preparation for the other foot to push off. The change in function between the shoes may be a result of the firmer shoe construction and thicker and stiffer sole of the therapeutic shoe. The shoe and sole stiffness would likely provide resistance to foot movement and with this, lower pressures are experienced on the 2-5MPJ region when walking. Potentially, the lower pressure on the lateral forefoot in the therapeutic shoe may change the balance of pressure flow through the forefoot and may increase ulceration risk to the 1MPJ and/or hallux. Specific sole stiffness has been reported to be an essential requirement for forefoot ulceration protection using footwear (Dahmen, Haspels, Koomen, & Hoeksma, 2001; Fuller, 1994; Janisse, 1995). However, the present study found that the stiffer sole shoe did not translate into protecting the hallux ulceration from higher peak pressures and in fact, the graph of the hallux (ulceration) region (*Figure 46*) shows that the ulceration bore slightly higher peak pressure when walking in the stiffer therapeutic shoe when compared to the athletic shoe. These results suggest that it may be necessary to prescribe a cushioning insole to be used with the therapeutic shoe to offset the higher pressures experienced by the ulceration when walking in the stiffer therapeutic shoe.

When the graphs of the 1MPJ ulceration sub-population are examined, the therapeutic shoe can also be seen to provide protection from high peak pressures on the 2-5MPJ region when compared to walking in the athletic shoe, but not until later in stance phase than when

ulceration is present on the hallux. The change in peak pressure and foot function in the 1MPJ ulceration sub-population occurs from 50% of stance phase. From this time, the foot is bearing full body weight while the other limb is non-weight bearing and swinging level with the weight-bearing limb. Once again, the study found that the protection for the 2-5MPJ region did not translate to protection to the 1MPJ ulceration and as with the graph of the hallux (ulceration) region, the graph of the 1MPJ (ulceration) region (*Figure 52*) shows that the ulceration bore slightly higher peak pressure when walking in the therapeutic shoe when compared to the athletic shoe. Once again, these results suggest that a cushioning insole may be required in a therapeutic shoe to offset the higher pressures experienced by the ulceration when walking in the stiffer therapeutic shoes.

The descriptive statistic study results for the hallux ulceration sub-population agree with Lavery, Vela, Fleischli et al.(1997) that peak pressure on hallux ulceration is slightly lower when walking in a therapeutic shoe compared to a athletic shoe. However, the peak pressures reported on hallux ulcerations by Lavery, Vela, Fleischli et al. were much lower (211 (110) kPa compared to 301.87 (109.85) kPa for this study) and they found a 9.0 percent difference between the shoes as compared to 4.9 percent for the present study. However, the present study descriptive statistic results for the 1MPJ ulceration sub-population disagree with Lavery, Vela, Fleischli et al. in that they reported that peak pressure on 1MPJ ulceration was 28.6% lower, whereas the present study found peak pressure to be 11.42% higher, when walking in the therapeutic shoe compared to athletic shoe. The differences between results from the 1MPJ ulceration sub-populations may be due to differences in the shoe types, or may suggest that both samples were of insufficient size to be representative of this population.

Therapeutic shoe versus therapeutic shoe with rocker-sole modifications

The descriptive statistic, ANOVA and *post hoc* results showed that there were no differences in absolute values for the hallux or 1MPJ sub-populations when walking in therapeutic shoes with and without rocker-sole modifications. These results were confirmed by the pressure-time graphs. However, the graphs do suggest that there are slightly higher but not clinically different pressures on the ulceration when walking in the unmodified therapeutic shoes for both the hallux and the 1MPJ ulceration sub-populations.

The results of the present study are in opposition to the body of literature that has drawn conclusions from their positive peak pressure reduction results from rocker-soled shoe modifications in non-ulcerated populations to mean that there will be positive reduction and protective benefits on populations with ulcerations. Additionally, the results of the present

study do not support the anecdotal but extensive clinical experience-based evidence that rocker-soled shoes are effective in healing ulceration and preventing re-ulceration due to lowering peak pressures during walking. Technological advances into instrumental measurements of shear forces are expected to provide insight into a causative relationship between peak pressures and ulceration. Already peak pressures and peak shear forces were found to co-occur on the same anatomical regions of the foot in neuropathic individuals, although at slightly different times (Perry, Hall, & Davis, 2002). The confirmation from the present study that pressure-time pattern provides more insight into potential differences between ulcerations than the absolute peak pressure value may be more clinically useful for shoe design development and selection when shear force data can be simultaneously compared.

If the extensive positive pressure reduction benefits from reports of rocker-soled shoes worn by healthier populations are valid, then potentially the mechanism by which peak pressures reduce when walking may not apply once foot ulceration has occurred. Alternatively, the anecdotal clinical evidence to the protective benefit that rocker-soled shoe modifications have on ulceration, may relate to the success of individuals prescribed these modifications specific to their foot presentation by an experienced clinician. Further investigation using additional structural and functional measures in combination with in-shoe plantar pressures is required to provide further insight into the aetiology of rocker-sole modification efficacy.

Individual subject results measured on their ulceration in all shoes

There was a large diversity in individual response to both the absolute value and over stance time peak pressure results as demonstrated by the wide ranges (minimum to maximum values) and broad upper and lower 95% confidence bands that limit the sub-population means. High individual variation and the lack of a most beneficial sub-population-wide rocker-sole shoe modification to protect either ulceration found in the present study points to the conclusion that shoe therapy is individual and therefore, requires individual assessment. Praet and Louwerens (2003) (from their study of ten diabetic women with ulceration) supports this conclusion, and their concluding statement is also apt for the present study:

> Predicting the effect of therapeutic footwear on an individual scale remains difficult. Therefore, for certain individual patients, in-shoe pressure measures seem to be necessary for evaluating an individual therapeutic shoe prescription (p 444).

The individual results presented in *Figure 56* to *Figure 59*, showed that shoe selection for ulceration protection was specific to each individual. The pressure protection achieved on the ulceration ranged from small to large gains by changing from an athletic to therapeutic shoe or adding a rocker-sole modification. Over all, though these results confirm the population results that there was not one shoe or modification for routine prescription to protect ulceration by lowering of peak pressures. Even with the rigor of the application of the method for this study, the box plots showed large variability in the peak pressure and pressure-time integral results on ulceration. To note, is that when the whiskers of the box plots overlapped between shoes, this meant that there were not true differences between these shoes. Conversely the opposite is true and there were distinct and true differences between several shoes seen in the individual results that do not agree with the population results. Of most importance, there were specific shoes or rocker-sole modifications that provided some individuals with protection to ulceration from high plantar pressures. Consequently, with individual assessment-based shoe prescription using the methods developed for this research, patients could achieve positive outcomes without limitations being placed on their ability to walk.

The pressure-time graphs for the individuals with 1MPJ ulceration showed that by changing shoes, the peak pressure on the ulceration also changed in both the absolute peak value (by about 200kPa) and also the timing that the peak occurred. In both cases it can be seen that these results agreed with the population mean and pressure-time graphs and showed that the 25 degree rocker modified shoe afforded the best protection due to having the lowest peak pressure when compared to the other shoes. The individual pressure-time graphs however, showed the 25 degree rocker modified shoe peaking earlier and lower that the other shoes and it remains unknown whether either or both a change in the absolute peak value or the time in the stance phase in which the peak occurs may be useful for ulceration protection.

The pressure-time graphs for the individuals with hallux ulceration showed a similar response to that of the 1MPJ ulceration examples for absolute peak value change with shoe change, except that the range of change in peak pressures is much higher (about 100 kPa change in Subject 2 and about 300 kPa in Subject 15). Of interest is that in Subject 2, all shoes peak at the same time (90 percent of stance phase), while in Subject 15 the shoe peaks occur earlier at between approximately 70 and 85 percent of stance phase. The low peak and the consistency of the timing for Subject 2 could suggest that the subject's gait was of a shuffling style. Rocker-sole modification would not be useful and indeed contraindicated with a shuffling type gait due to potentially destabilizing the subject's gait and putting the subject at risk of falling. The gait style and its positive or negative influence on clinical decision to prescribe

rocker-sole modification for ulceration protection was not identified as a contraindication in any of the literature reviewed for this research, and is an important avenue for future investigation.

Conclusion

Several studies have tested the effect on peak pressures during walking in therapeutic shoes with rocker-sole modifications but none included people with actual ulceration (Brown et al., 2004; Fuller et al., 2001; Nawoczenski et al., 1988; Peterson et al., 1985; Schaff & Cavanagh, 1990). These reports concluded that rocker-sole shoe modifications reduced peak pressures in their study populations. They then generalised that this same protective reduction in peak pressure would be afforded to ulceration. This thesis makes a significant contribution to knowledge by testing the efficacy of these shoe modifications to protect the ulceration. The population results of the present study do not support the generalised conclusions reported in the literature. Instead, the present study found that peak pressures on ulceration were lower in the flexible athletic shoe and that all rocker-sole modifications provided slight pressure relief on ulceration when compared to the stiffer therapeutic shoe, but the extent of protection afforded to the population was not clinically significant. Therefore, no single shoe or rocker-sole modification was found to be effective for routine prescription to protect hallux or 1MPJ ulceration in patients with diabetes and neuropathy.

A small sample of individual results were examined and they were found to have different responses to different shoes, including the extent and the timing of peak pressure experienced on their ulceration. In some individual subjects there were specific shoes or rocker-sole modifications that provided effective protection to their ulceration from high peak pressures. At the same time though, there were shoes and rocker-sole modifications that had no effect or were detrimental and increased the peak pressures born on the ulceration. Consequentially, unless individual in-shoe plantar pressure assessment is available to evaluate shoe intervention efficacy, then prescription should be made with caution.

CHAPTER NINE

CONCLUSIONS

Limitations of the thesis studies design

Sample bias

The archival dataset was created from study databases created several years prior to this thesis and the data were collected and analysed by research staff that have since resigned from the study institution. Although the procedures are published in the literature (Lavery, Vela, Fleischli et al., 1997; Lavery, Vela, Lavery et al., 1997) and were confirmed orally with the principal investigator, the stringency by which subjects were recruited, the data collected and analysed cannot be verified. However, as the aim for utilising archival data was to determine the protocol and procedures for further thesis study, if the data were less stringent, then the limits defined would be expected to be broader and more conservative. Specifically, this limitation would have the most effect on the calculation of the measurement accuracy. The accuracy determined was ± 11.31 percent, and as the mean differences in the thesis studies that were found to be statistically significant were always well short of this figure, then conservative accuracy was considered to be an acceptable limitation.

The subjects with diabetes but without neuropathy that were recruited for the sock selection and protocol safety study were people that attended a general and public diabetes education presentation given by the author on *foot health and diabetes*. It is therefore, likely that these volunteers were more aware of their disease and healthier than the greater population with diabetes. The provision of the incentive of providing plantar pressure assessment for participation in the studies may have also biased the population towards the more aware and healthier population. However, as study of these subjects were utilised to determine potential risks to future studies of neuropathic subjects, than subjects with heightened awareness of their disease would be expected to provide useful feedback.

The three-hour duration of testing, the lack of transport to and from the testing session, the lack of cash payment for participation and no reimbursement for expenses, may have limited the number of subjects willing to participate in the studies. The duration of testing and lack of transport may especially have biased the sample population away from the frail, elderly or financially limited and towards the more independent and healthy subjects. The lack of cash payment for subjects may have biased against participation as an artefact of the setting of the research. In the large American city and corporate support-university medical school context in which the data were collected, patients were inundated with advertising alerting them to the fact that willing subjects could expect cash payment for research participation, in addition to reimbursement for travel and bonus items (meals, prescription medication, wound dressing materials, and gifts). Unfortunately, as subjects that met the studies' inclusion criteria were invited to meet with the author by their treating clinician, the actual impact that lack of cash payment, transportation and reimbursement had on subjects willing to participate is unknown.

The decision to limit the population of study for the shoe studies to those with only two plantar ulcerations and an absence of foot surgery, severely limited the sample size available for study. This decision was made, to provide results that were applicable to hallux and 1MPJ diabetic ulceration knowledge, rather than more generally to diabetic foot knowledge.

Laboratory not 'real-life' testing environment

The laboratory based study design severely limits the applicability of the results to the actual environment in which patients generally walk or use the therapeutic footwear investigated and this is especially true of the sock data that was collected without wearing shoes. However, as the thesis aimed firstly to define the limits of the protocol and procedures to enable comparisons to be made between interventions, then it was necessary to rigorously limit any environmental influences on the measure of interest, that is, pressure.

The use of new footwear during testing limits the applicability of the results to the actual clinical circumstances in which they are prescribed and therefore, relates only to the first few hours of the experience of the therapeutic intervention. Generally, when prescribed a therapeutic footwear intervention, the patient is encouraged to limit the use of the footwear to small but regular time slots over a period of weeks to facilitate the wearing in and softening of the shoe and allow gradual acclimatisation and modification of the gait/foot to occur. It is therefore, plausible that differences would emerge dependant on the duration of the therapy. However, such differences would require careful research design that included individual

assessment and shoe use monitoring to determine whether changes had taken place in the person or the footwear and to ensure that the ulceration did not incur further injury.

Physical test exclusion

The exclusion of a battery of physical tests limits insight that may have been gained into explanation for the high variability found within the pressure measure variables. The large variability may have most likely been due to the failure to define the sub-populations into further groups based on physical characteristics. However, a far larger sample size than that obtained for the thesis studies would be required to explore this possibility further. Physical tests that may have been useful are joint range of motion measurements of the foot and ankle (Birke et al., 1988), flexibility (Katoulis et al., 1996) and strength (Mueller, Minor et al., 1994) of major lower limb muscle groups, and balance (Menz, Lord, Fitzpatrick, & St George, In Press).

Strengths of the thesis study design

Archival analyses for protocol development

The major strength of the thesis studies is in the thorough development, testing and refinement of the protocol and procedures prior to study. Using archival analysis ensured that data collection methods utilised for the thesis studies were rigorous and adequate to meet the aims of, and allow valid conclusions to be drawn from, each study. Additionally, the archival analyses have made, and will make, a significant contribution to the literature, because the uncertainties associated with in-shoe plantar pressure measurement have been unknown for the population of people with diabetes, neuropathy and forefoot ulceration.

Stringent inclusion and exclusion criteria

The selection of subjects without foot deformity or a history of foot surgery provided general applicability to the studies on several fronts. The exclusion of foot deformity ensured that subjects could wear standard but appropriately sized ‘off-the-shelf’ footwear, which enabled strict standardisation of the athletic and therapeutic shoe styles. Standard footwear also meant that standard sized in-shoe sensor matrices could also be employed across all tests, limiting variability in the data obtained due to sensor numbers and size variations incurred from using

different sensor sizes. The exclusion of foot surgery ensured that the anatomical regions of the foot could be standardised across subjects and studies, limiting potential variability inherent from foot-structure and function modification from surgery.

The exclusion of subjects with multiple foot ulcerations and inclusion of only plantar hallux and plantar1MPJ ulcerations for testing provided general applicability to enable clear comparisons and definite conclusions to be drawn between sub-populations and footwear interventions. In particular, with the aim to investigate ulceration protection efficacy from rocker-sole modified shoes, then the hallux and 1MPJ ulcerations tested are the most logical sites of ulceration to be prescribed these footwear.

Correct statistical tests

The testing for normal distribution status in central limit theory and selection of the appropriate statistical tests for repeated measures analyses of the absolute value results would not be expected to be stated as a strength of a study, but rather be assumed to have been done. However, it is unfortunate to find that few published studies reported their reasoning for selection of the statistical test conducted, nor checking for normal distribution status. Therefore, strength in the thesis studies is not only the checking for and selection of the appropriate statistical tests, but also the results from the archival analyses that enabled discussion of significant differences found in reference to the limits of the measurement method.

Although the calculation of the 95 percent confidence bands using the appropriate bootstrap methods for continuous data, showed only slightly wider bands than the point-by-point method, they ensured that there was no doubt to the high variability of the data and therefore, unlikelihood that there were true clinical differences between the sub-populations and interventions tested.

Overview of major findings

Guidelines for a standard protocol for in-shoe plantar pressure measurement were produced.

A standardised protocol for in-shoe plantar pressure analyses was not identified from a thorough analysis of the published literature. The IPGPPM (Barnett, 1998) were an attempt to rectify this lack of standardisation. However, other than the selection of 'mid-gait' steps, their recommendations have not been universally adopted. Therefore, without a published standardised protocol to follow for future thesis studies, a default position was developed and guidelines produced based on the results from the protocol analysis and good practice.

A method for mid-gait walking validity checking was produced and tested.

Even though the validity of mid-gait stepping is assumed by ensuring that the subjects practise and become consistent with the testing activity, and an investigator visually monitors each trial, the resulting data set needs to be checked to ensure that any inconsistent steps are removed. Inconsistent steps were identified by screening for inconsistencies in the total area of the foot measure. Both a manual-visual and a computerised-algorithmic method of screening were evaluated and both were found to identify inconsistent steps. It was found that the computerised-algorithmic method was the more time effective of the two methods. Screening for, and removal of, inconsistent steps reduced the variability of the dataset, but did not compromise the validity of the original data set.

The reliability, precision and accuracy limits of in-shoe plantar pressure measurement were defined.

The number of repeated steps necessary for inclusion in the calculation of a reliable and precise average step had not been established for the population of people with diabetes, neuropathy and ulceration. For reliable analysis using the peak pressure variable, then only two steps were found to be required for inclusion in the average step calculation. Other variables ranged from two to eight steps. Precision was expressed unit-less so as to allow comparisons across variables. All in-shoe variables were imprecise and were outside the limits of acceptable variability (15%).

The number of repeated steps required for inclusion in the average step calculation to achieve maximum practical accuracy was unknown. For the variable peak pressure measured over the whole foot, its variability did not improve markedly beyond ±8.8 percent after nine steps were included in the average step calculation. This variability was found to be associated with measurement uncertainty of ±6.31 percent while the documented instrument accuracy is ±5%. Therefore, the overall maximum practical uncertainty associated with nine steps included in the average step calculation of peak pressure over the whole foot was ±5 percent (instrument error) plus ±6.31 percent (measurement error) resulting in ±11.31 percent error. If other variables were to be included in the analysis, then at least 14 steps were required to be included in the average step calculation to reach the minimum practical uncertainty.

The variables of peak pressure and pressure time-integral were found most useful for ulceration identification from in-shoe plantar pressure measurement.

The archival data set contained 72 variables and which of these variables were most useful in investigations of location specific ulceration were unknown. The peak pressure and pressure-time integral variable measures were found to be the most useful in localised ulceration identification. A combination of five variables were found to produce a model that correctly identified ulceration locality in 69.6% of subjects with a sensitivity range of 83 to 90% and a specificity range of 69 to 87%. The five variables identified were peak pressure on the 1MPJ and 2-5MPJ and the pressure-time integral over the whole foot and on the 1MPJ and 2-5MPJ regions.

Sock fabric did not affect in-shoe plantar pressure measures outside of measurement limits. Sock seams may pose an injury risk.

The literature shows that the wearing of socks made from padded fabric can provide significant cushioning benefits to the foot via reduction of peak pressures. To determine the most suitable sock for standardised use in in-shoe plantar pressure analyses, socks of different fabrics and thickness were compared. Once the high variability and accuracy of the peak pressure measurements were taken into account, then in opposition to the published literature, there were no significant differences found in peak pressures due to sock fabric. Additionally, further experimentation revealed that the toe seam associated with the joining of the thick fabric to manufacture the sock could pose a significant injury risk to the foot, if trapped within a constrictive environment (shoe) due to the creation of a localised region of high

pressure. Standard sock selection was therefore, based on removal of the injury risk posed by a toe seam and a seamless sock was selected.

Procedures for in-shoe plantar pressure measurement did not pose an injury risk to adults with diabetes.

The literature anecdotally and repeatedly states that in-shoe plantar pressure measurement prior to and for intervention selection could prevent and heal ulceration in people with diabetes. However, there was a dearth of acknowledgement of or checking for the safety to the foot from the measurement procedures. The standard protocol developed for in-shoe plantar pressure analysis of walking for the thesis studies was tested under normal laboratory conditions and found not to pose an injury risk to adults with diabetes and was therefore, adopted for future study.

Pressure-time graphs provide more useful information than do absolute peak pressure values.

The peak pressure results were explored beyond the common absolute value method to graph their relationship to time. Graphs of peak pressure as it related to percentage-normalised stance time were constructed to conform to the presentation and description conventions of other gait analysis instruments. The mean and its 95 percent confidence limits were calculated firstly using the force, then mean pressure and finally peak pressure results to facilitate comparisons with and therefore, cross validation, with the published literature.

The peak pressure-time graphs were constructed using both the commonly used, but inappropriate point-by-point method for calculation of the mean and 95 percent confidence limits and compared with the bootstrap method appropriate for use with continuous data. These graphs provided far more information especially relevant to showing the pattern of pressure related to time on an anatomical region and specific sensors than the absolute value results. A change in the pattern rather than a change in the absolute measured value of peak pressure over an anatomical region or specific sensor is therefore, anticipated to provide clinically useful insight into the aetiology of pressure related injury and ulceration in the population of people with diabetes, neuropathy and ulceration. The graphs constructed were utilised as baseline patterns against which future studies of diabetic foot complications and interventions could be compared.

There are tendencies towards different trends in peak pressures during walking when neuropathic.

Significant differences were found in the absolute values measured for pressure-time integral on the 1MPJ, 2-5MPJ and heel regions for the population of adults with diabetes when walking with neuropathy compared to neuropathy-free. However, these differences were less than the uncertainty associated with instrumental and measurement error and are therefore, not of routine clinical use.

The pattern of peak pressure as it relates to stance time during walking with neuropathy was established. Although the pattern of peak pressure varied between the two conditions, distinct differences were only found in the later 15 percent of stance phase, where neuropathic peak pressures were lower than when neuropathy-free. Regionally, the hallux experienced lower, while the 1MPJ region experienced higher, peak pressures when neuropathic compared to when neuropathy-free. Peak pressure was higher on the heel with neuropathy and inconsideration of the other regions, the differences lead to the posturing that neuropathic gait may be of a shuffling style.

There are tendencies towards different trends in peak pressures during walking when neuropathic with ulceration on the hallux or the 1MPJ

Significant difference was found in the absolute values measured for peak pressure on the 1MPJ region when the population of adults with diabetes walked with 1MPJ ulceration and neuropathy compared to the neuropathy-free population. However, these differences were less than the uncertainty associated with instrumental and measurement error and are therefore, not of routine clinical use. No distinct differences were found in the results between hallux and 1MPJ ulcerations, or between hallux ulcerations and neuropathy-free analyses.

The pattern of peak pressure as it relates to stance time during walking with hallux and 1MPJ ulcerations compared each other and to the neuropathy-free reference data were established and the three sub-population results were found to differ. Specifically, when there was ulceration on the hallux, then hallux peak pressure pattern was lower than ulceration and neuropathy-free, but higher than 1MPJ ulceration results. However, when there was ulceration on the 1MPJ, then 1MPJ peak pressure pattern was the same as ulceration and neuropathy-free results, but much lower than hallux ulceration results.

There are tendencies towards different trends in peak pressures during walking when neuropathic with ulceration on the hallux or the 1MPJ in therapeutic shoes

Absolute value analyses show that there were no significant differences in peak pressure or pressure-time integral per hallux or 1MPJ ulceration between the flexible athletic and the therapeutic shoes. However, the differences found on the 2-5MPJ regions on both ulcerations suggest that a functional change occurs in ulcerated feet when walking in the different shoes.

The pattern of peak pressure as it relates to stance time during walking with hallux or 1MPJ ulcerations show that the ulceration sites bore higher peak pressures when walking in the stiffer therapeutic shoe compared to the flexible athletic shoe. Therefore, prescription of a cushioning insole may be required with therapeutic shoes to offset and protect the ulceration from the higher pressures experienced on the ulcerations when walking in therapeutic shoes. Alternatively, an athletic shoe may have therapeutic benefits and a therapeutic shoe and insole may not be necessary.

There are tendencies towards different trends in peak pressures during walking when neuropathic with ulceration on the hallux or the 1MPJ in therapeutic shoes with rocker-soled shoe modifications

Absolute value analyses of the population results show that there were no significant differences in peak pressure or pressure-time integral per hallux or 1MPJ ulceration when walking in any of the rocker-sole shoe modifications compared to the unmodified therapeutic shoe. There was not a specific rocker-sole modification design found that could routinely be prescribed to this population to protect either hallux or 1MPJ ulceration sites from high peak pressures. However, there were distinct differences found for individual subjects and assuming that reductions in peak pressures are therapeutic, then with individual in-shoe plantar pressure measurement, patients could be prescribed particular shoes and their ulceration be protected without limitations being placed on their ability to walk.

The pattern of peak pressure as it relates to stance time during walking with hallux or 1MPJ ulcerations show that pressures are slightly lower on the ulcerations in all rocker-sole shoes when compared to the unmodified therapeutic shoe. However, the differences were very slight and well within the 95 percent confidence bands, confirming that there was not a rocker-sole modification design for effective routine clinical use.

Rocker-soled shoe modifications were not found to routinely protect ulceration by the lowering of peak pressures as had been assumed from clinical experience-based evidence and hypothesised in reports of experimental evidence obtained from ulceration-free and healthy populations. Additionally, the contradictory thesis results compared to the experimental literature from ulceration-free and healthy populations suggest that either the positive peak pressure reduction protective benefit afforded by walking in rocker-soled shoes is lost once ulceration is present, or else protection is afforded by another variable. This also raises the question to whether there is a change in neuropathic foot function when ulceration is present, which negates the effect of the rocker-sole modification. Alternatively, is there a change in neuropathic foot function that results in ulceration and is it this change that negates the rocker-sole modification effect? It may be likely that the person with diabetes, neuropathy and ulceration has developed gait strategies to ensure stability and prevent falling, and that these strategies negate the protective influence from the rocker-sole modification.

Indications for further research

The methods described in this thesis provide a useful model for future studies of in-shoe plantar pressure measurement. Aspects of the thesis results have identified particularly useful points for research and these will be outlined as follows.

Physical and gait tests with in-shoe plantar pressure

The high variability within the results and the lack of clinically useful and statistically significant differences found in peak pressure absolute values and pressure-time graph patterns between disease status and therapeutic interventions suggests that there may be other physical tests necessary to define the physical population and gait. Particularly useful may be the correlation and synchronisation between dynamic kinematic and electromyographic studies and in-shoe plantar pressure analysis. Pilot study results from preliminary synchronisation studies are being examined.

Prospective ulceration analysis

The natural flow on from the thesis is to repeat the rocker-sole shoe studies over time to determine whether there is an adaptation in the gait/foot of the subject from the shoe intervention. In addition, it would be useful to include video gait analysis methods in

combination with further in-shoe pressure measurement studies. These analyses could determine whether the subject's gait was actively propulsive and if the rocker-sole component of the shoe was utilised. The time line would need to be short, due to the morbidity, amputation and mortality that occurred within the first year following the study for the majority of the thesis subjects.

Prospective in-shoe plantar pressure assessment in ulceration-free with neuropathy in newly diagnosed (pre-neuropathic-pre-ulceration)

The high morbidity and mortality of the subjects as described in the prior point emphasises the necessity to determine the usefulness of evaluating in-shoe plantar pressures and prescribing effective interventions to subjects that are at high risk of ulceration (neuropathic) and newly diagnosed (generally pre-neuropathic) prior to ulceration occurrence.

Determine the pressure protective efficacy afforded to ulceration from commonly prescribed cushioned and functional insoles

As cushioning and functional modification insoles are routinely prescribed to people with diabetes with and without therapeutic modified shoes, then potentially, it may be the pressure protective efficacy afforded by the insole that led to the clinical experienced-based evidence that supports ulceration management with therapeutic footwear with rocker-soled shoes rather than the shoes. Preliminary investigations have been completed and are currently under analysis into the pressure protection efficacy afforded to newly diagnosed (pre-neuropathic) adults with diabetes.

Determine the safety of walking for exercise in diabetic population at difference stages of disease

The point where protective footwear becomes paramount is for use when newly diagnosed (pre-neuropathic) adults with diabetes walk daily for exercise as part of their self-management of their obesity and cardiovascular risk factors. Preliminary investigation into the stability of pressures measured during a 20 minute walking exercise has been completed and is currently under analysis.

Define ‘normal-healthy’ and expand sample size of thesis pressure-time patterns database

Definition of any differences in pressure-time graph patterns between disease statuses could be clinically useful to guide selection and evaluation of appropriate foot protective interventions. The formation of an ideal baseline pressure pattern towards which to aim an intervention, would be the healthy adult pattern. Such as pattern, as well as other defined disease state patterns, could be integrated into the in-shoe pressure analysis software for development of a clinical test, and the standardised protocol produced for this thesis lends itself ideally for the establishing a healthy baseline as well as other patterns, including potentially dangerous ones.

Conclusions

The analyses, experiments and studies presented in this thesis provide a major contribution to understanding the usefulness, uncertainties and limits of walking plantar pressures at different stages of diabetic foot disease and in different footwear. With reference to the thesis research questions, the following conclusions can be made:

1. When in-shoe plantar pressure measures of walking in the adult with diabetes, peripheral neuropathy and ulceration are filtered to confirm for midgait stepping validity, they are:

    a. Reliable (ICC(3,1)>0.80) when at least two steps are included in the average step calculation of the peak pressure variable, and if all in-shoe pressure variables are to be included in an analysis then eight steps are required.

    b. Imprecise and all variables exceeded the minimum criterion of CV<15% (Peak pressure over the whole foot CV = 61.10%).

    c. Accurate to ±11.31% (±6.31% measurement + ±5% instrument error) when at least nine steps were included in the average step calculation for peak pressure, and

    d. Useful for ulceration identification. A combination of five of the 72 in-shoe plantar pressure measurement variables correctly identified the specific location of forefoot ulceration in 69.9% of adults with diabetes, peripheral neuropathy and ulceration, with a sensitivity range of 83 to 90% and a specificity range of 69 to 87%.

2. In-shoe plantar pressure measurement of walking in adults with diabetes:

   a. Was not affected by different sock fabrics beyond the limits of the inherent variability of the measurement (Range: 9.4 to 22.2% CV), and

   b. Did not pose any specific foot injury risk from the protocol and procedures developed for the thesis.

3. In-shoe plantar pressure measures of walking in the adult with diabetes, peripheral neuropathy and ulceration are not significantly affected by: a) ulceration location, b) shoe type or c) rocker-sole shoe modifications.

   Significant differences were not found in peak pressure absolute values between hallux and 1MPJ ulcerations. However, significant differences were found between the 1MPJ ulceration sub-population and the neuropathy-free population.

   Significant differences were not found in peak pressure absolute values between therapeutic shoes compared to athletic shoes when measured on the ulceration site. However, significant differences were found between shoes on measures of the 2-5MPJ region.

   Significant differences were not found in peak pressure absolute values between rocker-sole shoe modifications and an unmodified therapeutic shoe.

4. A particular rocker-sole shoe modification design (angle and pivot position) was not found that afforded more protection from peak pressures to ulcerations on the plantar hallux nor the plantar first metatarsophalangeal joint.

5. Examinations of plots of peak pressures as they relate to percentage-normalised stance time provide more clinically useful insight into the pattern of pressures during walking than the absolute peak values. Different trends in pressure patterns are useful as they can potentially be correlated with likely or measured foot, limb and body actions that may describe the effect on walking from disease stage and footwear change. Trends towards potential differences were seen in:

   - Walking with neuropathy and ulceration on both the hallux and 1MPJ compared to the neuropathy-free sub-population.

- Walking in the therapeutic compared to the athletic shoes.
- Walking in the therapeutic shoe compared to the five different rocker-sole shoes.

Appendices

Appendix A: International Protocol Guidelines Plantar Pressure Measurement

Appendix A

Barnett, S. (1998). International protocol guidelines for plantar pressure measurement. *The Diabetic Foot*, 1(4), 137-140.

International protocol guidelines for plantar pressure measurement

Sue Barnett (University of the West of England, Bristol) on behalf of the Footpressure Interest Group

The Footpressure Interest Group (FIG) exists to enhance the knowledge and accessibility of plantar pressure measurement systems, and to assist in the dissemination of relevant information and research. One aim of FIG is to enhance comparability of work done with various systems at various centres, enabling easier access to more analogous data, and assisting interpretation of results. This article presents guidelines for the use of plantar pressure measurement systems and invites comments from readers.

FIG has developed draft standardised guidelines for the use and interpretation of plantar pressure measurement systems. These have been produced for data collection with platform systems and in-shoe systems, and for interpretation and presentation of data. The guidelines were initially developed by delegates attending the 4th Footpressure Interest Group Meeting, held in May 1997. (A list of the individuals involved in this process is available in our most recent newsletter at www.figroup.com or from Sue Barnett.)

The guidelines were then written up and circulated to the international membership of FIG, inviting comments. We would also like to invite comments from the readership of *The Diabetic Foot*, which we will then incorporate where possible. The guidelines require further refinement, but they have been embraced by many researchers and clinicians, and are already helping to introduce comparability of data and interpretation of results utilising plantar pressure measurement.

Draft protocol guidelines: Platform workgroup

This workgroup was convened by Dr Matthew Young, Consultant Diabetologist, Royal Infirmary of Edinburgh.

General comments

- If best practice guidelines are adopted, exceptions to these are acceptable, but must be clearly justified.
- The sampling frequency used for data collection, both per sensor and for the entire matrix (where applicable), should be stated.
- The kiloPascal (kPa), an internationally recognised, standard unit of measurement, should be employed (*Table 1*).

Use of platforms

- State the number of platforms used and justify this decision. The data sampling area of the platform should be as large as possible.
- Collect the fourth step (right and/or left feet), unless otherwise justified.
- Subject should be 'free walking' at a comfortable speed, rather than metronomic walking. The walking speed should not be controlled, but should be recorded and presented in the results.
- In terms of data collected, the range and the median should be observed rather than the mean, as the mean will never have existed in real life. For some investigations we need to know whether or not there is a variability in the gait cycle. The range should provide sufficient data to determine maximum and minimum data points. This is very important when considering intervention studies. The number of trials recorded should be stated. Currently, at least five footsteps are recommended. Further work is needed in this area.

Table 1. Conversions for Pascals and other units

One Pascal is defined as the pressure of 1 Newton per square metre, which is a very small number. Pressures under the foot are typically in the region of hundreds of thousands of Pascals. Thus, the following accepted SI prefixes are almost always associated with pressure values in biomechanical studies:

1 kiloPascal (kPa) = 1000 Pa

1 megaPascal (MPa) = 1000,000 Pa

Conversion from Pascals to other units

1 kPa = 0.145 psi

100 kPa = 1.02 kg/cm^2

100 kPa = 1 bar

100 kPa = 0.77 mmHg

1 kPa = 0.295 inches Hg

100 kPa = 0.401 inches H_2O

100kPa = 0.99 atmosphere

Conversion from other units to Pascals

1 psi = 6.9 kPa

1 kg/cm^2 = 98.1 kPa

1 bar = 100 kPa

1mmHg = 133.3 Pa

1 inch Hg = 3.386 kPa

1 inch H_2O = 249.1 Pa

1 atmosphere = 101.3 kPa

Cavanagh PR, Rodgers MM, Liboshl A (1987) *Foot and Ankle* 7: 262-76

Use of walkways

- If a walkway is used, it should be specified and described in the published work.
- Trials should be rejected if they are considered to be under strided, over strided, hesitant, or targeted. Trials that partly miss the platform, or are close to the edge of the data sensing area, should not be used.
- The weight of the subject should be recorded and presented with the rest of the data.
- Peak pressures alone do not give sufficient information. Temporal parameters should also be quoted, e.g. pressure/time integrals, contact time, etc. This should be supplied as a minimum information set, but raw data should also be retained as it may be useful for future studies or for sharing.
- The centre of load/pressure lines requires further information to determine the value of the information that they produce.
- All systems should be able to reproduce a standardised division mask if required (*Figure 1*).
- The spatial resolution of the system used should always be quoted.

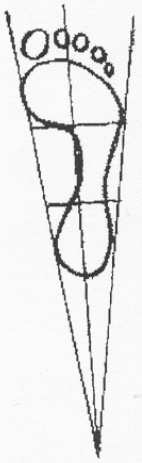


FIG suggests dividing the foot vertically along the long plantar angle. Divide the foot horizontally into three sections, with the distal section 40% of the total length, and the other two sections each being 30% of the total length of the long plantar angle where it falls on the foot. This will produce six regions:

- Distal medial
- Distal lateral
- Mid medial
- Mid lateral
- Proximal medial
- Proximal lateral.

Figure 1. Standardised division mask.

Draft protocol guidelines: In-shoe measurement workgroup

This workgroup was convened by Professor Steven West, Dean of the Faculty of Health and Social Care, University of the West of England, Bristol.

The group discussed what should be standardised: the methodology, the report, the systems?

A number of general questions were considered:

- What is 'normal'?
- Should subjects be shod or unshod?
- Should measurements be taken level and flat, uphill, downhill, turning?
- Should measurements be taken with acceleration and deceleration?
- Should subjects wear their own shoes or standardised shoes?
- Velocity?

The group discussed factors that might affect the ability to standardise:

- Sensor systems are very different: have the manufacturers set up protocols? (Novel gmbh, Germany, and Tekscan Inc, USA, have done this)
- Different output measurement
- Clinical profile of the patient
- Methodology

Standardisation of the report

The following should be standardised:

- System specification (thresholds, etc)
- Floor surface
- Data collection run (number of steps per run)
- Socks
- Velocity

Manufacturers' protocols

- Must be acknowledged and understood
- Usually require acclimatisation, bedding in and in-shoe calibration
- Should be stated in reporting

Floor and walkway

- Should be non-slip, flat, level and stable
- Should consist of a figure of eight if possible
- Protocols exclude acceleration and deceleration data and this should be recognised
- Data should be recorded mid-cycle
- PC and wires should be positioned so that they do not constitute a distraction

Footwear

- For longitudinal studies, use standardised (manufacturer-supplied) footwear, depending on the research question
- For intervention studies, use patients' own comfortable shoes. These should be classified and the degree of wear recorded.
- Should reflect real-life footwear

Socks

- Pop socks (thin nylons) should be used
- Dressings should be removed and film-type (e.g. Opsite, Tegaderm) dressings used to cover wounds

Callus

- State whether or not callus has been removed, and the reasons for this decision. This should be uniformly applied to all subjects in the trial

Walking speed

- Should be self-selected at a comfortable speed as determined by the patient
- Velocity must be noted and reported

Inserting and removing insoles

- Controlled by the researcher
- Allow for 'bedding in'

Calibration

- Must reflect life. How reasonable is it to calibrate and evaluate sensors in the laboratory? Sensors are designed to perform in the shoe, not on a laboratory bench
- Manufacturer's guidelines should be followed for optimum use and must be published

Factors to bear in mind when choosing a system

- Know the limitations
- Identify what you want
- Do NOT reject systems purely on bench or lab evaluation
- Carefully consider the number of sensors needed. Are arrays really necessary? Would 10 sensors be enough?
- Data overload is a problem; data smoothing may be a problem

Draft protocol guidelines: Analysis and presentation of data workgroup

This workgroup was convened by Dr Matthew Pepper, Medical Electronics Research Group, University of Kent, Canterbury.

The group was unable to produce a set of protocols, primarily because foot pressure measurement analysis is still in its infancy. Thus it is not yet known which parameters are of definite clinical use, or how those parameters can be used for anything more than tracking the effect of intervention on a particular individual. Because of this, the group developed a mix of protocol and 'wish list'.

The basic long-term goals were thought to be:

- ***Normal standard data:*** The development and provision of normal data within the software analysis packages for normals, however defined. Specific and well-defined non-normal populations.
- ***Intersystem comparison:*** The ability to relate measurements made with one system to those made under similar conditions with other measurement systems: in-shoe to in-shoe, whether matrix or discrete transducer arrays; platform to platform, whether total foot loading or matrix; and in-shoe to platform.
- ***Data interchange:*** The ability to transfer data to the analysis packages of other systems and to compensate for differing transducer densities or numbers of transducers. This will enable comparative analysis and help maximise use of the data available.
- ***Difference plots:*** Before and after intervention on the same display would be useful.
- ***Software:*** Because there are so many options available, it would be helpful if what are thought to be the key analysis parameters were presented first.

Force plates and pressure mats

The following points were raised in the discussion:

- SI units should be used as standard (kPa).
- There should be standard colour codes for displays with the options for: absolute display; relative display; and patient weight-normalised display.
- The units used and the manipulations behind the presentations must be made explicit in all publications and presentations.
- Appropriate axis scales to be used in presentation of data should be agreed upon.
- The following were thought to be key parameters:

Area under pressure curve: Software should be able to allow the analysis of sections of those curves. The method used to obtain the values should be made explicit.

Averages: The mathematics used to obtain averages and deviations must be made explicit as there are several ways of obtaining mean values.

Centre of pressure (CoP) — gait line: The way in which the CoP is obtained should be made explicit. Calculation of deviations from the CoP should probably use root mean square calculations.

Lateral medial force index (LMFI): The criteria used to draw the LMFI should always be stated.

Rates of change of acceleration/velocity

Pressure/time curves and force/time curves

Masking: Definitions of the regions of measurement and how they are detected should be given.

In-shoe systems

The same requirements as listed for force plate and pressure mats were suggested. A wish list was also drawn up:

- Dynamic display enabling comparison of left and right feet on screen at the same time
- Identification and measurement of a parameter at single or multiple sites, applied to all steps recorded and displayed on screen.

Concluding comments

- If foot pressure measurements are to be more than 'pretty pictures' or solely a means of confirming clinical opinion or monitoring the effect of intervention, it is vital that a more scientific and numerate assessment is carried out.
- It is beginning to emerge that patterns exist for abnormality and it is important to identify whether this is the case.
- The whole area of repeatability of footsteps requires investigation.
- The effect of the many variables on gait requires investigation.
- The volume of data collected and the many analysis options currently available with commercial software systems can result in information overload and unrealistic time demands for that analysis. Thus the identification of key parameters is very important.

Appendix B: Protocol Analysis

Appendix B

Citations of reports from in-shoe plantar pressure measurement studies evaluated for the protocol analysis.

(Ahroni et al., 1998;

Albert & Christensen, 1994;

Albert & Rhinoie, 1994;

Brown et al., 2004;

Brown et al., 1996;

Cavanagh et al., 1998;

Conti et al., 1996;

Kernozek et al., 1996;

Lavery et al., 1995;

Lavery, Vela, Ashry et al., 1997;

Lavery, Vela, Fleischli et al., 1997;

Lavery, Vela, Lavery et al., 1997;

Lord & Hosein, 1994;

Mandato & Nester, 1999;

Martin & Conti, 1996;

McPoil et al., 1995;

Mueller, Sinacore et al., 1994;

Mueller & Strube, 1996;

Novick et al., 1993;

Perry et al., 1995;

Praet & Louwerens, 2003;

Randolph et al., 2000;

Redmond et al., 2000;

Rose et al., 1992;

Rozema et al., 1996;

Sarnow et al., 1994;

Shaw et al., 1997;

VanZant et al., 2001;

Woodburn & Helliwell, 1996b)

Appendix C: Reliability and Precision

Appendix C

The number of steps required to calculate the average step for variables measured over the whole foot (Total) to reach acceptable reliability (ICC > 0.80) and their associated reliability (ICC alpha) and precision (95% CI range).

	Anatomical region	Number of steps	Reliability ICC alpha	Precision 95% CI range
Area (cm^2)	1MPJ	2	0.91	1.03
	2-5digits	2	0.94	0.85
	2-5MPJ	2	0.98	0.08
	Hallux	2	0.96	0.46
	Heel	2	0.97	0.87
	Midfoot	2	0.96	2.48
Force (N)	1MPJ	4	0.86	5.16
	2-5digits	2	0.93	1.19
	2-5MPJ	2	0.92	1.29
	Hallux	2	0.95	0.76
	Heel	2	0.96	5.23
	Midfoot	2	0.96	1.73
Force-Time Integral (N s)	1MPJ	4	0.84	1.30
	2-5digits	3	0.91	0.59
	2-5MPJ	3	0.89	4.59
	Hallux	2	0.93	0.33
	Heel	2	0.93	1.79
	Midfoot	2	0.97	1.36
Loading begin (%)	1MPJ	4	0.86	4.86
	2-5MPJ	2	0.87	3.81
	Hallux	3	0.92	8.49
	Heel	3	0.96	2.37
	Midfoot	3	0.96	1.36
	2-5digits	3	0.84	6.96
Loading end (%)	1MPJ	7	0.86	0.45
	2-5 digits	2	0.87	1.08
	Hallux	3	0.94	0.40
	Heel	2	0.93	1.41
	Midfoot	3	0.87	7.57

	Anatomical region	Number of steps	Reliability ICC alpha	Precision 95% CI range
Loading Time (%)	1MPJ	6	0.90	3.65
	2-5digits	3	0.85	5.74
	2-5MPJ	2	0.89	3.30
	Hallux	2	0.89	8.71
	Heel	2	0.93	1.41
	Midfoot	2	0.89	6.11
Loading Time (ms)	1MPJ	2	0.87	81.14
	2-5digits	3	0.87	27.03
	2-5MPJ	2	0.95	43.78
	Hallux	2	0.88	9.92
	Heel	2	0.95	41.10
	Midfoot	2	0.90	104.89
Pressure Instant of Peak (%)	1MPJ	3	0.82	6.27
	2-5digits	2	0.85	4.69
	2-5MPJ	8	0.84	7.40
	Hallux	4	0.91	4.87
	Heel	3	0.89	4.52
	Midfoot	3	0.86	8.40
Pressure Instant of Peak (ms)	1MPJ	2	0.94	24.16
	2-5digits	2	0.92	50.38
	2-5MPJ	3	0.90	48.94
	Hallux	2	0.93	77.03
	Heel	2	0.89	26.63
	Midfoot	2	0.89	52.08
Pressure-Time Integral (kPa s)	1MPJ	3	0.82	22.10
	2-5digits	2	0.95	4.00
	2-5MPJ	2	0.86	12.10
	Hallux	2	0.91	10.40
	Heel	2	0.93	11.50
	Midfoot	2	0.91	14.40

Appendix D: Limits of measurement accuracy

Appendix D

The accuracy results per variable and anatomical regions. The number of repeated steps included in the average step calculation was obtained at two points where dA/dS (0.5 and 1.0) was considered virtually flat (see *Figure 10*). Additionally, the minimum number of repeated steps required to calculate the average step to be within 5% of that calculated to be likely at 50 steps was calculated.

Variable n=62 limbs	Anatomical region	dA/dS<1%		dA/dS<0.5%		dA/dS_{50}-5%		50 steps
		Steps	Accuracy	Steps	Accuracy	Steps	Accuracy	Accuracy
Area (cm^2)	1MPJ	5	3.20	6	2.62	4	4.31	1.09
	2-5digits	7	8.48	9	7.27	6	9.52	4.67
	2-5MPJ	4	1.78	5	1.35	3	2.80	0.51
	Hallux	6	4.39	7	3.82	5	5.32	1.88
	Heel	4	1.18	4	1.18	3	2.01	0.27
	Midfoot	7	7.56	9	6.32	6	8.65	3.78
	Total foot	5	2.88	6	2.40	3	5.97	1.08
Force (N)	1MPJ	10	12.22	12	11.00	10	12.22	7.37
	2-5digits	9	13.25	12	11.35	10	12.46	7.98
	2-5MPJ	8	7.77	10	6.70	7	8.63	4.18
	Hallux	9	12.45	12	10.65	9	12.45	7.46
	Heel	7	6.99	9	5.82	6	8.02	3.43
	Midfoot	9	13.93	12	11.86	10	13.06	8.23
	Total foot	5	3.26	6	2.72	4	4.28	1.22
Force-time integral (N s)	1MPJ	10	14.59	13	12.64	11	13.79	8.88
	2-5digits	11	17.52	14	15.67	13	16.17	11.67
	2-5MPJ	9	10.39	11	9.18	9	10.39	5.94
	Hallux	10	16.66	13	14.71	12	15.23	10.81
	Heel	8	11.37	11	9.42	8	11.37	6.37
	Midfoot	10	16.27	13	14.24	12	14.78	10.25
	Total foot	6	4.92	7	4.31	5	5.92	2.18

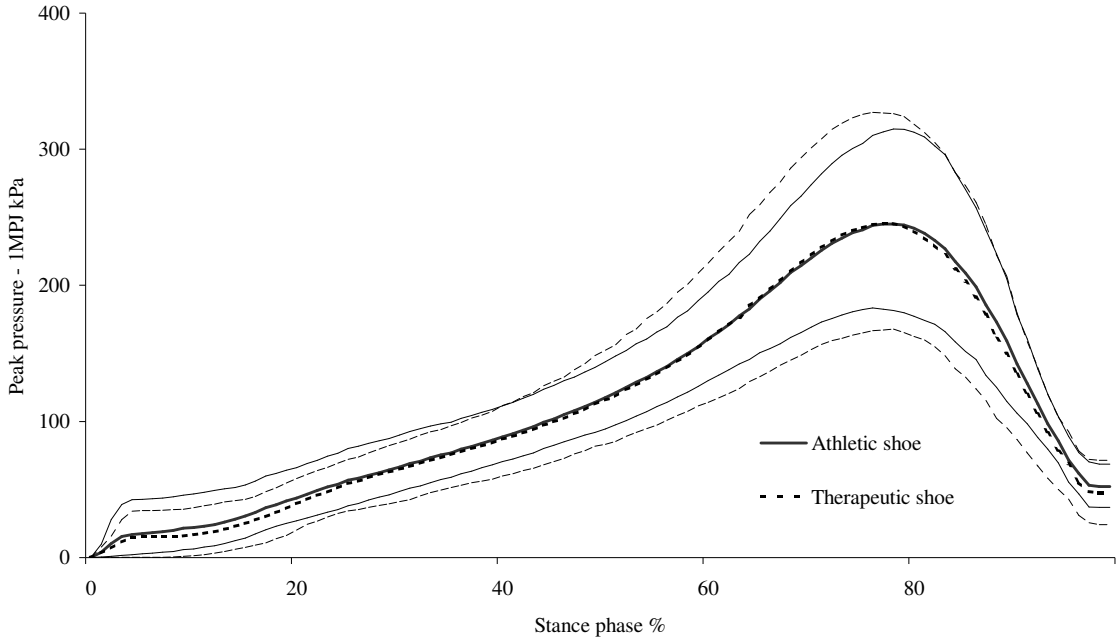
Variable n=62 limbs	Anatomical region	dA/dS<1% Steps	dA/dS<1% Accuracy	dA/dS<0.5% Steps	dA/dS<0.5% Accuracy	dA/dS_{50}-5% Steps	dA/dS_{50}-5% Accuracy	50 steps Accuracy
Loading begin (%)	1MPJ	10	16.45	14	13.85	21	12.00	10.16
	2-5digits	10	16.19	13	14.36	19	12.66	10.68
	2-5MPJ	10	20.63	13	18.82	20	12.31	10.56
	Hallux	10	15.89	13	14.12	19	17.09	15.02
	Midfoot	10	17.29	13	15.47	20	13.60	11.77
Loading end (%)	1MPJ	3	0.50	3	0.50	2	1.36	0.08
	2-5 Digits	4	1.79	4	1.79	2	5.14	0.68
	2-5MPJ	2	0.63	3	0.24	2	0.63	0.04
	Hallux	3	1.02	3	1.02	2	2.11	0.26
	Heel	7	7.19	9	6.12	6	8.11	3.86
	Midfoot	5	3.99	7	2.90	4	5.27	1.46
	Total foot	2	0.39	3	0.15	2	0.39	0.02
Loading time (%)	1MPJ	6	4.69	7	4.07	5	5.74	1.94
	2-5digits	8	9.01	10	7.88	7	9.92	5.12
	2-5MPJ	4	2.77	5	2.15	3	4.22	0.87
	Hallux	8	10.58	10	9.23	8	10.58	5.98
	Heel	7	7.23	9	6.16	6	8.15	3.88
	Midfoot	6	4.44	7	3.92	4	6.83	2.08
	Total foot	2	0.40	3	0.15	2	0.40	0.02
Loading time (ms)	1MPJ	7	6.09	9	5.06	6	7.01	2.96
	2-5digits	8	10.35	11	8.55	8	10.35	5.74
	2-5MPJ	6	4.70	7	4.17	4	7.12	2.26
	Hallux	8	11.23	11	9.30	8	11.23	6.29
	Heel	7	8.17	9	6.95	6	9.23	4.37
	Midfoot	7	5.74	8	5.18	6	6.59	2.82
	Total foot	6	4.77	7	4.23	4	7.24	2.29

Variable n=62 limbs	Anatomical region	dA/dS<1%		dA/dS<0.5%		dA/dS_{50}-5%		50 steps
		Steps	Accuracy	Steps	Accuracy	Steps	Accuracy	Accuracy
Pressure instant of peak (%)	1MPJ	6	4.62	7	4.03	5	5.59	2.00
	2-5digits	6	5.66	8	4.58	5	6.70	2.69
	2-5MPJ	6	4.39	7	3.75	5	5.45	1.68
	Hallux	6	3.67	7	3.19	4	5.96	1.56
	Heel	10	15.78	12	14.52	11	15.08	10.58
	Midfoot	10	17.98	13	15.90	12	16.45	11.75
	Total foot	9	16.07	12	14.14	10	15.27	10.57
Pressure instant of peak (ms)	1MPJ	7	6.16	8	5.61	6	6.97	3.25
	2-5digits	7	6.98	8	6.39	6	7.84	3.82
	2-5MPJ	7	5.94	8	5.36	6	6.81	2.94
	Hallux	7	5.97	8	5.40	6	6.81	3.01
	Heel	10	16.65	13	14.90	11	15.94	11.32
	Midfoot	10	19.05	14	16.43	12	17.48	12.59
	Total foot	10	16.68	12	15.44	11	15.99	11.51

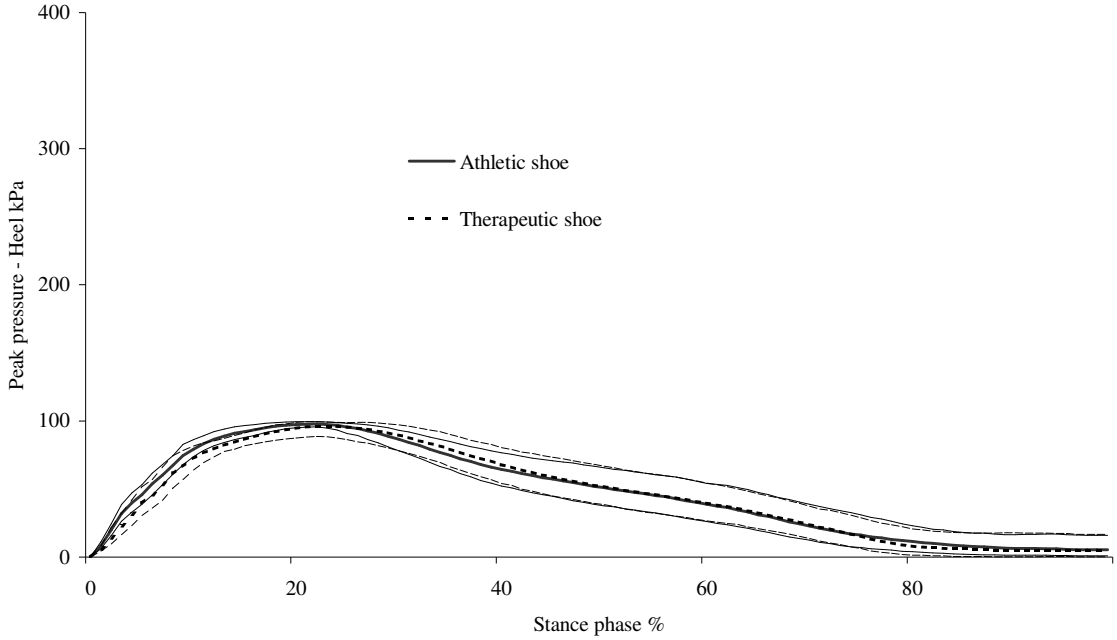
Appendix E: Peak pressure measures of athletic shoes versus therapeutic shoes over percentage-normalised stance phase for the hallux ulceration sub-population.

Appendix E Graphical results of peak pressures over percentage-normalised stance time from the hallux ulceration sub-population per anatomical region for the athletic and therapeutic shoes.

Legend: The means are labelled in the legend and the 95% confidence bands (Bstrap) for the rocker-soled shoes are the outer dashed lines and the therapeutic shoes are the outer continuous lines.



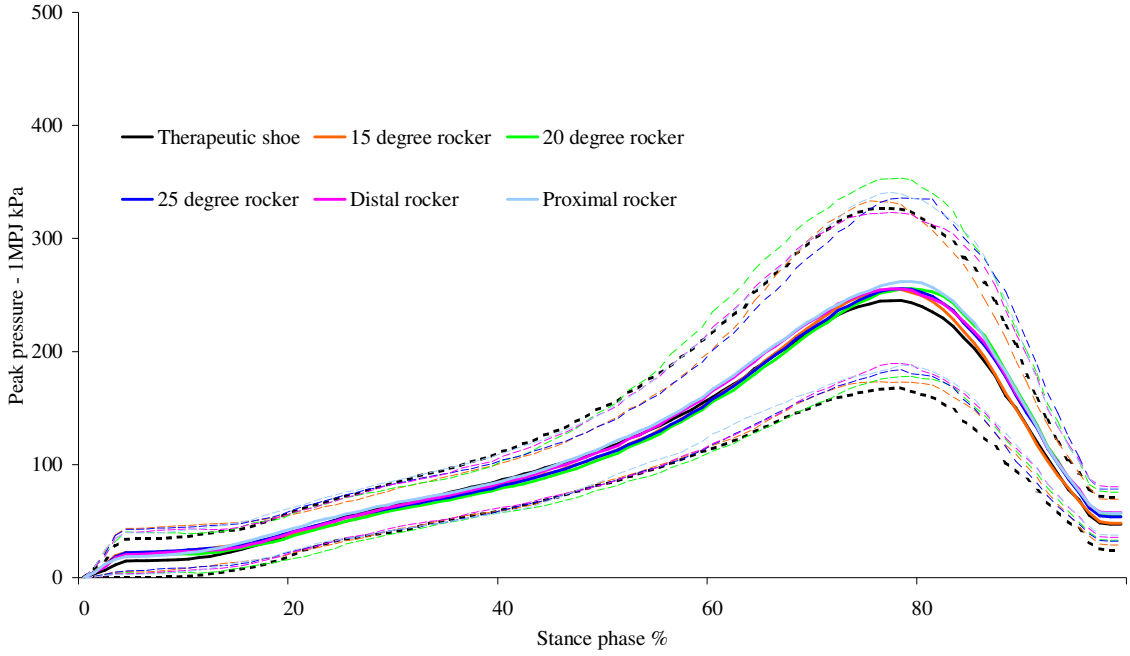
Appendix E: Figure 1. The means and 95% confidence bands (Bstrap) (the outer lines) for peak pressure-1MPJ for the hallux ulceration sub-population per shoe type.



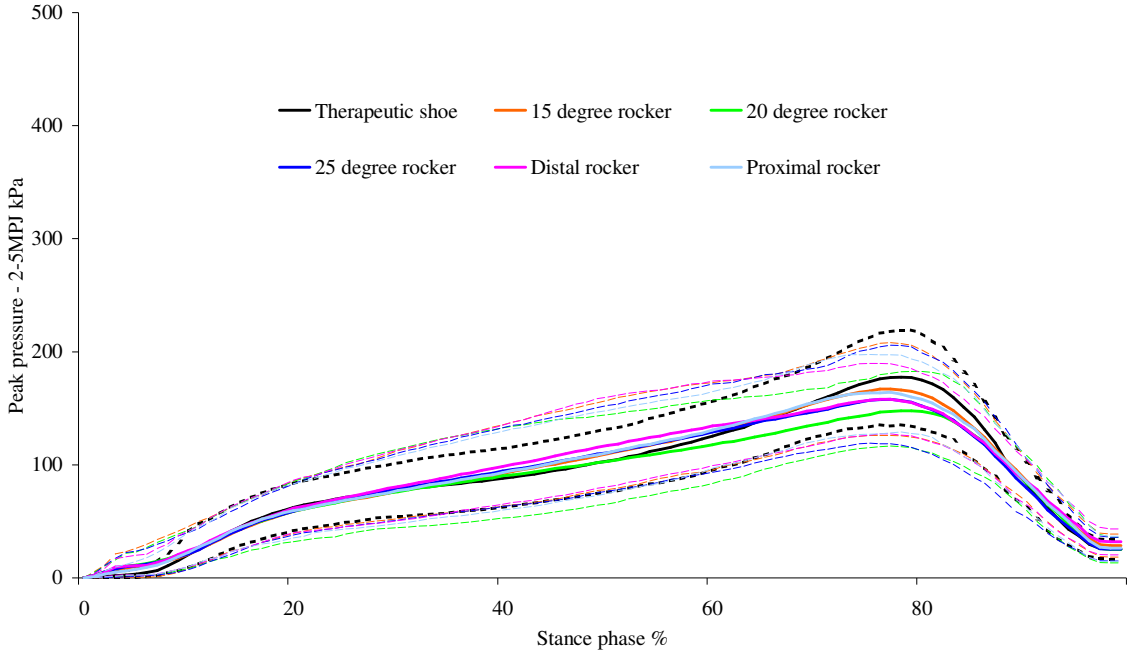
Appendix E: Figure 2. The means and 95% confidence bands (Bstrap) (the outer lines) for peak pressure-heel for the hallux ulceration sub-population per shoe type.

Appendix F: Peak pressure measures of therapeutic shoes with rocker-sole modifications over percentage-normalised stance phase for the hallux ulceration sub-population.

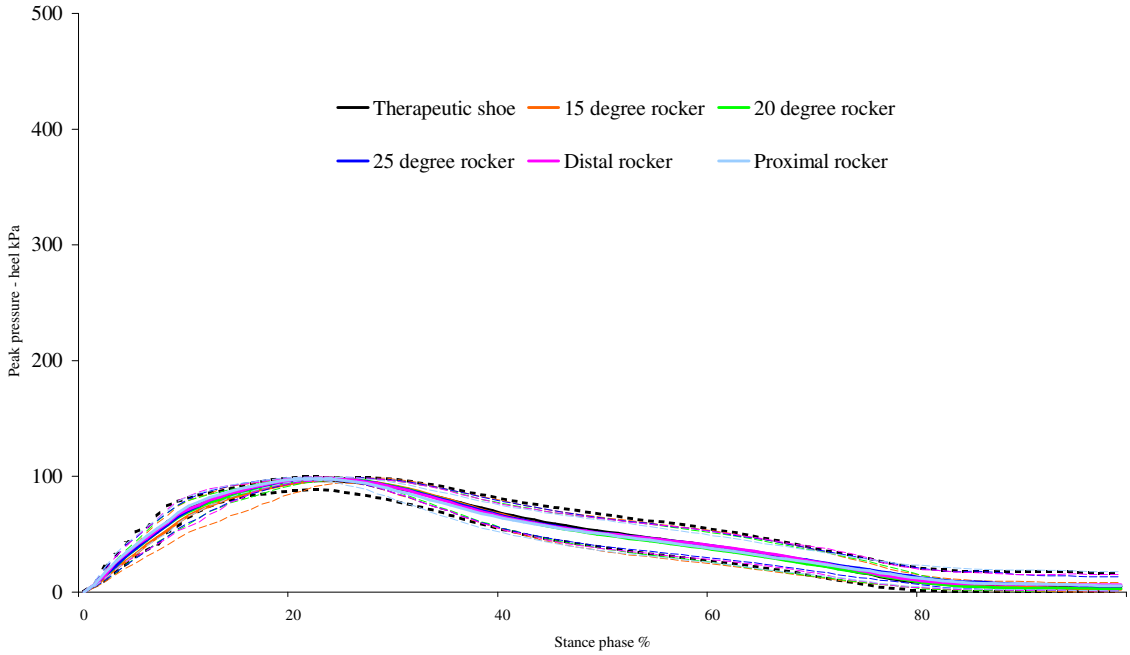
Appendix F Graphical results of peak pressures (kPa) over percentage-normalised stance time from the hallux ulceration sub-population per anatomical region for the therapeutic shoes with and without the rocker-sole modifications.



Appendix F: Figure 1. The means and 95% confidence bands (Bstrap) (the outer dashed lines) for peak pressure-1MPJ for the hallux ulceration sub-population per shoe type.



Appendix F: Figure 2. The means and 95% confidence bands (Bstrap) (the outer dashed lines) for peak pressure-2-5MPJ for the hallux ulceration sub-population per shoe type.

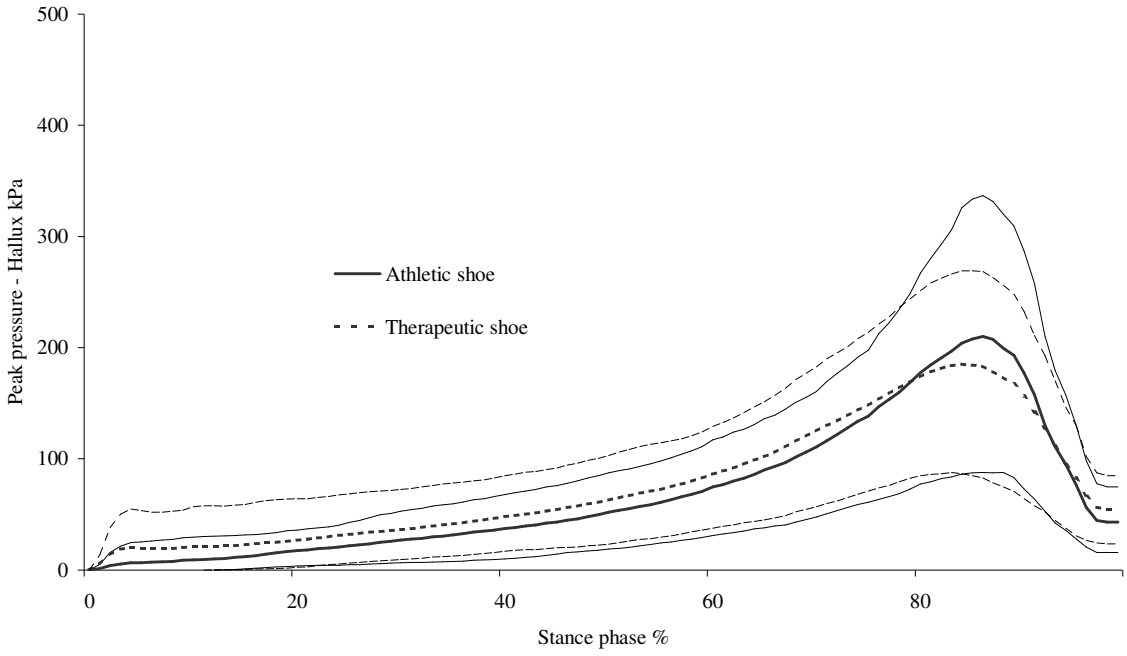


Appendix F: Figure 3. The means and 95% confidence bands (Bstrap) (the outer dashed lines) for peak pressure-heel for the hallux ulceration sub-population per shoe type.

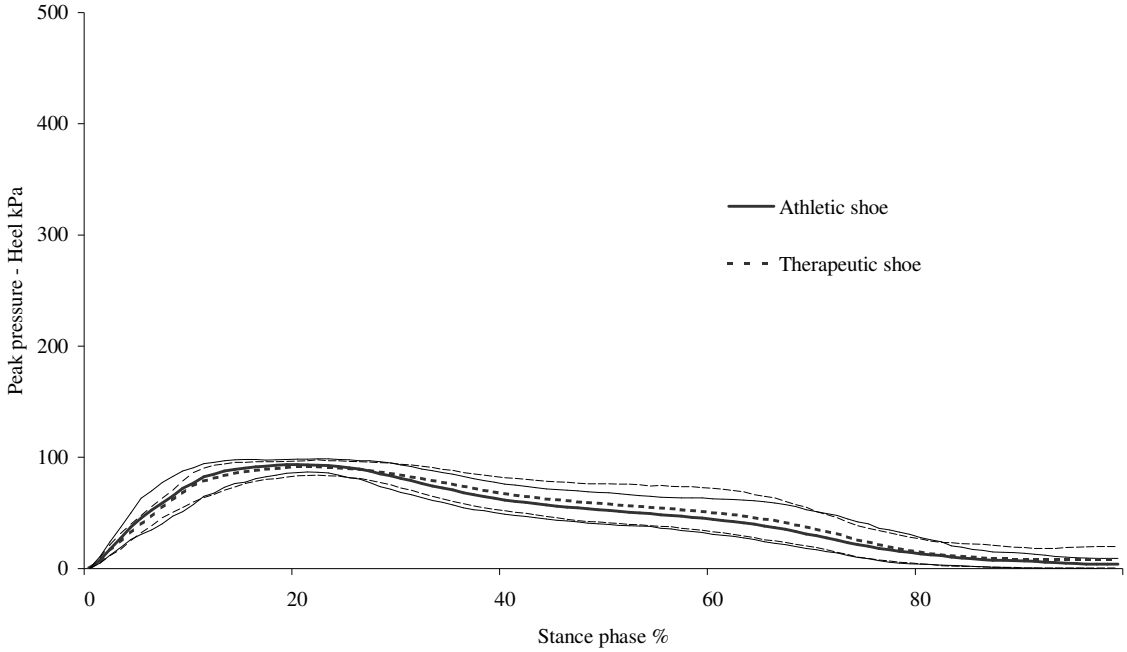
Appendix G: Peak pressure measures of athletic shoes versus therapeutic shoes over percentage-normalised stance phase for the 1MPJ ulceration sub-population.

Appendix G Graphical results of peak pressures over percentage-normalised stance time from the 1MPJ ulceration sub-population per anatomical region for the athletic and therapeutic shoes.

Legend: The means are labelled in the legend and the 95% confidence bands (Bstrap) for the rocker-soled shoes are the outer dashed lines and the therapeutic shoes are the outer continuous lines.



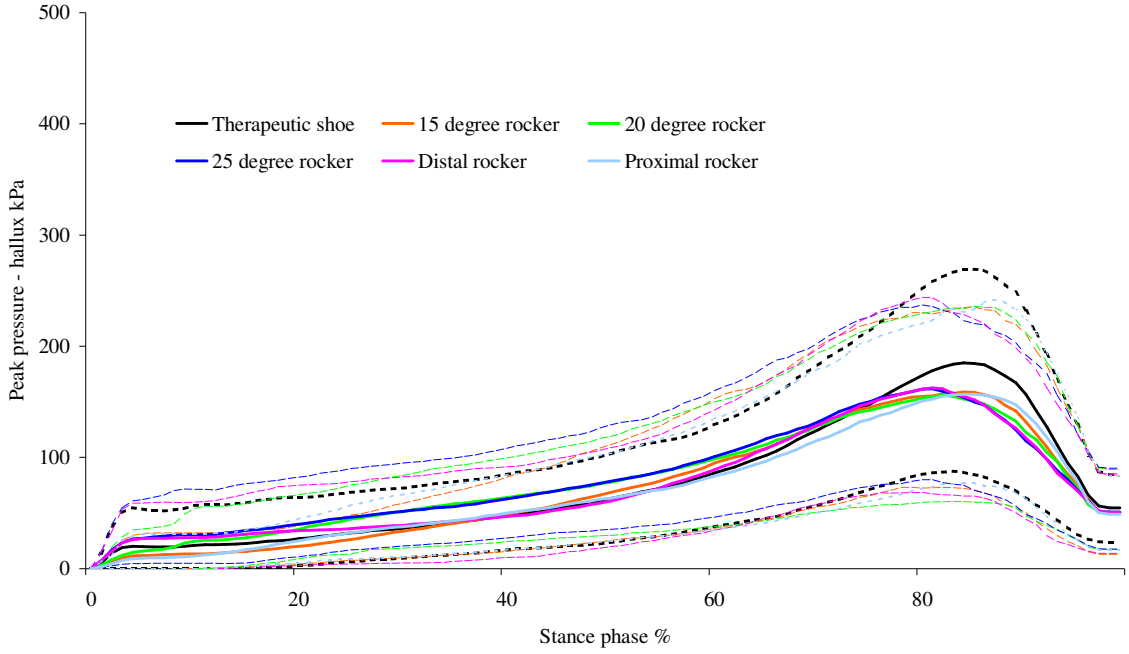
Appendix G: Figure 1. The means and 95% confidence bands (Bstrap) (the outer lines) for peak pressure-hallux for the 1MPJ ulceration sub-population per shoe type.



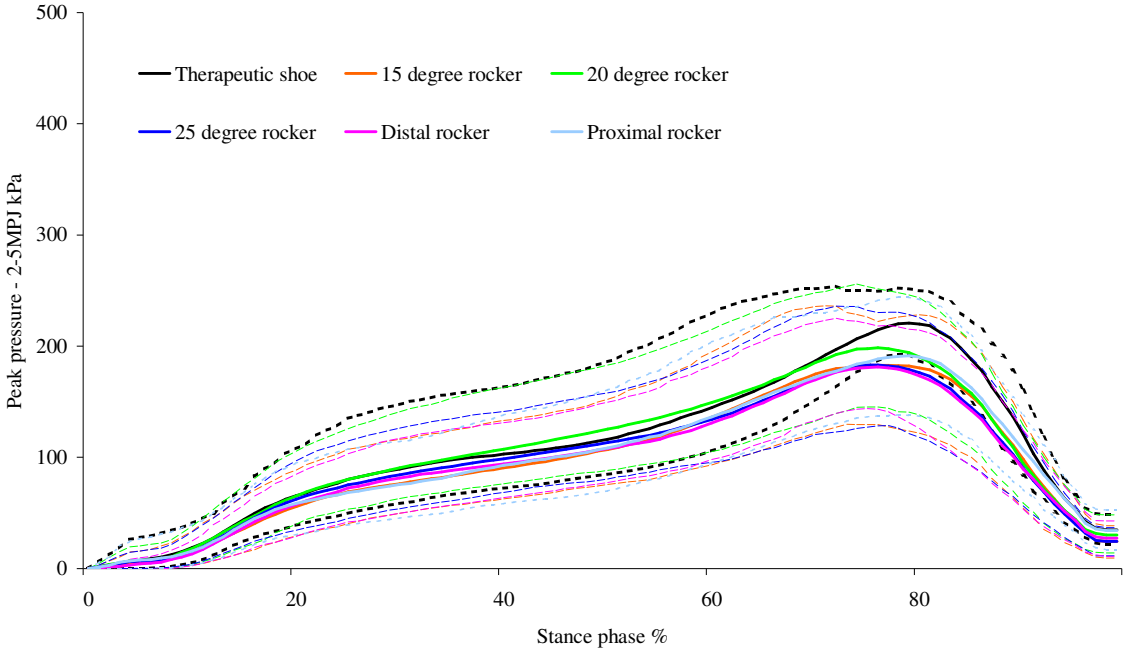
Appendix G: Figure 2. The means and 95% confidence bands (Bstrap) (the outer lines) for peak pressure-heel for the 1MPJ ulceration sub-population per shoe type.

Appendix H: Peak pressure measures of therapeutic shoes with rocker-sole modification over percentage-normalised stance phase for the 1MPJ ulceration sub-population.

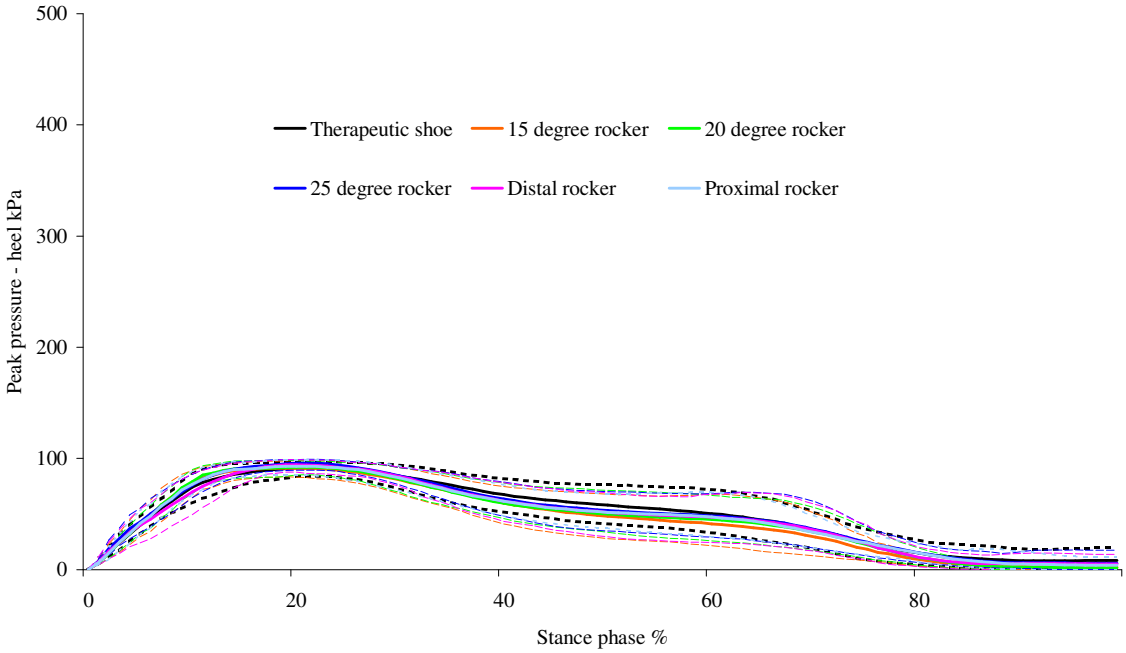
Appendix H Graphical results of peak pressures over percentage-normalised stance time from the 1MPJ ulceration sub-population per anatomical region for the therapeutic and rocker-soled shoes.



Appendix H: Figure 1. The means and 95% confidence bands (Bstrap) (the outer dashed lines) for peak pressure-hallux for the 1MPJ ulceration sub-population per shoe type.



Appendix H: Figure 2. The means and 95% confidence bands (Bstrap) (the outer dashed lines) for peak pressure-2-5MPJ for the 1MPJ ulceration sub-population per shoe type.



Appendix H: Figure 3. The means and 95% confidence bands (Bstrap) (the outer dashed lines) for peak pressure-heel for the 1MPJ ulceration sub-population per shoe type.

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