Improving the design of the curved rocker shoe for people with diabetes

Jonathan D Chapman

PhD Thesis 2014

Improving the design of the curved rocker shoe for people with diabetes

Jonathan D Chapman

SCHOOL OF HEALTH SCIENCES

UNIVERSITY OF SALFORD, SALFORD, UK

Submitted in Partial Fulfilment of the Requirements of the Degree of Doctor of Philosophy, 2014

"Well I guess this is growing up"

(Mark Hoppus)

Contents

List of tables

Chapter 5

List of figures

Chapter 1

Chapter 2

Chapter 3

Chapter 4

Chapter 5

Acknowledgements

I would like to thank my two supervisors, Dr Stephen Preece and Professor Christopher Nester, for their patience, guidance and for giving me this opportunity to complete this PhD project.

The research leading to these results has received funding from the European Community's Seventh Framework Programme (FP7/2007-2013) under SSHOES project, Grant Agreement no. NMP2-SE-2009-229261.

I would like to thank my parents, my sister Kate and Ollie for their support during the last four years. I would also like to thank Karen for being a true friend during my PhD. Finally, I would like to thank my supervisor from UCLan, Dr Sarah Jane Hobbs, because her passion for biomechanics inspired me to pursue a career in biomechanics research.

Abbreviations

CoP = centre of pressure

PP = peak pressure

PTI = pressure time integral

MTH = metatarsal head

MTP = metaphalangeal joint

ANN = Artificial neural network

Abstract

Introduction

Foot ulceration and re-ulceration are a serious problem in people with diabetes as the outcome can be lower limb amputation, reducing quality of life and increasing mortality. The pathogenesis of foot ulceration is multifactorial with neuropathy, alterations in foot structure, callus formation and increased plantar foot pressure. The most effective intervention for reducing plantar pressure is the curved rocker outsole. To date this design has been prescribed from clinical intuition rather than scientific evidence. Therefore the studies within this thesis aimed to improve our understanding of how to best to design, and also prescribe, a rocker sole.

Methods

Ethical approval was obtained from the University of Salford and the NHS. **Study 1** investigated the independent effect of varying the three outsole design features (apex angle, apex position and rocker angle) on plantar pressure in 24 people with diabetes and healthy participants. In-shoe pressure data was collected using Pedar-x and analysed using Matlab. **Study 2** investigated the effect of varying apex position in combination with rocker angle, in 87 people with diabetes, and aimed to establish how many people would receive sufficient offloading when wearing a pre-defined rocker design. **Study 3** investigated a new method of prescribing a rocker sole using artificial neural networks with an input of gait variables on 78 people with diabetes. Gait data was collected using Vicon and analysed using Visual-3D and Matlab.

Results

The results of **Study 1** suggested that fixing apex angle at 95° would be a suitable compromise to offload the high risk areas (medial forefoot). It also suggested that apex position and rocker angle needed more investigation. Therefore, in **Study 2** the combined effect of two rocker angles and four apex positions were investigated. Despite some inter-subject variability, this study showed that over 60% of participants received sufficient offloading when walking in a mean optimal design. Furthermore, over 60% of people received sufficient offloading with the smaller rocker angle of 15°. The results in **Study 3**

showed there was low accuracy when predicting an individual optimal shoe using gait variables as inputs (34-49%).

Conclusions

This project has shown it is possible to significantly reduce plantar pressures in people with diabetes with a well-designed rocker shoe (95° apex angle, individual apex position and 15° rocker angle). This finding paves the way for future clinical trials which could provide robust clinical evidence for the use of rocker shoes.

Chapter 1: Introduction

1.1 Diabetes and the impact of plantar foot ulcers

Diabetes is a metabolic disease categorised by high blood sugar levels (hyperglycaemia) resulting from failings in the insulin secretion, insulin action or both. Insulin is a hormone secreted by the pancreas and is central to regulating carbohydrate and fat metabolism in the body. The chronic hyperglycaemia of diabetes is associated with long term health complications making it a large problem for health services. Diabetes is a serious condition which is escalating across the world. Worldwide, there is a prevalence of 8.3%, which summates 382 million people suffering from diabetes. This figure is predicted to rise to 592 million by 2030 (Foundation and Federation, 2006), with some of the increase being associated with increasing population size (Sicree and Shaw, 2007) and some of the rise is associated with increasing levels of obesity (Mokdad et al., 2003). In the UK, there are approximately 2.9 million people who have been diagnosed with diabetes, costing the NHS in the region of £10 billion every year. This constitutes 10% of the entire NHS budget. In North America, 11% of the population suffer with diabetes and approximately 1 in every 7 health care dollars are spent on caring for these people (Levin and O'Neal, 1988). Diabetes can be fatal. In the United States, it is considered to be the third largest cause of mortality which includes direct and indirect outcomes of the disease.

Several health complications are associated with diabetes. Diabetes is the leading cause of blindness in adults with approximately 24,000 people each year becoming blind as a result of the disease (Levin and O'Neal, 1988). Renal disease is also linked with diabetes accounting for 40% of patients who require dialysis. Furthermore, people with diabetes are also more likely to suffer from ischaemic heart disease or a stroke compared to the general population (Rubin et al., 1994). There is also a higher risk of lower limb amputation in people with diabetes which is caused by a number of factors such as infection and foot complications. It has been identified as the leading cause of non-traumatic lower limb amputations in the United States (Levin and O'Neal, 1988).

A common complication in people with diabetes is foot ulcers. A foot ulcer is an erosion on the skin and is characterised by the inability to self-repair (Levin and O'Neal, 1988). Foot ulcers account for a large proportion of the overall health costs of diabetes.

Developing an ulcer increases the chance of a person being admitted to hospital. They are also the main cause of lower limb amputation (Sicree and Shaw, 2007). It has been reported that 15% of people with diabetes will develop a foot ulcer (Cheer et al., 2009) and this accounts for more hospital admissions than any other diabetes-related complication. Hospital admissions for people with a foot ulcer may be as high as 24,000 pa in the UK (Boulton et al., 1994). There are also indirect costs associated with diabetes, including lost working time. Although difficult to quantify, this is likely to be substantial (Boulton et al., 1994). In the United States, the direct costs of treating diabetic foot ulcers have been reported to be as high as $150m (Reiber, 1992). These statistics demonstrate the significant health care costs of treating diabetes.

The development of a foot ulcer can cause serious health problems. If left untreated infections can develop which, in some cases, can lead to an amputation. Approximately 85% of amputations could be avoided by early detection of an ulcer, patient education, and early stage interventions (Leung, 2007). The impact of an ulcer can have a negative effect on the patients' lifestyle. Patients who have suffered from an ulcer have been shown to be less active and less social than patients who have not (Maluf and Mueller, 2003). Plantar ulcers have also been associated with increased levels of stress (W. G. Meijer, 2001). The impact of ulcers on a patient's lifestyle and wellbeing is an important reason to prevent patients developing ulcers. The number of people with diabetes is growing globally and this will inevitably lead to an increase in foot ulceration. It is therefore essential that effective strategies are developed to minimise the rate of foot ulcerations in people with diabetes.

1.2 Aetiology of ulceration in diabetes

There are a number of contributory factors that cause ulcers (Figure 1. 1). These factors include physiological processes, skin mechanics, neuropathy and plantar pressure (Reiber et al., 1999). The foot will not ulcerate spontaneously as a number of these factors need to interact for an ulcer to develop (Waaijman and Bus, 2012). There are two main types of ulceration associated with diabetes: neuropathic and ischaemic .

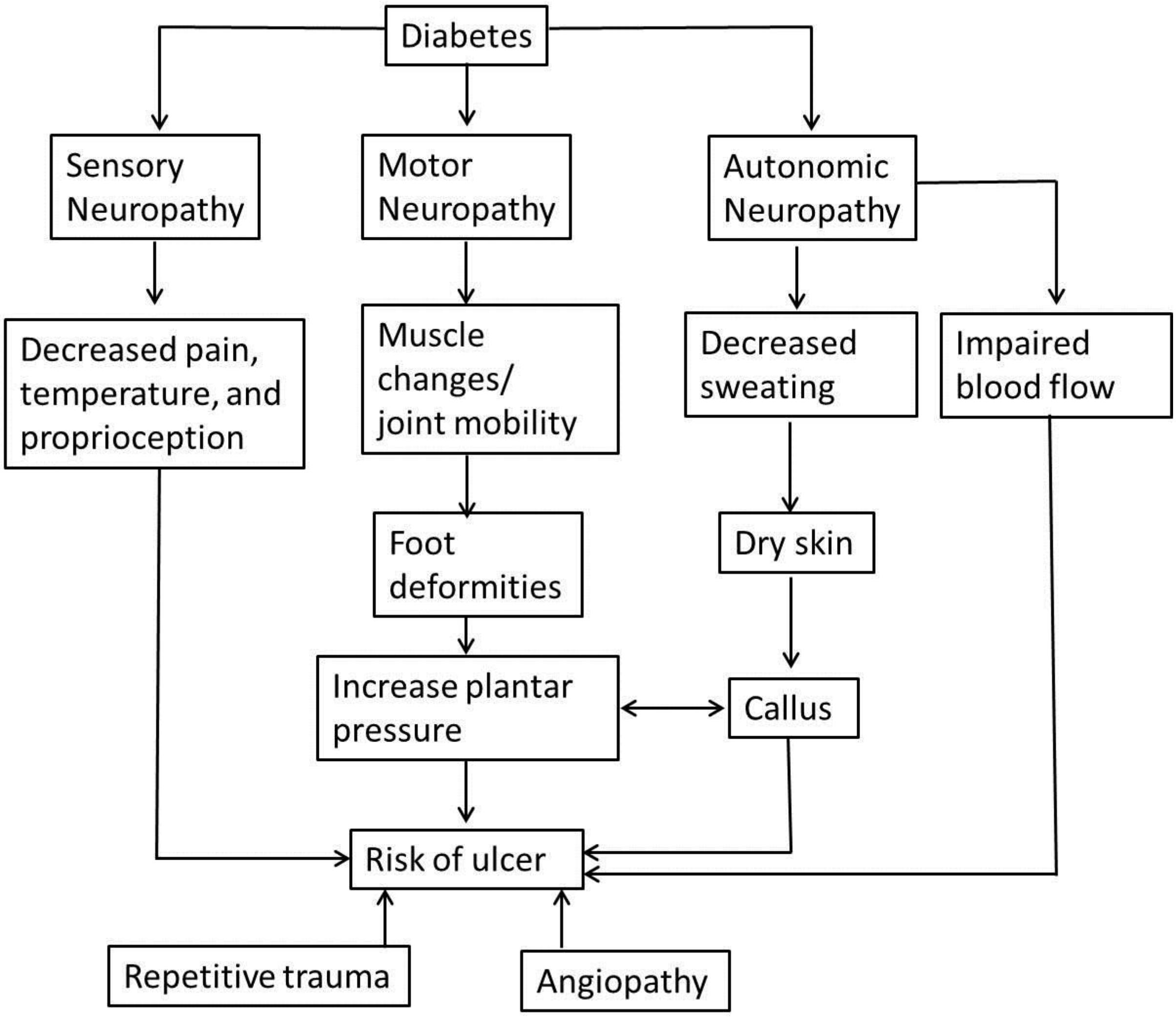

Figure 1. 1: Factors which lead to a neuropathic ulcer. The different types of neuropathy will be discussed in more detail below.

Ischemic ulcers are caused by a lack of blood flow to the foot, which results in the skin becoming very delicate (Oyibo et al., 2001b). Ischemia is a complication of peripheral vascular disease, a condition associated with diabetes. Peripheral vascular disease is the narrowing of the arteries that supply the legs and feet, decreasing the blood flow to the extremities which increases the chance of skin damage and infection (Kumar and Clark, 2009). Ischemia is the reduction of blood flow to an organ [ref]. In relation to soft tissue breakdown, ischemia is caused by capillary closure due to local pressure gradients across the vessel wall (Bouten et al., 2003). Ischemic ulcers can occur over any part of the foot where there has been a break in the skin and are classed by their irregular shape and colour (Oyibo et al., 2001b).

The process causing a neuropathic ulcer differs greatly from the process causing an ischemic ulcer. The skin acts as a mechanical protective layer which shields the foot from external stresses. Soft tissue is constructed of three layers: the epidermis (the outer layer), dermis (second layer) and subcutaneous tissues (layer between the skin and muscle) (Levin and O'Neal, 1988) (Figure 1. 2). Dry skin, in combination with high plantar pressures leads to the formation of a callus (toughened area of skin). Due to the repetitive nature of walking a callus forms under the prominent bony areas such as the metatarsal heads. The process of keratinisation becomes stimulated by over activity due to the repetitive compression applied during walking. This results in hypertrophy of the stratum corneum which is thought to increase the proliferation of epidermal cells (Murray et al., 1996). A callus increases the risk of developing an ulcer. This is due to increased hardness and density of the skin which increases pressure during walking (Reiber et al., 1998, Boulton et al., 1994).

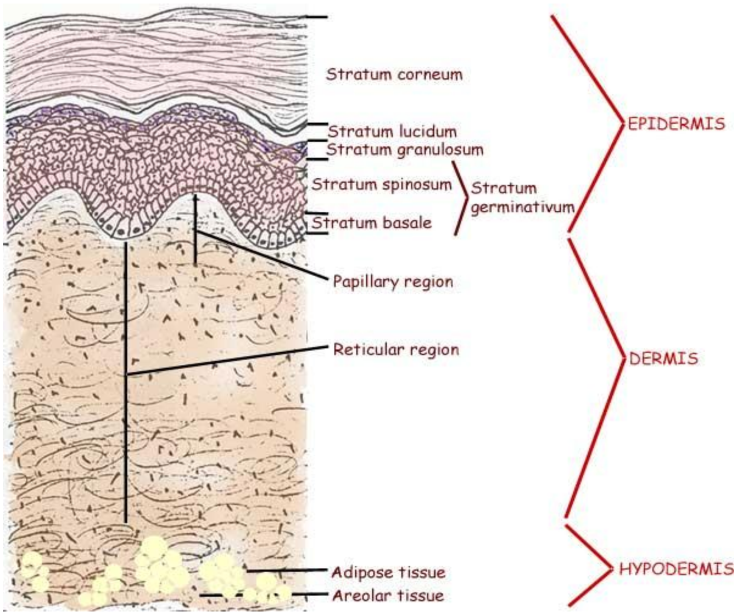

Figure 1. 2 : Layers of the plantar skin

Neuropathic ulcers differ greatly to ischemic ulcers (Oyibo et al., 2001a). Notably, they differ in form to ischemic ulcers by having a more rounded shape and they often occur in the middle of a callus. They are also far more common in people with diabetes with a prevalence of approximately 70% (Oyibo et al., 2001b). Therefore due to the high rate of neuropathic ulcers in people with diabetes, this project has focussed on the pathways and the interventions with regards to neuropathic ulcers and for the rest of the thesis the term "ulcer" will refer to a neuropathic ulcer.

Plantar foot ulcers typically develop at points of the foot where there is high pressure. Sites of increased pressure typically occur over bony prominent areas during walking (Ledoux et al., 2013) and there have been a number of studies (Waaijman et al., 2012) which have reported that the most common locations of plantar foot ulcers are in toes and metatarsal heads. (Waaijman et al., 2012). The 1st MPJ (metaphalangeal joint) is the most common site with reports of 27% of ulcers occurring in this region, the hallux is also a common location of ulceration with reports of 18% (Waaijman et al., 2012). It is clear that there is a correlation between site of ulcer and the magnitude of pressure.

1.3 The epidemiology of foot ulceration in people with diabetes

1.3.1 Overview of the different risk factors

A number of prospective cohort studies have been carried out to identify the risk factors for diabetic ulceration (Boyko et al., 1999, Hurley et al., 2013). A cohort or observational study, follows a group of people over a set period of time and uses correlations to determine the absolute risk of the factors. In diabetes research, a common design is to follow a group of people with diabetes and compare the factors to a group of people who developed an ulcer to those who did not (Boyko et al., 1999). Another common design used in diabetes research is a case-control study. This type of design is often used in epidemiological studies and it aslo identifies the risk factors of a medical condition. However, instead of following the participants over a period, the factors for a group who do not have the condition are compared to the factors of those who do at a single point in time (Owings et al., 2009b). Both of these types of studies have identified a range of risk factors associated with plantar foot ulcers in diabetes.

Epidemiological studies have identified a range of contributory factors in foot ulceration (Boulton, 2008, Reiber et al., 1999, Crawford et al., 2007, Frykberg, 1998). Between these studies, a wide range of factors were measured which included, neuropathy, plantar pressure, age, sex, weight, and alcohol consumption (Crawford et al., 2007). Not one of these studies measured every possible risk factor of ulceration, however, Reiber et al (1999) identified the most common combination of factors to be neuropathy, external trauma, and foot deformity. Apart from external trauma, none of these factors will result in an ulcer in isolation (Boulton, 2013). External trauma is classed as repetitive pressure causing continuous stress, such as walking, or a short duration of a period of high pressure, such as standing on an object, which results in tissue damage. Increased pressure due to poor footwear was identified by Macfarlane and Jeffcote (1997) as being a risk factor in 20% of all ulcers. Poor footwear includes factors such as, rubbing and increased plantar pressures, new shoes, shoes provided by an orthotist, and poor choice of(Boyko et al., 1999, Hurley et al., 2013) footwear, e.g. Wellington boots. However, the risk of ulceration is significantly increased if high pressure occurs in combination with other factors such as neuropathy (Nather et al., 2008).

There is a strong association between the presence of neuropathy in a patient with diabetes and foot ulceration (Boyko et al., 1999, Jayaprakash et al., 2009, Lavery et al., 1998, Nather et al., 2008, Abbott et al., 1998). Neuropathy is defined as loss of sensation in the feet, is caused by nerve damage (Levin and O'Neal, 1988) and has a prevalence of approximately 28%. Abbot et al (1998) reported that people with neuropathy are seven times more likely to develop an ulcer than those without. However, despite neuropathy being a powerful predictor of ulceration, it needs to occur in combination with high pressure for an ulcer to develop (Levin and O'Neal, 1988). When in combination with high plantar pressure, it increases the risk of ulceration significantly (Macfarlane and Jeffcoate, 1997). Lack of sensation reduces a patient's awareness of an external trauma. Studies have identified accidents, such as falls, standing on an object, pressure from footwear, immobilisation from other illnesses, and poor foot care as common risk factors to developing an ulcer (Deshpande et al., 2008, Macfarlane and Jeffcoate, 1997). Given neuropathy leads to a loss of sensation on the plantar aspect of the foot, patients who suffer with this condition can develop skin damage when standing on an unnoticed object (Levin and O'Neal, 1988). Similarly, patients with neuropathy have been shown to be at significantly greater of a fall in comparison with patients without neuropathy because of damage to the nerves affecting proprioception (Dingwell and Cavanagh, 2001).

A number of physiological factors have been linked to increased risk of developing an ulcer. These factors were highlighted in a recent a large scale cross-sectional study which classified patients into different risk categories for foot ulceration using a number of factors

(Mugambi-Nturibi et al., 2009). The study classified 33% of the 218 subjects as being at high risk of ulceration. Apart from the presence of neuropathy, the key ulceration risk factors were age, male gender, duration of diabetes, unsystematic blood sugar, systolic blood pressure, and the presence of a foot deformity. However, a limitation of this study was that the authors did not measure plantar foot pressure. Given the findings of other studies (Pham et al., 2000) which have shown elevated foot pressure to be a risk factor for ulceration, it is likely that increased classification accuracy could have been obtained with the addition of this risk factor. The physiological risk factors identified by Mugambi-Nturibi et al (2009), e.g. blood pressure, can be controlled through patient education programmes and improved screening. It is clear that increased pressure, the presence of neuropathy and the presence of a foot deformity are the main risk factors of ulceration and will be now discussed in more detail.

1.3.2 Neuropathy as a risk factor for ulceration

A large number of studies have identified neuropathy as risk factor of ulceration (Boulton, 2008, Boyko et al., 1999, Deshpande et al., 2008, Macfarlane and Jeffcoate, 1997, Nather et al., 2008). Neuropathy is one of the long-term complications of diabetes and is defined as damage to nerves (Levin and O'Neal, 1988). Neuropathy is caused by high blood glucose levels damaging the small blood vessels which supply the nerves which prevents nutrients reaching them (Levin and O'Neal, 1988). The prevalence of diabetic neuropathy increases with age (Young et al., 1993). For example, neuropathy is uncommon (<5%) in patients with diabetes aged 20-29 (Young et al., 1993), however, the prevalence has been observed to increases to over 40% of people aged between 70-79 (Young et al., 1993). Furthermore, neuropathy also increases with duration of diabetes and is has been shown to be present in nearly 40% of patients who have been diagnosed with diabetes for longer than ten years (Young et al., 1993).

Neuropathy can be quantified using a variety of methods in clinical practice. These methods include; a tuning-fork, hot and cold tests, needles, or assessing Achilles tendon reflexes (Levin and O'Neal, 1988). However, the most common method is to use a monofilament (Boada, 2012). Monofilaments test the patients’ sensitivity to pressure by applying a load (commonly 10 g) to several sites of the plantar aspect of the foot. Patients are then asked if they can feel the pressure caused by the monofilament. If the patient cannot feel a pre-defined number of sites, which varies depending on the classification method, they are classed as neuropathic. For instance, the method described by Paisley et al (2002) uses five sites on each foot (1^{st}, 2^{nd}, 3^{rd}, 5^{th} MTH and hallux). If a patient can feel the pressure of the monofilament in less than eight sites, they are deemed as neuropathic (A. N et al., 2002).

These sensation tests are used to determine a patient's current level of risk. Patients with diabetes are classified as low risk if they have been diagnosed with diabetes, but do not exhibit any neuropathy (therefore still have protective sensation) (Levin and O'Neal, 1988) (Table 1. 1). A patient is deemed to be high risk if they have loss of protective sensation and have a possible ulcer history, a patient is deemed to be at serious risk if they have loss of protective sensation and a foot deformity (Table 1. 1).

Table 1. 1: Patient class of diabetes

Category	Protective sensation	Ulcer history	Foot deformity
0 (Low risk)	Yes	No	No
1 (High risk)	No	No	No
2 (High risk)	No	Yes	No
3 (Serious risk)	No	Yes/no	Yes

There are three types of neuropathy seen in people with diabetes: sensory, motor, and autonomic. The onset of sensory neuropathy is gradual and symptoms often go unnoticed in the early stages. It occurs due to the deterioration of nerve function, this is why it can be described as "loss of protective sensation". A loss of sensation on the plantar aspect of the foot means that people with neuropathy are unable to sense areas of high plantar pressure which would result in pain in a healthy individual (Boulton et al., 1994, Levin and O'Neal, 1988). It has been suggested that the presence of high pressure in combination with sensory neuropathy significantly increases the chance of developing an ulcer (Boulton et al., 1994). This idea has been confirmed by studies which have shown that patients with severe neuropathy have more chance of developing an ulcer than patients without neuropathy (Dinh et al., 2012, Veves et al., 1992). For example, Veves et al (1992) studied people with diabetes and found 45% of people in the neuropathic group developed an ulcer compared to only 8% in the non-neuropathic group.

Motor neuropathy causes atrophy and weakness in the muscles of the foot (Boada, 2012). Furthermore, this type of neuropathy often leads to foot deformities such as claw/hammer toe because it causes a reduction in the stabilisation of the metatarsophalangeal joints. Foot deformities such as claw/hammer toe, cause the toes to be pulled up, and therefore lead to an increase in plantar pressure under the toes and metatarsal heads (Reiber et al., 1999). As stated previously an increase in pressure will increase the risk of ulceration (Boada, 2012).

Autonomic neuropathy is associated with damage to the nerve fibres that supply the sweat glands (Boada, 2012). This leads to dryness of the skin causing cracks or fissures, and eventually a callus (Figure 1. 1). Callus is associated with an increase in plantar pressure (Murray et al., 1996) and therefore increases the risk of an ulcer developing (Di Carli et al., 1999). Autonomic neuropathy also causes a reduction in the microcirculation of the foot. The presence of one of these classifications of neuropathy will increase the chance of an ulcer developing (Figure 1. 1). However, ulcers can still occur in people without neuropathy (Veves et al., 1992).

1.3.3 Elevated plantar pressure and other risk factors for ulceration

The cause of foot ulceration is multifactorial and includes a number of structural and disease related factors. It is well documented that pressures under the foot are higher in people with diabetes which increases the chance of tissue breakdown (Payne et al., 2001). There have been a number of factors identified which interact to increase plantar pressure during walking. These include a higher body weight, age, skin and soft tissue characteristics. Tissue mechanics and characteristics will be discussed in more detail in the Literature review. This section will provide an overview of the other factors associated with pressure.

People with diabetes have been shown to exhibit higher pressures compared to healthy people (Bacarin et al., 2009). High plantar pressures during walking have the potential to cause skin breakdown and increase the likelihood of an ulcer developing. These pressures may result from high loads over a small bony area of the foot which can occur during normal walking (Boulton et al., 1994). If we consider the total force generated during the single limb support phase of gait, it is approximately 1.1 x body weight. Assuming this vertical force is distributed evenly across the plantar aspect of the foot, then the average pressure across a typical male foot would be 75 kPa (Boulton et al., 1994). However, measurements have been reported of up to 15 times this number in barefoot walking (Rozema et al., 1996). This is because the load is distributed over a small area of the foot such as a bony prominence (1st MPJ). Therefore, pressure is often described as the critical factor that determines the harm done by the force (Levin and O'Neal, 1988). Plantar pressure is therefore a strong predictor of the location of an ulcer. Strong correlations have been reported between the location of ulcers and the highest plantar pressures (Waaijman et al., 2012). Despite pressure appearing to be a strong predictor of ulceration, there are a number of other factors linked to increased pressure and ulceration in people with diabetes.

Studies have reported varying results when comparing body weight and pressure. Some studies (Menz and Morris, 2006, Hills et al., 2001) which have shown a relationship between plantar pressure and bodyweight whereas other studies (Birtane and Tuna, 2004) have shown little or no correlation between increased weight and pressure. However, all of these studies evaluated barefoot pressures not in-shoe. One study (Martinez-Nova et al., 2008) evaluated the effect of bodyweight and age on in-shoe pressure in the forefoot using a healthy cohort. Bodyweight was reported as an independent predictor of pressure under the forefoot region, however, the variability explained between subjects was low. A similar relationship was also reported for age. Although weight and age may be associated with ulceration, they are not as strongly associated as neuropathy and foot deformity.

Foot deformity has also been identified as a risk factor for diabetic foot ulceration (Bus, 2008a). The most common abnormalities are callus formation and prominent metatarsal heads which are then followed by a claw and hammer deformities (Bus, 2008a). Hallux valgus and limited joint mobility are also major indicators of ulcer development (Bus, 2008a). These foot deformities are caused by muscle atrophy (decrease in muscle mass) which, in the foot, causes an imbalance leading to hammer toe (Levin and O'Neal, 1988). The formation of hammer toe increases the risk of ulceration by increasing the load under this region. A number of factors have to interact, such as motor neuropathy, trauma, and metabolic abnormalities of the bone, before a deformity develops. These factors associated with foot deformities occur as the duration of diabetes increases, however, increases in plantar pressure, and the subsequent risk of tissue breakdown, is evident in people prior to developing a foot deformity (Veves et al., 1992).

It is clear there are a number of factors which are associated with ulcer development. Plantar pressure, neuropathy and foot deformity have been shown to be the main three factors which will lead to tissue damage and an ulcer. Neuropathy develops as the duration of diabetes increases (Veves et al., 1992) and foot complications develop after neuropathy (Figure 1. 1). However, plantar pressure has been shown to be increased prior to the onset of neuropathy, suggesting there is a need for offloading during the early stages of diabetes (Veves et al., 1992). The increases in plantar pressure are most likely due to a variety of structural changes to the plantar tissues caused by the metabolic consequences of diabetes (Bus, 2008b, Pai and Ledoux, 2010). An increase in plantar pressure is the first warning sign that a person with diabetes may develop an ulcer. It is also a factor which has the potential to be manipulated using simple off-loading interventions. This idea is discussed in more detail in the Literature review.

1.4 Interventions designed to reduce the risk of ulceration diabetes

There are a number of proposed interventions to reduce the risk of ulceration. These range from general foot care, surgical techniques, and offloading interventions. People with diabetes are advised to have regular visits to a podiatrist for sensation tests and callus removal. The removal of callus has also been shown to reduce plantar pressures by 24-32% (Pitei et al., 1999). However, regular visits to a podiatrist may not be feasible for all patients.

Other strategies have been proposed to reduce plantar pressure during walking. These methods include footwear, insoles, hosiery, surgical strategies, and injections (Bus et al., 2008a, Bus et al., 2008b, Bus et al., 2009, Garrow et al., 2005, Maluf et al., 2004, van Schie et al., 2002). A large amount of evidence exists for the effectiveness of footwear and offloading (Boulton, 2004, Bus et al., 2008a, Cavanagh, 2004, Cavanagh et al., 2000, Maciejewski et al., 2004). Footwear aimed at offloading the plantar foot has been shown to reduce pressure by up to 50% (van Schie et al., 2000). The effectiveness of insoles have been investigated by a number of authors (Bus et al., 2004, Guldemond et al., 2007b, Janisse, 1995, Zequera et al., 2007). Studies have reported varying levels of pressure reduction, ranging from 20-35% (Guldemond et al., 2007b, Lavery et al., 1997). When prescribing an insole there are a number of factors to consider such as material, material thickness, moulding, supports (e.g. metatarsal bars), and reliefs (e.g. plugs) which makes the design of an insole extremely complex.

People with diabetes and neuropathy are often advised to wear specially designed socks. These designs are free of seems, ridges, and holes which could chafe the skin (Levin and O'Neal, 1988). Socks for people with diabetes also need to contour the skin so that they fit properly and avoid wrinkles and should not be made of a constricting material. With regards to material, any patient with a tendency for excessive perspiration should avoid cotton and use a material which will help remove the moisture away from the skin. Socks have also been shown to reduce plantar pressure. A study investigated the effect of socks with extra cushioning, on plantar pressures (Garrow et al., 2005) and only reported a 10% reduction in peak plantar pressure (Table 1. 2).

An alternative strategy for reducing pressure involves surgical lengthening of the Achilles tendon. This approach has been to reduce pressure under the forefoot by 27% (Maluf et al., 2004). Similarly, silicone injections under the metatarsal heads have also shown to reduce forefoot pressures, for up to 24 months, by an average of 165 kPa (van Schie et al., 2002). However, these are expensive and invasive methods are unlikely to be adopted by people with diabetes because they only offer temporary relief, therefore more studies are needed before it can be prescribed for widespread use (Table 1. 2) (Cavanagh and Bus, 2011).

Table 1. 2 shows the reductions in pressure which have been reported by different offloading interventions. It is clear these interventions vary in the effectiveness of pressure reduction. Specialist socks were shown to be the least effective, only showing a reduction of 10%. Insoles, callus removal, surgery and injections showed similar levels of pressure reduction ranging from 20-35%. However, footwear interventions have been shown to reduce pressure by up to 50%. Footwear is also a non-invasive method and will continually offload the foot, providing the patient acceptance. Footwear is also a more cost effective method compared to surgery and injections, which also only offer a temporary relief. Foot care, such as the removal of callused skin, should go in tandem with an effective offloading intervention such as a therapeutic shoe (Levin and O'Neal, 1988). Optimising footwear design has the potential to significantly reduce the risk of ulceration because of the large reductions in pressure. It also has the advantage of being non-invasive and cheaper than some other interventions.

Table 1. 2: Reported reductions in plantar pressure from different interventions

Intervention	Reported pressure reduction	Study	Comments
Footwear	40-50%	(Boulton, 2004, Bus et al., 2008a, Cavanagh, 2004, Cavanagh et al., 2000, Maciejewski et al., 2004, van Schie et al., 2000)	• Cost effective • Non invasive • Large reductions
Insoles	20-35%	(Guldemond et al., 2007b, Lavery et al., 1997)	• Cost effective • Designs not fully understood • Reductions may vary between footwear
Hosiery	10%	(Garrow et al., 2005)	• Not as effective as footwear or insoles
Surgery/injections	27%/165kPa	(Maluf et al., 2004, van Schie et al., 2002)	• Expensive • Invasive • Temporary reduction (12-24 months for injections)
Callus removal	24-32%	(Pitei et al., 1999)	• Advised to be undertaken as general foot care • Temporary reduction (8-10 weeks)

1.5 Structure of the literature review

The introduction section above presented an overview of the factors which can lead to ulceration in individuals with diabetes. This review identified elevated plantar pressure to be one of the most important modifiable risk factors. Different strategies for offloading the plantar foot were then discussed and current evidence summarised. This evidence points towards the use of footwear as the most effective intervention for reducing plantar pressure.

Given the importance of elevated pressure and using footwear to reduce pressure; the following four topics were chosen as the basis for an exhaustive literature search:

1. **Pressure and the relationship with ulceration**
2. **Pressure measurements methods**
3. **Factors which influence pressure**
4. **Types of footwear used to reduce ulceration and pressure**

The rationale for looking at pressure measurement methods is that a number of systems exist which can measure in-shoe pressure and each of these has different benefits and disadvantages. There are also a number of different methods which have been proposed for the analysis of pressure data and the key principles behind these different approaches are discussed in the following chapter.

The purpose of reviewing the literature which has focused on factors which influence pressure, was to develop an in-depth understanding of the biomechanical variables which may be relevant for footwear design. People with diabetes can be prescribed a number of different types of footwear aimed at reducing the risk of ulceration. However, before any one design could be investigated in detail, it was first necessary to understand and synthesise previous evidence relating to the efficacy of pressure reduction in the different footwear designs.

1.6 Structure of the thesis

The following chapter (Chapter 2:) contains a detailed literature review on the topics defined above. This literature review highlighted the potential for the curved rocker sole to reduce in-shoe pressure in people with diabetes. However, it also highlighted that further investigation was need to understand the precise effect of each of different rocker designs. Therefore the main aim of this PhD was to improve curved rocker sole design for people with diabetes. To accomplish this, three subsequent studies, each with a number of objectives, were defined. Each of these studies is presented in a separate chapter which includes an introduction, methods, results, discussion and conclusions section.

The first experimental study (Study 1) is reported in chapter 3. In this study, the effect of varying three principle design features, which characterise a rocker sole; was evaluated using plantar pressure as an outcome measure. Due to the number of possible design configurations it was not viable to evaluate every shoe design in the first experimental study. Therefore, starting with a current design, each design feature was individually adjusted. The findings were then used to design shoes with a smaller range of design features in Study 2.

The second experimental study (Study 2) is reported in chapter 4. In this study, different combinations of design features were evaluated. In Study 2, a smaller range of design features was selected, based on the results of Study 1, which enabled every combination to be evaluated. The set of design features was selected based on their potential to significantly reduce plantar pressure. An additional aim of Study 2 was to quantify the proportion of people that a mean optimal design would provide sufficient offloading and the proportion of people who would need an individual design. This is an important question for designers and clinicians because it is preferable to prescribe a standard shoe due time and cost constraints. In addition, the study sought to establish the proportion of people for which a smaller, more aesthetically pleasing rocker angle would provide sufficient offloading. This is important because, as stated in the boundaries of the project, the style and aesthetics of footwear interventions heavily dictate whether the patient will wear the shoe.

The final experimental study (Study 3) is presented in chapter 5. The aim was to develop an algorithm to predict the individual optimal design from an input of gait data. Results from the previous two studies showed there was a degree of inter-subject variability between optimal designs and that a mean optimal shoe would not provide sufficient offloading in every patient. This method would be more efficient than using in-shoe pressure analysis because it only requires a simple gait analysis and does not require the patients to try on multiple pairs of shoes.

Finally, the concluding chapter summarises the overall findings of the thesis and then provide useful guidelines which can be used when prescribing a rocker sole for a person with diabetes.

1.7 Statement of ownership

This project was funded by the EU project SSHOES. There is therefore a need to explain the original contribution of the author (JD Chapman), the work which was originally proposed in the grant application and the work carried out by my supervisor Dr Stephen Preece. The brief for the SSHOES project was very broad in its scope and did not identify rocker soles as the most effective method (see SSHOES project objectives below).

SSHOES project objectives

1. Through review and consensus to evaluate the value of the clinical and biomechanical variables which can influence footwear design in the context of the diabetic foot
2. To evaluate potential measurement approaches for these variables in context of where such system will be used in practice by SME customers.
3. Research the biomechanics of the human foot under appropriate experimental (controlled) and real world conditions to drive the definition of footwear components and designs from measured clinical and biomechanical data.
4. Create suitable framework to enable the relationship between data and footwear design to be integrated into the project KB.

Rocker soled shoes were identified by myself and Dr Stephen Preece using an large literature search on footwear for people with diabetes. Dr Stephen Preece designed the shoes which were used in Study 1. The designing of the protocol, data collection and interpretation was completed by myself. The shoes used in Study 2 were then defined by myself, with minimal guidance from my supervisor, using the results from Study 1. Throughout the project, the designing of lab protocols, designing of data processing protocols and interpretation of data was completed by myself. Data collected was only used for the research presented in this PhD thesis. Data analysis in this project was largely conducted using Matlab. Throughout this project a number of custom pieces of Matlab software were used to analyse the data which were all written by myself. The in-shoe pressure data (collected using Novel-Pedar) was processed and analysed using software written in Matlab. Motion data was processed using Visual-3D-v4. However, the pipeline command list was created using Matlab and Visual-3D was called within a Matlab script using the system function. Matlab was then used to post-process the data (remove any poor trials or misidentified gait events) and create databases containing ensemble average curves ready for analysis. The statistical analysis was also conducted by myself using a combination of Matlab and SPSS. Finally, the interpretation of results was conducted by myself as well as the hypothesis, which are discussed in the Literature review.

Chapter 2: Literature review

The literature review will be presented in the following order:

1. **Pressure and the relationship with ulceration**
2. **Plantar pressure measurements methods**
3. **Types of footwear used to reduce ulceration and pressure**
4. **Factors which may influence in-shoe plantar pressure and therefore influence how an individual responds to a specific rocker shoe design**

A number of search terms (Table 2. 1) were used to identify appropriate literature on each of these four topics. Literature was selected using the following inclusion/exclusion for each of the four topics: Once a paper was deemed relevant it was added to the literature database which was divided into specific groups which corresponded to specific sections or paragraphs in the literature review (Table 2. 2).

- All papers must be written in English

1. **Pressure and the relationship with ulceration**
   The literature in this area is investigating a very specific topic and there was no need to exclude for an exclusion criteria.

2. **Pressure measurements methods**
   - Must in-shoe pressure methods

3. **Types of footwear used to reduce ulceration and pressure**
   - Not post-operative methods, for instance total contact casts
   - Not specialist footwear
   - Not sandals
   - Not evaluated on people with amputation

4. **Factors which influence pressure**
   No specific inclusion/exclusion criteria
   Like topic 1, the literature in this area is investigating a very specific topic and there was no need for an exclusion criteria.

Once a paper was deemed relevant it was added to the literature database and placed within one or more specific groups, each of which corresponded to specific sections within the literature review (Table 2. 2).

	Pressure and the relationship with ulceration	Pressure measurements methods	**Factors which influence pressure**	**Types of footwear used to reduce ulceration and pressure**	
Search terms	1. plantar+pressure diabetes 2. plantar+pressure ulceration diabetes 3. plantar+pressure skin breakdown diabetes 4.increased+plantar+pressure diabetes 5. In-shoe+plantar+pressure diabetes 6. plantar+pressure threshold diabetes 7. shear+pressure/force diabetes 8. pressure risk+ulceration	1. in-shoe+plantar pressure measurement 2. plantar+pressure measurement 3. plantar+pressure reliability 4. plantar+pressure reliability 5. pedar+reliability 6. f-scan+reliability	1.plantar+pressure predictors 2. plantar+pressure Kinematics 3. plantar+pressure Gait 4. plantar+pressure Varaince 5. gait shoe design 6. gait shoe prescription 7. predicting shoe design	**General footwear** 1. shoe+design "diabetes/diabetic" 2. diabetic+sandals 3. diabetic+comfort shoes 4. extra+depth shoes diabetes 5. comfort+shoes pressure 6. trainsers+diabets **Apex position & toe angle** 1. rocker+sole 2. rocker+footwear 3. footwear+apex 4. shoe+apex 5. rocker+shoe 6. footwear toe+angle 7. shoe toe+angle 8. footwear toe+spring 9. shoe toe+spring 10. footwear rocker+angle 11. shoe rocker+angle **Sole Stiffness** 1. shoe+stiffness pressure 2. in-shoe+stiffness pressure 3. footwear+stiffness pressure 4. sole+stiffness pressure 5. shoe+stiffness loading 6. in-shoe+stiffness loading 7. footwear+stiffness loading 8. sole+stiffness loading	**Heel height** 1. heel+height gait 2. heel+height pressure 3. heel+height loading 4. heel+lift pressure 5. heel+raise pressure 6. heel+lift loading 7. heel+lift loading Rocker shoes 1. rocker+shoe "diabetes/diabetic" 2. rocker+sole 3. rocker+sole gait 4. rocker+sole plantar pressure 5. rocker+sole apex position 6. rocker+sole rocker angle

Table 2. 1: Search terms used for the literature review for each of the topics. (the "+" between certain words dictates that the search engine mush look for these two words together. For example, entering "pressure" would produce a huge number of irrelevant papers).

Table 2. 2: Number of papers included in the different sections of the literature search. Some papers were used in more than one topic.

Topic/section	Number of papers
Pressure	29
Pressure opening two paragraphs	8
Aietiology of ulcers	40
Tissue mechanics	15
Epidemiology	35
Foot problems	14
Pressure threshold	5
Neuropathy and testing	10
Risk factors for ulcers	20
Shoes worn by diabetics	32
Footwear and ulcers	12
Extra depth shoes	7
Rocker shoes	41
Footwear aesthetics	5
Diabetes gait	11
Centre of pressure	11
Gait and rockers	9
Shoe uppers	3

2.1 Pressure and the relationship with ulceration

2.1.1 Epidemiological studies investigating the link between plantar pressure and ulceration

It has been known for some time that there is strong association between increased loading under the foot and ulceration (Boulton et al., 1983). Boulton et al (1983) conducted one of the first studies, using a case control design, to evaluate the effect of abnormal foot pressures on ulceration history. Despite pressure measurement techniques being in their infancy, this study reached the same conclusions as much later studies which used more sophisticated measurement techniques (Ledoux et al., 2013, Stess et al., 1997, Veves et al., 1992).

A study by Veves et al (1992) using a longitudinal cohort design to understand if elevated foot pressure (within 30 months of the baseline pressure assessment) were associated with subsequent ulceration. Normal foot pressures were defined using a previous study (Veves et al., 1991) which stated that pressure over 12.kg^2, which summates to 1,175 kPa, would be at risk of developing an ulcer. However, this value was established using barefoot pressure. There was an increase in the number patients (55 compared to 43) above the normal threshold between the baseline and follow up measurements. This shows that, as the duration of the disease increases, foot pressures also increase. However, the key finding was that the patients below the normal foot pressure threshold did not develop an ulcer over the thirty months.

Another study also reported that pressure was higher in people who had developed an ulcer (Stess et al., 1997). In this study the barefoot plantar pressures were compared between people with diabetes (control), people diabetes and neuropathy (DN) and people with diabetes with neuropathy and a history of ulceration (DU). There was an increase in mean peak pressure when the control group was compared to DU group. The DU group also had the highest pressures in all regions of the foot compared to the other two groups. These results also suggest there is a threshold of pressure for ulcer development.

The quantification of a threshold where ulcers develop was investigated by Armstrong et al (1998). However, the only conclusion to be made from this study was that the higher the plantar pressure the greater the risk of ulceration. The studies by Armstrong et al (1998) and

Veves et al (1992) evaluated barefoot plantar pressures. However, in order to provide a threshold which could be used to evaluate an offloading intervention, in-shoe pressure needs to be evaluated. There has been an increase in the monitoring of pressure between the foot and shoe because footwear is widely believed to be an effective therapeutic method for foot complications in diabetes (Cavanagh et al., 1992). Furthermore, a large proportion of the time spent walking is when wearing shoes making the measurement of barefoot pressure less clinically relevant.

The best evidence to date of a target threshold for offloading was provided by Owings et al (2009). They carried out a case control study to establish the risk factors which were linked to re-ulceration in patients with diabetes. A number of characteristics were identified, however, the main difference was that patients who had not re-ulcerated had much lower pressures than those who had. Based on the in-shoe pressure data a conservative goal of <200 kPa was recommended to avoid ulceration. This evidence was supported by Cavanagh and Bus (2011), who stated that even though the threshold for ulcer development may vary between individuals, until better evidence is available, the 200 kPa value can serve as a goal for offloading. It is clear the evidence in the literature points towards a reduction in pressure being the key factor for preventing ulcers and the threshold provided by Owings et al (2008) is the best example of a target threshold for offloading (Armstrong et al., 1998, Owings et al., 2009b, Veves et al., 1992, Cavanagh and Bus, 2011).

2.1.2 Plantar pressure versus shear

In addition to plantar pressure, shear forces also act on the foot during walking (Mueller et al., 2008). Shear stress results from forces parallel to the surface of the foot and have been suggested by a number of authors to be an important factor in ulcer development (Cavanagh et al., 2000). However, because of the difficulty in measuring these forces, they have received little investigation. Despite these difficulties, there have been a small number of studies which have reported in-shoe shear stress in people with diabetes. For example, Lord and Hosein (1999) measured shear stress and plantar pressure in a group of patients with diabetes. Their findings suggested that measuring shear stress would produce the same findings compared to measuring plantar pressure because the areas of highest shear also exhibit the highest plantar pressures. The medial locations of maximum shear corresponded to the areas prone to ulceration and the distribution of peak shear values and plantar pressure were not significantly different (Lord and Hosein, 2000). Despite this study, a definitive picture of the distribution of shear stress under the foot is yet to be established (Cavanagh et al., 2000). Therefore, until further research has gained a better understanding into the role of shear stress in ulcer development, plantar pressure remains to be the main variable reported.

2.1.3 Tissues mechanics associated with elevated plantar pressure

The process of increased pressure and foot ulceration originates from alterations to deeper layers of the soft tissues. Plantar soft tissue is comprised of a number of layers of skin, fat, fascia and muscle which work together to provide cushioning during walking (Chao et al., 2011). Changes to the tissue morphology can impact on the biomechanical properties which has the potential to affect cushioning. A study (Chao et al., 2011) evaluated the effect of diabetes on the plantar soft tissues using ultrasonography in a cohort of people with type II diabetes. This study reported overall tissue changes in people with diabetes compared to the control group. The main finding was the epidermal plantar skin became thinner and there was an overall increase in soft tissue stiffness in people with diabetes. These changes were significant if neuropathy was present. Mueller et al (2003) associated the thinning of the skin with increased peak pressure. In their study, soft tissue thickness was verified to be an important predictor of peak pressure at several of the metatarsal heads in people with diabetes.

A number of other studies have also reported a strong association with tissue thickness and pressure. Morag and Cavanagh (1999) reported tissue thickness under the heel and 1st metatarsal head to be a predictor of plantar pressure. However, Robertson et al (2002) reported no differences between healthy participants and people with diabetes with regards to tissue thickness. It was reported that older people (regardless of having diabetes) had thinner plantar tissue. Bus et al (2004) also investigated soft tissue thickness and its effect on plantar pressure. They reported a thinning of the metatarsal head (MTH) fat pads in neuropathic patients with diabetes when compared to healthy controls. The participants in the study carried out by Bus et al (2004) had a mean duration of diabetes of 32 years. This is considerably higher than the mean duration of only 20 years described in the study carried out by Robertson et al (2002). These contradictory findings may suggest that, although the presence of diabetes may affect tissue thickness, the effects may not become apparent until individuals have had the disease for over 20 years.

In a person with diabetes, changes to the density of soft tissue on the plantar aspect of the foot can increase pressure (Gefen et al., 2001). Robertson et al (2002) found that plantar soft tissue density was significantly lower in people with diabetes. Most likely, the reduction in density is due to fatty infiltration and replacement of the muscle (Robertson et al., 2002). Robertson et al (2002) also showed that there was a relationship between body-mass-index and tissue density for the control subjects. However, this relationship was not seen for the group of people with diabetes suggesting that other factors, such as a reduction in circulation, are associated with the tissue changes in people with diabetes (Robertson et al., 2002).

There have been a number of studies which have tried to determine the minimal degree of loading required to develop tissue damage (Daniel et al., 1981, Kosiak, 1961). These kinds of studies often use animals where skin is loaded externally and the onset of tissue breakdown is observed via histological examinations. An absolute value of pressure where the tissue begins to breakdown was not identified using this method, however, there is a relationship between magnitude and time. Higher pressures require less time to begin skin breakdown (Bouten et al., 2003). Diabetes has also been associated with higher plantar pressure values. This is caused when protective tissue is lost over an area of the foot, such as the metatarsal heads (Cavanagh et al., 2000). Elevated plantar pressure has been shown to be a strong predictor of ulcerations as it appears to accelerate the process of tissue and skin breakdown.

It is clear from the literature that changes to the tissue morphology can increase plantar pressure (Chao et al., 2011). Metabolic consequences of diabetes affect the plantar soft tissues which in turn increase plantar pressure. Studies have also shown that higher plantar pressures increase the rate of tissue breakdown (Bouten et al., 2003), and in people with diabetes tissue takes longer to heal. The changes to the structural and functionality of the tissue in people with diabetes is often un-avoidable, however, the outcome of increased pressure is a factor which can be controlled in order to reduce the chance of tissue breakdown.

2.1.4 Biomechanical factors associated with elevated plantar pressure

There is strong association between biomechanical variables and plantar pressure (Morag and Cavanagh, 1999, Morag et al., 1997). Previous studies have reported that people with diabetes exhibit a reduction in the range of motion in the foot and ankle joints (Chao et al., 2011). A person with normal foot mobility during walking will allow for better load compliance during the stance phase. For instance, the foot will transition from a flexible structure, which will dissipate the impact, to a rigid structure which allows for an efficient propulsion prior to toe off (Rao et al., 2006). A person with diabetes, who has limited joint mobility, may have a "stiff" foot and ankle complex on impact. This will reduce the compliance of the foot during stance and could ultimately lead to abnormally high plantar pressures. For example, a reduction in the dorsiflexion of the 1st MTP joint could lead to an increase in pressure under the hallux (Rao et al., 2011).

The relationship between reduced subtalar joint mobility and diabetes has been well documented (Abate et al., 2013, Fernando et al., 1991). It has been hypothesised that a reduction in calcaneal eversion will alter the plantar load distribution. Furthermore, a reduction in calcaneal eversion is thought to decrease forefoot mobility, thereby leading to a reduction in the compliance of the joints during stance. Rao et al (2010) used a segmental foot model in order to test this theory. They reported that 1st MTP sagittal motion and lateral forefoot frontal motion were negatively associated with the magnitude of plantar pressure under the respective region. However, a simple reduction in joint range of motion does not always lead to an increase in plantar pressure because joint mobility is one factor amongst many associated with increased plantar pressure (Levin and O'Neal, 1988).

Dynamic gait variables correlating to plantar pressure have been reported in several studies (Hastings et al., 2010). Simple measurements such as foot progression angle have been shown to influence pressure during walking. Hastings et al (Hastings et al., 2010) reported a strong correlation between increased foot progression angle and medial loading of the foot. It has also been demonstrated that dynamic dorsiflexion of the 1st MTP joint is a significant predictor of plantar pressure under the hallux (Morag and Cavanagh, 1999). The reasoning behind this is that a greater dynamic dorsiflexion allows time for the load to be distributed over the area of the hallux. In contrast limited motion would be expected to increase loading.

It is clear from the literature that people with diabetes exhibit limited joint mobility which leads to an increase in pressure. Limited joint mobility is a consequence of metabolic abnormalities caused by diabetes. There are common sites where people with diabetes develop ulcers (1st MTP and hallux) and the increase in pressure under these sites has been correlated with a reduction in specific joint kinematics (Morag and Cavanagh, 1999). The only way to facilitate this reduction in range of motion is to prescribe an intervention which requires less range of motion during the stance phase, therefore avoiding the increase in pressure.

2.1.5 Plantar pressure and the site of ulcers

A number of studies have investigated the most common locations for foot ulcers (Cavanagh et al., 2000, Kosiak, 1961, Veves et al., 1992). There have been a number of studies which have shown that the most common locations of plantar foot ulcers are the toes and medial metatarsal heads (Cavanagh et al., 2000, Kosiak, 1961, Veves et al., 1992). The most detailed information with regards to the common locations of ulcers was reported by Waaijam et al (2012). In their study, the 1st MPJ (metaphalangeal joint) was reported to be the most common site with 27% of ulcers occurring in this region. The medial toes were reported as the second most common and the hallux was third most common with 18% in the hallux region (Waaijman et al., 2012) (Figure 2. 1). These regions are bony prominences on the plantar foot so they have small surface areas (Murray et al., 1996) and therefore have higher pressure. However, there are other factors which cause ulcers to occur in these region.

There is an association between the location of highest pressure and site of ulceration (Cavanagh and Ulbrecht, 1994). The location of highest pressure often occurs in the 1st MTP or hallux region of the foot because of role the 1st MTP joint plays during stance. The 1st MTP joint dorsiflexes during stance in order to lift the heel and progress the foot. Normal values of 1st MTP dorsiflexion have been reported to be between 60-90 degrees (Hetherington et al., 1990). However, people with diabetes exhibit less range of motion which increases the pressure under this region (Rao et al., 2010). Ulcers rarely occur under the 5th MTH because pressures are much smaller in this region. During stance the centre of pressure of the foot progresses medially through to toe-off, which means the 5th MTH is in contact with the ground for shorter period of time compared to 1st MTP joint.

There are many factors which may influence plantar pressure (joint mobility, tissue mechanics). However, correlations between these variables and ulcer development have not been reported. Measurement of soft tissues is more complex than measuring plantar pressure and the location of a bony prominence does not always result in an area of high pressure because of influences from other variables, such as foot kinematics. Regional analysis is of the plantar foot is the most appropriate method for predicting if a person is at risk of ulceration and in which region.

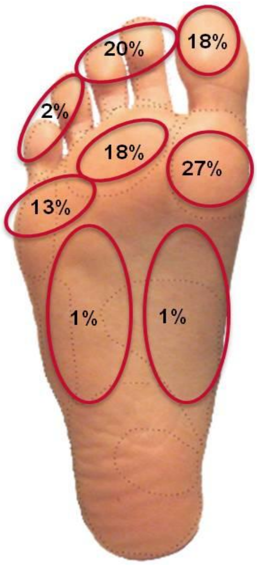

Figure 2. 1: Prevalence of ulcers for each region of the foot (Waaijman et al., 2012)

2.2 Plantar pressure measurement methods

2.2.1 Instrumentation

Interventions, such as footwear, are widely prescribed to people with diabetes to facilitate plantar pressure during walking (Cavanagh et al., 1992). In-shoe pressure measurements provide a meaningful understanding of how a shoe design effects both; the plantar pressure and the mechanics of the foot (using centre of pressure). It has been well documented that plantar pressure is strongly associated with ulceration, therefore, in-shoe measurement is a valuable tool, which can be used to provide evidence which ultimately may impact both in shoe design and clinical practice.

The first in-shoe pressure measurements systems employed transducers at specific anatomical locations but had the disadvantage that the sensors made an uneven surface between the foot and shoe and therefore altered the pressure (Cavanagh et al., 1992). In contrast, modern systems have a matrix of sensors arranged in rows and columns (Cavanagh et al., 1992) and enable monitoring of the entire plantar area of the foot during walking. This is especially important when analysing different designs of therapeutic footwear which are often manufactured to redistribute load from one area of the foot to another.

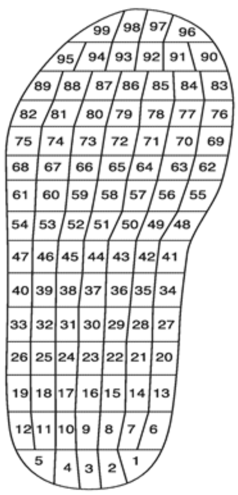

Figure 2. 2: Example of a Pedar matrix insole from Novel.

An in-shoe pressure system must produce reliable measurements when evaluating the effect of a number of different outsole configurations. The repeatability of pressure measurement systems was reported in a study by Ramanathan et al (2009). In-shoe pressure was collected at 50Hz on twenty seven healthy participants who walked in a neutral trainer on two occasions approximately one week apart. It was reported that peak pressure showed the highest repeatability under the heel, metatarsal heads and hallux, the 3rd to 5th toe regions were least repeatable. The data in this study show that plantar pressure measurement system can be used reliably to quantify plantar pressure in regions specific to diabetes research (high risk regions). It is therefore an appropriate tool for quantifying the effectiveness of footwear interventions aimed at reducing pressure in people with diabetes (Ramanathan et al., 2009). However, measurements under the toes are less reliable and careful consideration needs to be made when evaluating pressure under these regions.

2.2.2 Plantar pressure analysis

The first stage when analysing pressure data, is to divide the plantar area into regions of interest. This is important when considering foot ulceration because particular anatomical regions have higher susceptibility to ulceration. To obtain clinically applicable data from a large number of sensors, it is necessary to define masks which define the regions of high risk (Cavanagh, 2004). A mask simply defines the borders of the regions of interest using percentage measurements of the insole length and width. Because people with diabetes develop ulcers at specific sites, the mask must contain border regions of interest which represent these regions. The heel, metatarsal heads and great toe are potential areas of high pressure and must be included in any masking arrangement (Bontrager et al., 1997). Most commonly the mask used when measuring in-shoe pressure was defined using an inking system on a cohort of subjects walking barefoot (van Schie et al., 2000, Guldemond et al., 2007b, Stewart et al., 2007). Mean and standard deviations were calculated with the insole percentages to define the borders of the mask model (Bontrager et al., 1997). It was reported that peak pressure occurs consistently in the correct regions between subjects (Bontrager et al., 1997).

An alternative approach to analysing plantar pressure known as 'statistical parametric mapping' (SPM), has been proposed by Pataky et al (2008). This method was derived from the techniques used in cerebral imaging and does not use the regional analysis approach described above. One of the motivations for using this technique is that, when sub-dividing the foot into regions of interest, the results may become corrupted because regions on the plantar foot are overlapping borders of the mask (Abate et al., 2013). SPM requires no regional assumptions and generates a statistical map across the entire plantar area of the foot (Abate et al., 2013). Pataky et al (2008) also suggested that plantar pressure results might be biased by regionalisation of the plantar foot (Healy et al., 2013). Pataky et al (2008) showed that plantar pressure is highly sensitive to the definition of the regional boundaries. However, this technology is in its infancy and regional peak pressure has been shown to be correlated with the sites of ulcers.

Regional peak pressure is the most common variable reported in studies comparing footwear for people with diabetes (Bus and Waaijman, 2012). It is defined as the highest pressure measured under the foot during stance in a specific region and is the value reported in the epidemiological studies discussed in section 2.1.1 (Waaijman and Bus, 2012). The value of also reporting pressure time integral as well as peak pressure has been debated in a number of studies (Waaijman and Bus, 2012). Pressure time integral is defined as the area under the peak pressure curve (Waaijman and Bus, 2012). Although, many studies also report pressure time integrals in addition to peak plantar pressure, the justification for doing so is often lacking. A recent review concluded that the value of reporting pressure time integral is limited because the differences in outcomes between these parameters were often small (Bus and Waaijman, 2012). It has also been reported that the two parameters are interchangeable because of significant correlation coefficients at all regions of the forefoot (Waaijman and Bus, 2012). At present, peak plantar pressure is still the most common variable reported when comparing offloading interventions in people with diabetes. It is also the variable reported in epidemiological studies to be heavily associated with ulceration (section 2.1.1). Given the previous used of this outcome, it was felt to be an appropriate outcome measure for use in this project.

2.3 Types of Footwear used to reduce ulceration and pressure

2.3.1 The evidence for the prevention/recurrence of ulceration and pressure with therapeutic footwear

Modifications of patients' footwear are designed to reduce plantar pressure during walking (Bus et al., 2008a). Clinical recommendations for people with diabetes include the provision of therapeutic footwear. It is widely accepted therapeutic footwear is effective in preventing ulcers especially for patients with peripheral neuropathy (Bus, 2012, Bus et al., 2011, Bus et al., 2013, Cavanagh and Bus, 2011), however, there is a lack of scientific evidence identifying the best design.

Clinical trials are often used to evaluate the effect of footwear interventions. However, these studies tend typically used ulceration rate as the outcome measure rather than plantar pressure (Litzelman et al., 1997, Reiber et al., 2002). Previous RCTs, designed to test the effectiveness of therapeutic footwear at reducing ulceration risk, typically compare two groups, one wearing a therapeutic shoe and the other a control shoe (typically their own footwear). Although this is the best approach for testing the clinical efficiency of a shoe, it may not be the best method for evaluating pressure reduction. A typical RCT will only measure the clinical effect of one therapeutic shoe, and compare the results to a group who did not receive this shoe. There is a high chance of error because the control group may purchase new shoes during the trial and patients in the experimental group may not wear the therapeutic footwear (Litzelman et al., 1997, Reiber et al., 2002). If we want to test pressure reduction in a range of shoe designs in a controlled way, a cross over design is needed, in which every participant wears every shoe. With this design it is possible to quantify the effectiveness of the footwear at reducing pressure. This information can then be used to inform footwear choice for future large-scale RCT studies which aim to evaluate the clinical efficacy of therapeutic footwear reducing the risk of ulceration.

The review carried out by Bus et al (2008) highlighted the existence of contradictory findings of studies investigation the effectiveness of therapeutic footwear. Although some studies showed significant reductions in re-ulceration rates (Chantelau et al., 1990, Uccioli et al., 1995), others demonstrated no benefit from therapeutic footwear (Litzelman et al., 1997, Reiber et al., 2002). Patient groups were not necessarily consistent between studies with different findings. Diabetes type, neuropathy state, and previous plantar ulcer sites are often not reported and this may account, to some degree, for the contradictory findings. However, it is also possible that the RCTs did not show a positive effect of therapeutic footwear because they did not test shoes which were effective at reducing pressure.

There are a number of different studies which have investigated the effectiveness of therapeutic footwear in the reduction of plantar foot ulceration (Chantelau, 2004, Lavery et al., 2008, Uccioli et al., 1995). The shoe design which has been tested mostly in clinical trials is the extra depth shoe. An extra depth shoe is an off-the-shelf shoe with an adjustable depth insert, which is typically made using a mould of the patient's foot. They provide extra cushioning to the foot, which reduces the plantar pressure and subsequently tissue breakdown during walking (Lavery et al., 1997). In general, these types of shoes have been shown to reduce the rate of re-ulceration in people with diabetes (Chantelau, 2004, Lavery et al., 2008, Uccioli et al., 1995), however, other types of shoes have been shown to be more effective at reducing pressure.

2.3.2 Evidence for reduction in pressure with therapeutic footwear

The review carried out by Bus et al (2008) focussed mainly on randomised control trials (RCT) carried out on individuals with diabetes. The main findings were that a number of studies have reported footwear to be effective at reducing ulceration recurrence (Chantelau et al., 1990, Uccioli et al., 1995). However, there was no evidence to demonstrate the effectiveness of footwear in ulcer prevention or the effect of footwear at reducing plantar pressure. From these types of studies it is not clear whether any reduction in pressures obtained with the use of therapeutic footwear ultimately leads to a corresponding reduction in foot ulceration. Therefore, studies were identified which evaluated the effect of footwear on plantar pressure.

The most common therapeutic designs, which have been shown to reduce plantar pressure, are extra depth shoes (Lavery et al., 1997), insoles (Owings et al., 2008), running shoes (Perry et al., 1995), and rocker soled shoes (Schaff and Cavanagh, 1990). An extra depth shoe simply has extra cushioning which helps reduce pressure as well as a wider toe area (Maciejewski et al., 2004). Insoles are common additions to either extra depth shoes or conventional footwear and can be moulded to the patients' foot. The idea is that the insole provides an extra interface between the shoe and the foot and shifts pressure away from areas of high risk (Owings et al., 2008). Running shoes have also been shown to reduce plantar pressure and callus formation due to the advances in the cushioning materials (Perry et al., 1995, Soulier, 1986). They also have the advantage of having a soft upper and wider toe box compared to Oxford-styled shoes (Perry et al., 1995). Rocker shoes incorporate a curved or sharply contoured outsole which is designed to rock the foot forward during the stance phase of walking. This rocking motion reduces the range of movement of toes and ultimately reduces plantar pressure (Hutchins et al., 2009). Due to its effectiveness (Schaff and Cavanagh, 1990), the rocker shoe is the most commonly prescribed therapeutic shoe patients with diabetes (Schaff and Cavanagh, 1990).

The mechanism of extra depth shoes is to relieve pressure under high risk regions. An extra depth shoe simply has added cushioning which helps reduce pressure as well as a wider toe area (Maciejewski et al., 2004). However, very few studies have evaluated their effectiveness in a controlled environment. A study by Lavery et al (1997) is one of the few studies to test the effectiveness of extra depth shoes using a cross over design study. Each participant had diabetes and an existing or recently healed plantar forefoot ulcer. The study reported extra depth shoes can reduce plantar pressure compared to a canvas oxford shoe by, however, the 1st MTH saw a greater reduction (42-48%) compared to the and hallux (3-18%) (Lavery et al., 1997). This would suggest that footwear choice maybe dependent on the site of ulcer.

Extra depth shoes are commonly worn with an insole, whether it is contoured using the foot of the patient or an off-the-shelf design prescribed by a clinician (Owings et al., 2008). By adding an insole to an extra depth shoe it provides an extra interface between the shoe and the foot and works by shifting pressure away from areas of high risk (Owings et al., 2008). The addition of an insole to an extra depth shoe has been shown to alleviate plantar pressure compared to a shoe with no insole (Ashry et al., 1997, Owings et al., 2008). Ashry et al (1997) evaluated the effect of the addition of four different insoles to an extra depth shoe. The findings show that mean peak plantar pressures were significantly reduced under all of the metatarsal heads as well as the heel compared to an extra shoe with no insole. However, there was no mean difference between the different insole configurations which suggests that there is a large amount of inter-subject variability between optimal insole designs. The support of insoles added to extra depth shoes is also supported by Owings et al (2008). They reported that insoles prescribed based on foot shape as well as plantar pressure are most effective at reducing pressure (Owings et al., 2008).

Previous studies have suggested that running shoes could significantly reduce plantar pressure (Perry et al., 1995, Soulier, 1986). Running shoes incorporate cushioning materials in the sole and the soft upper make them comfortable to wear compared to an oxford style leather shoe (Perry et al., 1995). Lavery et al (1997) evaluated the effectiveness of running shoes by comparing them with extra depth shoes and comfort shoes both with and without insoles. The comfort shoes used in this study were simply off-the-shelf extra depth shoes. The comfort and the running shoe both appeared to be sufficient alternatives to a traditional unmodified extra depth shoe. They were also often equivalent in peak pressure reduction compared to the extra depth shoe. However, the results indicate that the location of the high risk area may dictate the style and type of shoe. This study suggests that running shoes are a good alternative to extra depth shoes for reducing pressure under the 1st MTP with reductions of 35%, however, there was a small increase in pressure under the hallux of 16%.

In summary, a number of studies have shown that footwear is an effective intervention to reduce pressure and the risk of ulceration. There are a number of different types of footwear each varying designs and it is clear from the literature that there is room for improving these footwear interventions. The majority of research has only identified footwear as an effective method for reducing pressure, few studies have identified specific features of footwear which could be improved in future designs.

2.3.3 Features of footwear that affect plantar pressure

It is believed that different footwear designs affect in-shoe plantar pressure in different ways (Bus et al., 2008a). These differences must result from the interaction of the foot within the shoe which in turn depend on a range of different design characteristics, such as outsole geometry, upper volume and upper material. The upper of a shoe is the material which covers the dorsal aspect of the foot. Despite few studies reporting on the effects of the upper design on pressure (Fiedler et al., 2011, Ruperez et al., 2012), there have been a number of guidelines suggested for the design of the upper. These guidelines are based on risk factors for dorsal foot ulceration in a prospective study (Boyko et al., 1999). For example, if a shoe upper has insufficient width to accommodate the foot then ulcers can develop on the lateral side of the 5th MTH and medial side of the 1st MTH (Levin and O'Neal, 1988). It is commonly believed that the cause of the ulcer is due high pressure caused by tension between the foot and the upper.

There are two aspects of the upper which need consideration when designing shoes for people with diabetes: the volume and the material. As well as minimising the risk of elevated plantar pressure over bony prominences, appropriately designed uppers will also minimise shear forces (Rupérez et al., 2012, Cheer et al., 2009). The upper is in contact with the dorsal aspect of the foot, generating forces in the opposite direction to stop the foot sliding forwards (Levin and O'Neal, 1988). It also functions as a counter control mechanism to stop the heel lifting out of the shoe. The volume of the toe box is also an important aspect of the upper. People with diabetes are advised to wear shoes with a high and rounded toe box, such as extra-depth shoes (Levin and O'Neal, 1988). A narrow or pointed toe-box will create friction on the medial and lateral sides of the foot (Levin and O'Neal, 1988). A well designed upper will therefore work together with the outsole to reduce both plantar pressure and shear.

A shoe upper which can be adjusted with laces or Velcro is also recommended to allow for a better fitting. Different lacing techniques have been shown to affect plantar pressure, loose lacing techniques have been shown to result in small plantar pressure changes (6.5%) because of an increase in foot-in-shoe displacement (Fiedler et al., 2011). People with diabetes are therefore advised comfortably tighten their laces (Levin and O'Neal, 1988)]. Shoes, such as pumps or slip-ons, which cannot be adjusted have to be fitted more tightly and this, may increase the risk of dorsal ulcers. In order for the upper to work correctly, it must be adjustable, made from a soft material such as deer leather, and the volume of the toe-box must accommodate the forefoot region (Fiedler et al., 2011, Levin and O'Neal, 1988, Ruperez et al., 2012). To date, no studies have systematically adjusted the upper characteristics and therefore its effects on pressure are not fully understood.

The effects of outsole modifications have been shown to reduce plantar pressure in the high risk regions during walking (Cavanagh et al., 1996). There are various methods in which to reduce pressure by modifying outsole geometry. As discussed previously, orthoses and running shoes work by providing extra cushioning using specialist materials. To date the research does not allow for a definitive recommendation of the most appropriated orthosis material (Healy et al., 2010). Furthermore, running shoes are only viewed as the minimal choice for people with diabetes compared to wearing leather oxford shoes (Perry et al., 1995).

Another mechanism used to reduce pressure is to redistribute the load under the foot away from the areas at risk. When a foot extends, the skin under the foot moves distally to allow room for the toes causing an increase in plantar pressure. This is why the metatarsal heads are susceptible to ulceration. The most effective method to prevent this is to stop the foot from bending and the only way to accomplish this, without altering the gait, is to make the shoe rigid and create a rocking mechanism (Levin and O'Neal, 1988). This approach, known as a rocker sole, works by redistributing pressure away from areas of high risk to ulceration. The rigid outsole and angle at the front of the shoe create a rocking action which controls the motion of the metatarsophalangeal joint (MTP) (Hutchins et al., 2009).

Among clinicians there is disagreement about which type of footwear is most effective at reducing pressure. Rocker soles are the most commonly prescribed external shoe modification (Hutchins et al., 2009) but it is often argued that soft, well-cushioned shoes, such as extra-depth shoes, are just as effective. However, a number of studies have showed that rocker soles are the most effective at reducing plantar pressure in people with diabetes (Brown et al., 2004, Praet and Louwerens, 2003, Schaff and Cavanagh, 1990). To date, the prescription of rocker soled shoes has been based on theoretical considerations and empirical observations with minimal scientific evidence (Hutchins et al., 2009). The geometry of a rocker sole can be adjusted by changing the configurations of the design the features and this has been shown to effect pressure (Nawoczenski et al., 1988, van Schie et al., 2000). Despite this, rocker soles have been shown to have the highest pressure reductions (50%). Other studies have reported large reductions using other types of footwear, however, these studies reported poor reductions for the hallux region. The rocker sole was the only intervention to significantly reduce pressure in all of the high risk regions (1st MTP, hallux and medial MTH). Therefore, the subsequent discussion will focus on different designs of rocker soles.

2.3.4 Different approaches to designing a rocker outsole

A full literature search was completed on rocker soles shoes using the search terms shown in Table 2. . The different designs of rocker soles were reviewed first, which are discussed in this section. Following this, the overall effectiveness of rocker soles in comparison to other footwear was investigated. Finally, studies which have evaluated a range of rocker sole designs were identified and these are discussed in section 2.3.6.

There are a number of different rocker sole designs which can be prescribed for people with diabetes. These designs include; the toe only, negative and double rocker. The toe only rocker sole (Figure 2. 3) is designed to reduce pressures under the forefoot. It is defined by its angle towards the anterior part of the shoe and a pivot point or an apex where the outsole begins to contour away from the ground. The negative rocker sole (Figure 2. 3) is similar to the toe only; the only difference being that the posterior heel height is reduced creating a negative pitch (Hutchins et al., 2009). It is designed to reduce pressures under the forefoot. The double rocker sole (Figure 2. 3) is designed to alleviate pressure under the midfoot whilst also reducing pressure under the forefoot. The sole has the angle towards the anterior part of the shoe, the same as the toe only, however, the mid-foot sole thickness is reduced creating two points of contact on the ground (heel and forefoot) (Hutchins et al., 2009).

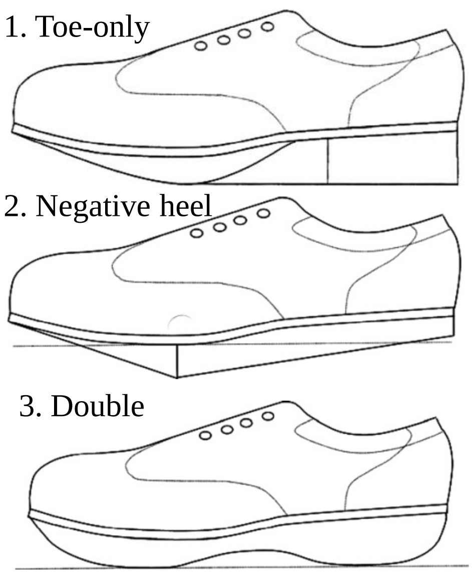

Figure 2. 3: Three different rocker sole designs, 1) toe-only, 2) negative heel and, 3) double.

Rocker soled shoes reduce pressure by shifting the load away from the forefoot (Hutchins et al., 2009). It achieves this by creating a rigid platform for the foot and rocking the foot from heel strike to toe off. This mechanism helps control the motion of the joints in the foot and ankle which reduces pressure by decreasing the anterior displacement of the metatarsal head soft tissue. This in turn distributes the forefoot load over a larger area (van Schie et al., 2000). Typically a rigid steel shank is embedded in the shoe's sole making it rigid (Brown et al., 2004). Despite the shoe being completely rigid, walking in them is achieved by the contours of the sole causing the foot to tip forward when the centre of mass passes over the apex of the shoe.

Rocker sole designs have been shown to reduce pressure by varying amounts (Brown et al., 2004). Brown et al (Brown et al., 2004) compared in-shoe pressure using the toe only, negative heel and double rocker sole compared to a control shoe (Brown et al., 2004). Percentage change in peak pressure was compared to the baseline shoe for each of the rocker designs. The toe only rocker was most effective at reducing pressure under the forefoot regions compared to the negative and double rocker. Pressures were significantly increased at the base of the 5th metatarsal in the toe only and negative rocker, only the double rocker reduced peak pressure in this region. Ulceration most commonly occurs under the forefoot (Waaijman et al., 2012). Therefore the results described above suggest that the toe only rocker may be the most suitable design for reducing forefoot pressure and subsequent ulceration in patients with diabetes.

There are two different variations of the toe only rocker shoe, the traditional, and the curved (Figure 2. 4). Both the traditional and curved have three principle design features; apex position, apex angle, and rocker angle. The apex position (Figure 2. 4) is the point along the long axis of the shoe where the shoe begins to tip forward (fulcrum). There are two methods of measuring or defining the apex position, simply in relation to the long axis of the shoe or in relation to the metatarsal heads (Hutchins et al., 2009). The apex angle (see figure 3) is the angle of the apex position and is expressed in terms of angle rotated around the long axis of the shoe (Hutchins et al., 2009). The rocker angle (Figure 2. 4) quantifies the size of the angle on the front of the shoe. This angle is altered by increasing or decreasing the thickness of the outsole. The difference between the traditional and curved is with regards to the rocker angle. The traditional rocker has an outsole geometry incorporating a sharp angle, and rocking occurs at this point. In contrast, to the curved rocker the rocking motion is achieved with a gradually contoured outsole profile. Given the large number of possible combinations of rocker angle, apex angle and apex position, it is necessary to have a clear understanding of how the design features influence plantar pressure in patients with diabetes.

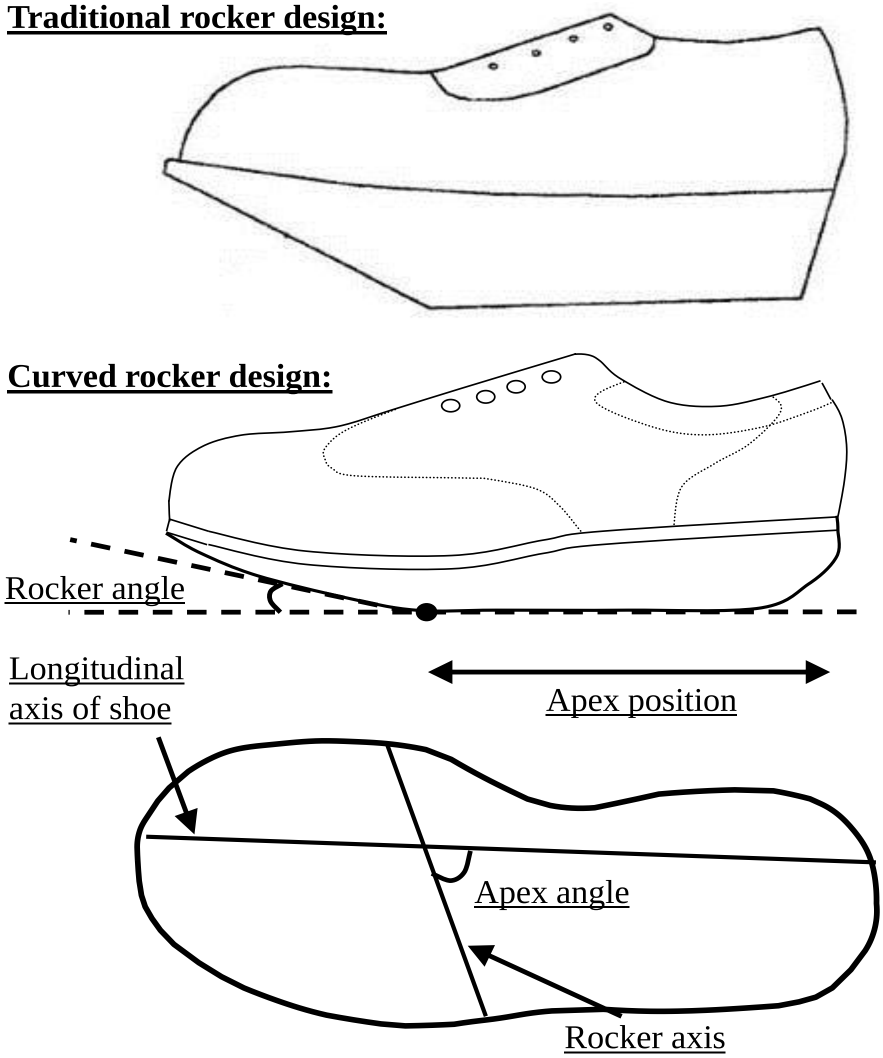

Figure 2. 4: The traditional rocker design and the curved rocker design with the three design features: 1) rocker angle, 2) apex position and 3) apex angle.

2.3.5 Evidence for the effectiveness of rocker shoes

A number of studies have shown the effectiveness of rocker soles compared to other conventional or therapeutic shoes (Brown et al., 2004, Hsi et al., 2004, Pollard et al., 1983, Praet and Louwerens, 2003). For example Schaff and Cavanagh (1990), produced data supporting the effectiveness of rocker shoes. They found rocker shoes to be more effective at reducing pressure compared to an extra depth shoe. Peak pressures were reduced by 30% at the central and medial forefoot, however, pressures went up in other areas of the foot such as the lateral forefoot and heel regions (Schaff and Cavanagh, 1990). Even though this study shows the potential effectiveness of rocker shoes, careful consideration needs to be made when prescribing such designs as to individuals with diabetes, as pressures can be elevated in certain regions of the foot. This simple approach to comparing two or three rocker shoe designs to a baseline shoe has been used in other studies (Bus et al., 2009, Fuller et al., 2001); which found similar results. However, the problem with this approach is that it fails to control for other design features that affect plantar pressure, such as last shape, upper material and sole stiffness. For a more rigorous design, the outsole geometry needs to be the only independent variable under investigation and should be varied systematically.

There have been a number studies which have evaluated a number of outsoles with differing upper designs and last shapes. A study simply comparing a variety of shoes for women was conducted by Praet et al (Praet and Louwerens, 2003). In shoe plantar pressure was collected using ten female participants with diabetes. They compared three types of shoe, “over the counter” leather shoes, semi orthopaedic extra depth shoes and customised plaster cast rocker bottom shoes which were made for each participant. The rocker shoe was the only condition to show a significant reduction in pressure under the forefoot in all the patients. However, as this was the only condition with a customised outsole, it is not possible to state whether the outsole or the foot/shoe interface are the cause of the pressure reduction. Upper material, lacing design and, the last should all be standardised when analysing outsole configurations in order to draw valid conclusions.

There has also been a lack of specificity in the research with regards to rocker soles. Rocker soles are prescribed to people with diabetes but a large proportion of research has been completed using healthy participants (Brown et al., 2004, Nawoczenski et al., 1988, van Schie et al., 2000). Brown et al (2004) compared in-shoe pressures of a baseline shoe and a toe only curved rocker sole and found a mean reduction in peak pressure compared to the baseline shoe. However, the clinical limitation of collecting the data on healthy participants reduces its applicability. It is well known that people with diabetes can exhibit gait abnormalities (Sawacha et al., 2009). People with diabetes walk slower, have greater step variability and present higher plantar pressures than healthy controls (Allet et al., 2008). Due to these gait abnormalities, rocker soles may have a different effect on people with diabetes. To increase clinical applicability rocker soles need to be tested on people with diabetes as well as healthy participants. A self-selected walking speed was also allowed whilst collecting the pressure data. To ensure the shoe condition is the independent variable, the walking speed between subjects needs to be controlled because variations in walking speed will affect the plantar pressure (Rosenbaum et al., 1994, Segal et al., 2004).

It is important for research studies to report clear information on the rocker configurations which have been tested. This allows other researchers to replicate the findings and also allows clinicians to implement specific designs in their clinical practice. For example, Pollard et al (1983) measured in shoe plantar pressure on ten healthy males in a variety of footwear designs, including a rocker shoe (Pollard et al., 1983). In this study, the rocker sole configuration was unclear as the authors reported the apex as being positioned "behind" the metatarsal heads, and the rocker angle was not defined at all.

In order to understand the precise effect of each of the design characteristics, it is necessary to test a range of possible designs. Studies which only use one rocker configuration limit the applicability of their result to only that configuration. An example of this is a study by Hsi et al (2004). They collected in shoe pressure data on participants with diabetes and neuropathy using a curved rocker sole which had an apex position at 65% of shoe length, an apex angle of 90˚, and a rocker angle of 13˚. In this study the rocker sole successfully redistributed the pressure from the central forefoot to the medial forefoot, compared to the control shoe. However, as this was the only configuration used, the results are only applicable to this rocker sole and it is not clear whether pressure reductions could be improved with other design configurations. It is clear from the research that rockers are effective offloading interventions, but the effect of each of the design features is not known.

2.3.6 Studies which have systematically varied the individual design features of rocker shoes

A rocker sole has three principle design features which can all be adjusted. The effect of the design features on pressure has not yet been fully evaluated. There is a need to isolate the design features systematically in order to improve the design of rocker sole. There have been only two studies which have systematically evaluated the effect of rocker sole design features (Nawoczenski et al., 1988, van Schie et al., 2000). Both of these studies involved testing a range of different outsole geometries to understand the effect of varying rocker angle and apex position on peak plantar pressure. These two studies used a controlled approach in which the same upper design was used and therefore outsole geometry was the only independent variable. The walking speed was also controlled with all participants walking at a pre-selected speed. A cross over design was used in both studies, testing a range of different rocker sole designs, where a detailed description of the configurations was also given. Each of these studies is now discussed in more detail.

The study by van Schie et al (van Schie et al., 2000) collected in shoe pressure on seventeen healthy males across nine rocker sole variations using the traditional design (Figure 2. 4). The nine rocker sole configurations included four rocker angles and five apex positions. Rocker angle was varied across the four angles of 20, 22.3, 26.3 and 30˚ and the apex position was kept constant allowing the effect of rocker angle to be analysed. Apex position was systematically varied, with a rocker angle of 20˚, using a total of five apex positions; 50,55,60,65 and 70% of shoe length. All of the rocker sole conditions incorporated the same upper and last shape and all of the participants walked at a speed of 1m/s making the outsole configuration(s) the only independent variable(s).

There were a number of significant results with regard to varying rocker angle and apex position. One of the key findings from this study was that at any apex position, a larger rocker angle (30˚) improved offloading compared to a smaller rocker angle (20˚). The explanation for this finding was that the additional height allows the person to utilise the rocking action of the shoe for a longer period before the distal part of the shoe comes into contact with the ground. The effect of varying apex position also had a significant effect on pressure reduction. van Schie et al (2000) reported that pressure could be reduced even further with the optimisation of the apex position. These results showed that, in most of the metatarsal head (MTH) regions, individually adjusting the apex position is likely to enhance the offloading. The mean worst shoe combination reduced pressure by 19% under the 1st MTH compared to a control shoe; this was increased to 34% using the best apex position. However, despite the mean results showing an overall reduction in plantar pressure; when the individual subject data was analysed it showed that at least one rocker sole configuration increased plantar pressure compared to the control shoe. This was evident in 14 out of the 17 subjects who exhibited peak pressures which were higher in the forefoot region compared to the control shoe (van Schie et al., 2000). This finding shows there is a large amount of variability between subjects and their response to a rocker sole design.

The study by van Schie et al (van Schie et al., 2000) contains a number of limitations. An improvement to the study would be to use a wider range of rocker angles, van Schie et al (van Schie et al., 2000) only used four rocker angles which ranged from 20-30˚. As current rocker soles are designed with a rocker angle of approximately 15˚ (Hutchins et al., 2009), studies evaluating the effectiveness of each design feature need to include what is currently prescribed to be able to quantify any improvements. As stated previously, apex angle is a principle design feature in the rocker sole configuration. The effect of varying apex angle was not analysed in this study. Therefore future studies need to include this design feature so as to gain an understanding of the effect of all the design features. Finally, including a group of participants with diabetes and using the curved design instead of the traditional shoe would have increased the clinical applicability.

The study by Nawoczenski et al (Nawoczenski et al., 1988) evaluated the effect of systematically varying rocker sole configurations in a curved design. Take-off point (apex position) and rocker curvature were analysed by collecting in shoe pressure data in twenty healthy male participants. Take-off-point is the position on the long axis where the sole begins to curve up. Only two take-off points were analysed; 50% and 60% of shoe length. It was reported that a take-off point of 50% was significantly more effective at alleviating pressure than at 60%. To analyse the effect of rocker curvature, rocker angle was kept constant at 20˚. Using this angle, radius of curvature was varied using the following values; 125%, 75% and 60% of shoe length. The rocker sole with a 75% curvature was the only design which reduced pressure across the whole forefoot. The curved designs were not as effective at offloading compared to the traditional design (zero degrees of curvature), however, the traditional rocker sole had a 30˚ rocker angle compared to a 20˚ rocker angle.

Nawoczenski et al (1988) make some valid findings in relation to rocker curvature design. However, their comparison of a traditional design with the curved designs is questionable as the traditional design had a much larger rocker angle (30˚ compared to 20˚). In order to compare a specific design feature, the other design features which are not under investigation need should remain constant. The results also do not provide good insight into the effect of varying apex position (take off point). By only using two values (50 and 60%), very few conclusions can be made with regards apex position. To gain a more in-depth understanding of this design feature and its effect on pressure, a wider range of positions needs to be used with smaller increments.

The two studies discussed above provide useful insight into the effects of varying specific design features of rocker shoes. However, further work is required to develop a complete understanding of the effects of varying outsole geometry in rocker shoes on plantar pressures. Specifically, future studies need to evaluate the effect of varying apex position, rocker and apex angle using a curved design on a cohort of participants with diabetes. By doing so, it would be possible to develop a full understanding of the mean effect of all the principle design features on pressure in a clinically relevant population. It is possible that the rocker soles may need to be prescribed individually from a large range of different designs in order to optimise pressure reduction. If this is to happen in clinical practice then knowledge is required on possible inter-subject variability in response to rocker outsole profiles. The results of the study by van Schie et al (van Schie et al., 2000) demonstrate that there is a large amount of inter-subject variability between the optimal positioning of the apex. Despite a mean pressure reduction being reported, van Schie et al (van Schie et al., 2000) also showed that there are apex configurations which will increase pressure in the majority of subjects. Therefore, careful consideration is required when prescribing a rocker sole. However, the only information with regards to inter-subject variability comes from apex position using a traditional design and there is no information when using a curved design.

2.4 Factors which may influence in-shoe plantar pressure and therefore influence how an individual responds to a specific rocker shoe design

2.4.1 The possibility of predicting shoe design using gait inputs

It is possible that different individuals with diabetes may require different rocker outsole designs to maximise pressure offloading. This idea is supported by the findings of van Schie et al (2000) who reported a large amount of inter-subject variability between optimal designs and it was anticipated that a similar level of variability would be seen in this project. The clinical implications of this finding is that that rocker soles may need to be selected individually from a range of different design configurations. The practical implication of this is patients will need to try on a number of shoes with a range of outsole configurations whilst in-shoe pressure is monitored. However, in a shop or clinic setting this may not be a practical approach due to the time-consuming nature of the measurements. A better method would be to have a system which can predict the optimal rocker outsole design for an individual without them being required to try on a large range of different shoes. One of the ways to achieve this is to use a system which could be based in a shop or clinic, which can predict an optimal set of rocker sole design using a set of biomechanical variables.

Ultimately, such a system would work by using an algorithm which accepts as input the biomechanical measures and then predicts the optimal outsole configuration. For this approach to work, the biomechanical input parameters need to be provided using a simple and time efficient method. For example, even if a full body gait analysis using a motion capture system accounted for a large proportion of the variance between the different optimal sole configurations it would not be practical or economical in a shop setting. The same restrictions apply for structural measurements. The use of MRI and x-ray machines may also provide valuable information used to prescribe the rocker sole but these would not be cost or time effective in a clinic or shop. It is clear from studies which have investigated a range of rocker soles (Nawoczenski et al., 1988, van Schie et al., 2000) that there is a degree of inter-subject variability between optimal designs, which suggests that the optimal design of a rocker sole may be correlated to a patients gait and biomechanical variables.

2.4.2 Hypothesis of how the different design features might affect pressure in different individuals

The effect of changing the rocker sole design may affect individuals in different ways. Between people there is a variability in gait kinematics and kinetics which could potentially cause differing responses to rocker sole designs. It has been reported that changes in joint ranges of motion can have an effect on barefoot pressure. Therefore, it is possible that between-subject differences in gait kinematics and kinetics could influence in-shoe pressure. In this project I propose to study three principle design features (apex angle, apex position and rocker angle) in detail as each of these has the potential to affect pressure differently in different individuals.

Apex angle

Apex angle is the only design feature which can be considered to affect movement in the transverse plane because it is rotated around the long axis of the shoe (page 51). Foot progression angle is a typical gait variable used in biomechanical studies and is calculated in the transverse plane (Chang et al., 2004). The foot progression angle affects the inversion and eversion moment of the foot and it has been shown that an increase in foot progression angle increases the medial plantar loading (Chang et al., 2004, Healy et al., 2013). In this project, different apex angles may affect the medial plantar loading under the foot depending on the individual foot progression angle. For instance, a person with small foot progression angle (Figure 2. 5 B) may benefit from a more perpendicular apex angle compared to someone with a greater foot progression angle (Figure 2. 5 A). The hypothesis behind this assumption is that pressure will be reduced when the apex angle is aligned with the foot.

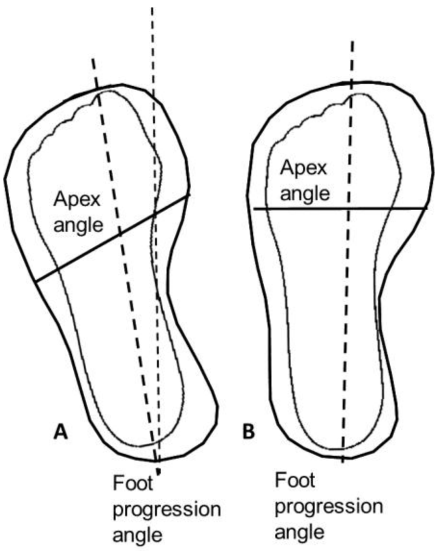

Figure 2. 5: Example of someone with a large foot progression angle (A) compared to someone with a small foot progression angle (B) in relation to apex angle.

Apex position

The mechanism of a rocker sole alters the force distribution under the foot (Hutchins et al., 2009).This is achieved by reducing the sagittal range of motion of the 1st MTP joint during stance, whilst not dramatically altering the overall gait (Levin and O'Neal, 1988). A number of studies have shown the 1st MTP ROM to be predictors of plantar pressure during barefoot walking (Morag and Cavanagh, 1999, Rao et al., 2010), it is therefore feasible that they may also be predictor of in-shoe pressure (Payne et al., 2001, Morag and Cavanagh, 1999). Taking this idea one step further, it is possible that different apex positions may have a specific effect on an individual which depends on both the positioning of their 1st MTP joint inside the shoe and also the 1st MTP range of motion (ROM) (Figure 2. 6). For example, the exact position of the 1st MTP joint inside the shoe will depend on the 1st MTH length (measured from the back of the heel) and also the hallux length. Furthermore adjusting the apex position anteriorly and posteriorly to the 1st MTP joint may affect how the joint behaves inside the shoe. In addition, the optimal position of the apex may also be dependent on kinematic properties of the joint. An individual with a greater range of motion in the sagittal plane may require a more anteriorly positioned apex in order to prevent the joint from excessively plantar-flexing and subsequently increasing pressure (Figure 2. 6).

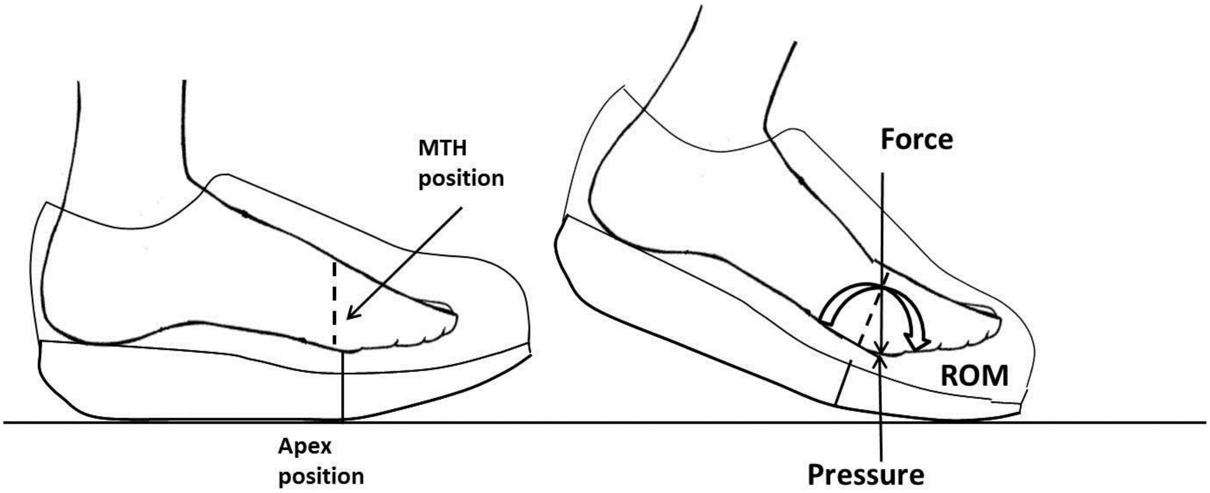

Figure 2. 6: A hypothesis of how the optimal positioning of the apex may be affected by the position of the MTH and 1st MTP joint range of motion (ROM).

Rocker angle

It is possible that adjusting rocker angle may also have a different effect on different individuals depending on their foot biomechanics (Figure 2. 7). The size of the rocker angle dictates the duration the individual has to exploit the mechanism of the sole (van Schie et al., 2000). For instance, a large rocker angle (30 degrees) will prevent the end of the shoe coming into contact with the ground and reduce plantar loading under the 1st MTP and hallux (Nawoczenski et al., 1988). Increasing the size of the rocker angle may have differing effects on people depending on their sagittal range or motion . People who have had diabetes for a duration over 19 years have been shown to exhibit a reduced segmental foot mobility and subsequently have increased loading under the foot (Rao et al., 2010). In these individuals, a larger rocker angle may be needed in order to utilise the rocking action and reduce the activity of 1st MTP joint (Figure 2. 7). Conversely, people with diabetes who do not exhibit a reduced ROM may be able to utilise a smaller rocker angle effectively.

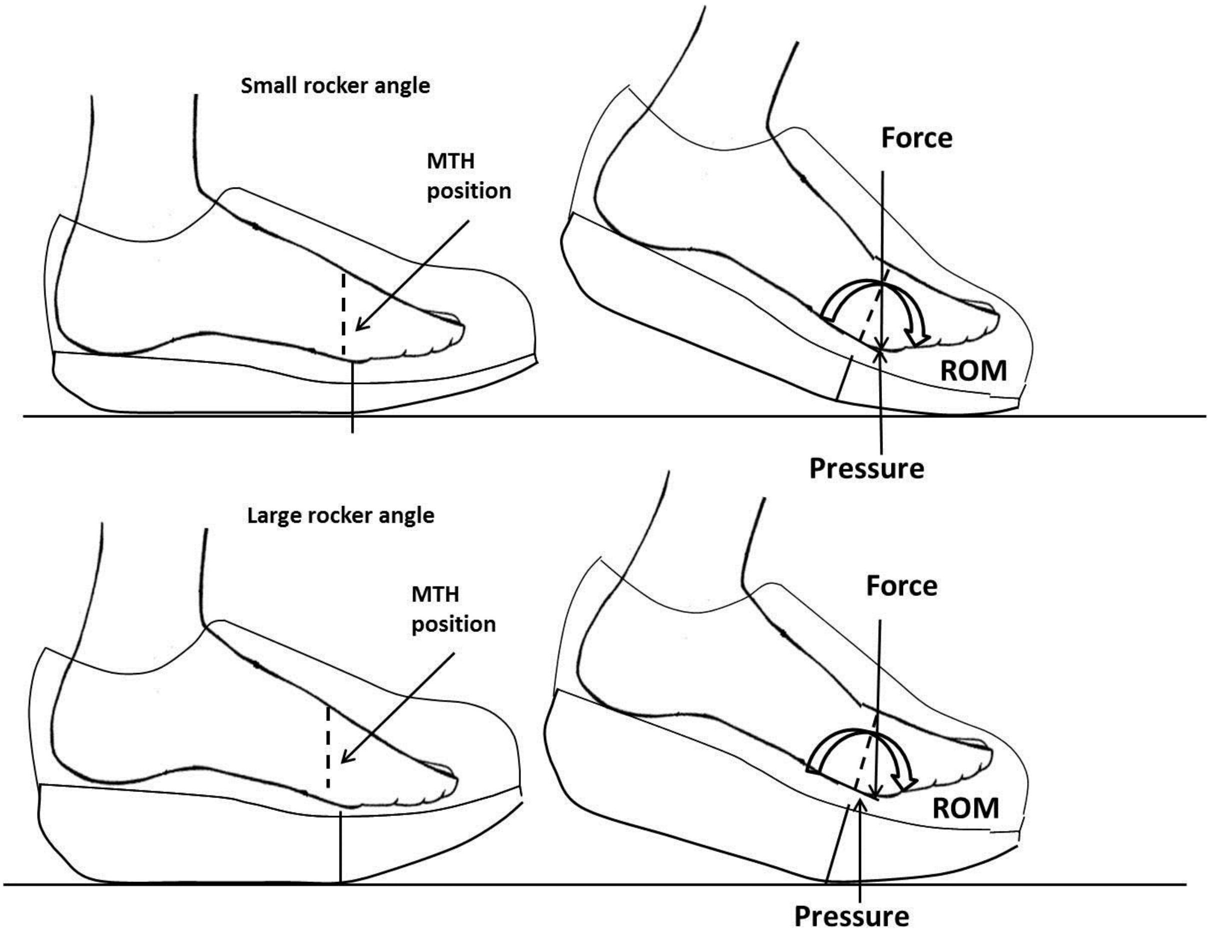

Figure 2. 7: A hypothesis of how increasing the rocker angle may be affected by the position of the MTH and 1st MTP joint range of motion (ROM).

A number of suggestions have been presented above to explain how different individuals (with different foot biomechanics) may respond differently to different footwear designs. However, the foot is a complex structure and therefore it is likely that there is a complex relationship between foot biomechanics and the change in pressure which occurs in response to a specific footwear design. It may therefore be appropriate to use a complex multi-segmental biomechanical model to understand such relationships and therefore possible variability in pressure between subjects. This idea is discussed in more detail in the final study (Study 3).

2.5 Summary of literature review

The review of the literature highlighted foot ulceration to be a major problem in people with diabetes. It is clear that the causes of ulcers are multifactorial but elevated plantar pressure has been consistently identified as an independent risk factor. Easy-to-use pressure measurement systems are now widely available and so it is relatively straightforward to quantify the efficacy of interventions designed to offload different regions of the foot. Furthermore, one epidemiological study has suggested that, for such offloading interventions to be effective, pressure must be reduced below a critical threshold of 200 kPa (Owings et al., 2009b). However, this is currently viewed as a relatively conservative goal when prescribing offloading interventions.

The review of the literature identified a number of different offloading interventions. However, the evidence pointed towards footwear and specifically the addition of a rocker sole as the most effective. There are a number of different rocker sole designs but the most commonly prescribed is the toe-only curved design (Hutchins et al., 2009). This is because it is not only effective at reducing pressure but is more aesthetically acceptable to patients than the traditional design (Nawoczenski et al., 1988). Within the toe-only curved design, there are three principle design features (apex angle, rocker angle and apex position) which can be adjusted, meaning there is myriad possible configurations. Studies have suggested that the design of the rocker sole may need to be adjusted for each individual for optimal offloading (van Schie et al., 2000). Before this can be investigated, the effect of the individual design features on pressure needs to be fully evaluated in order to reduce the number of possible designs to select an optimal for each individual. It was not possible to accomplish this using a single study because of the sheer number of configurations. Two studies were defined in order to evaluate the effect of the rocker sole design features (**Study 1 and Study 2**).

2.6 Scope and boundaries of the project

This research was funded by the 7th Framework EU project named “SSHOES” (FP7/2007-2013) (Appendix 5). The overall aim of this project was to investigate the variables which influence footwear for people with diabetes. For the results of this project to have clinical value, it was important to create footwear designs which would ultimately be accepted by the patients. Numerous studies have shown that if patients do not find shoes aesthetically appealing, they are unlikely to wear then, even if the footwear could lead to improvements in foot health (Macfarlane and Jensen, 2003, Nawoczenski et al., 1988, Williams and Nester, 2006). In order for footwear for people with diabetes to be effective it needs to be worn at least 60% of the time (Macfarlane and Jensen, 2003). However, studies have reported rates of compliance as low as 22% (Macfarlane and Jensen, 2003). In a recent study, patients were supplied with footwear in a diabetic foot clinic and feedback was collected using face-to-face interviews and structured questionnaires, (Knowles and Boulton, 1996). It was reported that 82% of a group of people with diabetes who had been prescribed therapeutic footwear disliked the style of their shoes and stated they were not cosmetically acceptable. Of the 50 participants, only eleven people wore their prescribed shoes regularly (Knowles and Boulton, 1996). From this study it is clear that despite the health benefits of therapeutic shoes they must be acceptable to the patients.

Both style and appearance of footwear are the factors which have been attributed to low levels of compliance. This idea was explored in detail by Williams and Nester (2006) who evaluated the specific features of footwear to understand what is important to patients. This study showed that the style of the shoe was considered the most important feature amongst a group of patients with diabetes. In addition, features such as, comfort, fit, support, and sole design were also rated as important by patients.

Given the importance patients ascribe to the appearance of a shoe, it may be necessary to strike a balance between pressure reducing capacity and appearance if high levels of compliance are to be achieved. For example, rocker shoes are commonly prescribed to people with diabetes. With this design, increasing the outsole thickness (to increase rocker angle) has been shown to reduce forefoot pressures (van Schie et al., 2000),. However, large increases in outsole thickness may not be acceptable to patients because of the shoe's appearance and perceived instability during walking (Nawoczenski et al., 1988). The curved rocker design can be manufactured to look more like conventional footwear than the traditional rocker design and is therefore likely to be accepted by patients (Nawoczenski et al., 1988). In order to create a design which incorporates both pressure reducing capacity and an acceptable appearance, a footwear designer may need to reach a compromise between pressure reduction capabilities and the aesthetics of the shoe. This need to strike a balance between these two aspects of the shoe was identified as one of the major boundaries of this PhD study.

Another boundary of the PhD related to the patient group on which the footwear was tested .The project brief stated the patient with diabetes who would be classified as low risk (see Table 1.1). This was because it was felt that new footwear designs should be tested on low risk patients before testing on those with neuropathy just in case there were any adverse effects of the new designs. However, it was felt that the results of the project would inform future projects aiming to evaluate the effectiveness of different footwear designs in patients with diabetes who suffer with neuropathy. This project scope was to investigate the effectiveness of footwear interventions to reduce forefoot plantar pressures in low risk people with diabetes. The scope of the project was also influenced by the objectives defined by SSHOES, these were discussed in more detail in section 1.7

Study 1: Understanding the effect of systematically varying the three principle design features of a rocker shoe in people with and without diabetes.

To develop a full understanding of effect of the three rocker soled design features, it is necessary to test footwear spanning the range of each of these features. Given that there are three important design features: rocker angle, apex angle and apex position, testing every possible combination (4-5 different values per feature) would require up to 125 shoes (5x5x5). Clearly this is experimentally infeasible. Therefore, the aim of the first experimental study was to understand the effect of varying apex angle, apex position and rocker angle by using a range of 4 - 5 different values. To understand the effect of each design feature, each of the values were adjusted individually whilst the remaining two features were kept constant. This made it possible to evaluate a range of each of the design features using 12 shoes instead of 125. The aim of this study was to identify the design features which could be fixed for all individuals and to identify the design features which may need to be adjusted. A new range of rocker sole configurations could then be defined for a subsequent study which would evaluate different combinations of specific design features.

Study 2: Understanding the effect of varying rocker angle and apex position.

This study develops further the understanding of rocker sole design. Study 1 evaluated a range of each of the design features systematically but it failed to evaluate different combinations of these design features. The strategy in this study was to evaluate combinations of the design features and to identify a small range of configurations for which an optimal can be chosen.

In order to make recommendations with regards to rocker sole design, the plantar pressure goal Suggested by Owings et al (2008) was incorporated. It was evident from the literature that the target goal of <200 kPa is the best current threshold available. If a rocker sole design was able to reduce plantar pressure to conservative target of 200 kPa, a clinician could be confident that they would not develop an ulcer and therefore the patient may not need an individual rocker design.

Study 3: Developing an algorithm to predict optimal rocker shoe design from an input of gait data.

Despite two studies evaluating a wide range of the rocker sole designs, it was expected there will still be a degree of inter-subject variability between optimal designs. This hypothesis was established based on the results of van Schie et al (2000) and Nawoczenski et al (1988). It was suggested by van Schie et al (2000) that varying gait parameters may account for the variance between the optimal designs. The relationship between biomechanical variables and in-shoe pressure needs to be investigated in order to design an algorithm which can predict optimal rocker sole design.

In biomechanics, prediction systems have been implemented to classify human movements based on characteristic variables (Barton, 1999, Barton and Lees, 1997, Gioftsos and Grieve, 1995, Holzreiter and Köhle, 1993, Schöllhorn, 2004).The use of prediction systems in footwear biomechanics is in its infancy, however, studies have reported some successful results. For example, a prediction system was able to distinguish between insole behaviour despite the differences between the two insoles not being significant (Barton and Lees, 1996). In this study the prediction system was trained to associated pressure data with the insole conditions. The study by Barton and Lees (1996) showed that it is possible to distinguish between types of footwear using a prediction system. The aim of Study 3 was to predict an optimal rocker outsole by from an input of gait data. There are a number of biomechanical factors which have the potential to influence in-shoe pressure. However, it is not clear whether these factors could be used to predict individual responses to rocker outsole design. In order to investigate this idea, it is first necessary to understand if specific biomechanical variables could explain inter-subject differences in pressure between the different rocker sole designs. Previous research has shown dynamic foot kinematics to be related to barefoot pressure and therefore it is possible that foot kinematics may also predict in-shoe pressures. Given this idea, Study 3 was designed to investigate whether segmental foot kinematics in combination with foot measurements and demographic characteristics, such as bodyweight and age, could be used to predict pressure responses to different footwear designs.

Chapter 3: (Study 1) Understanding the effect of systematically varying the three principle design features of a rocker shoe in people with and without diabetes

3.1 Introduction

The majority of studies which have investigated the outsole geometry of rocker shoes have simply compared peak pressure between two or three off-the-shelf shoes (Brown et al., 2004, Bus et al., 2009, Fuller et al., 2001, Praet and Louwerens, 2003, Schaff and Cavanagh, 1990). With this approach, it is not possible to understand the independent effect of the three design features which characterise outsole geometry: apex angle, apex position and rocker angle. To date only two studies (Nawoczenski et al., 1988; van Schie et al., 2000) have used a systematic approach to investigate the effect of these design features on plantar pressure. However, both studies investigated healthy participants rather than people with diabetes and neither investigated the effect of varying apex angle. Furthermore, the study by van schie et al. (2000) investigated the less aesthetically acceptable traditional rocker shoe rather than the currently prescribed curved rocker shoe.

A number of studies have shown that each of the three design features (apex angle, apex position and rocker) has the potential to influence in-shoe plantar pressure (Brown et al., 2004, Nawoczenski et al., 1988, Pollard et al., 1983, Praet and Louwerens, 2003, van Schie et al., 2000). Given the objective of minimising pressure, it is important to understand both the independent effect of varying these features and also how they interact together to influence pressure. However, to span an appropriate range of each design features would require at least 4-5 shoes, e.g. apex angles ranging through 70°, 80°, 90° and 100°. Therefore, to test all possible interactions between the three design features would require over 60 shoes (4x4x4) which would not be practical in a single laboratory testing session. In order to overcome this potential barrier, a two-phased approach to the experimental testing was adopted.

The first phase (Study 1), described in this chapter, involved an investigation into the independent effect of each of the three design features. To achieve this objective each of the individual design features was varied while the other design features were fixed. For instance, when evaluating apex angle, a range of four apex angles were analysed and apex position and rocker angle kept constant. The results of this study were then used to inform the choice of footwear used in the subsequent study (Study 2, Chapter 4). This aim of Study 1 was to investigate both the independent effect and the interactions between the footwear design features and therefore it was necessary to focus on a limited range of design features.

3.2 Study 1 research question

What is the independent effect of systematically varying the three principle design features of a rocker shoe in people with and without diabetes?

3.3 Study 1 research aims and objectives

Below are the research aims and objectives for Study 1. Each of the three objectives corresponds to a research aim.

Aims

1. To understand the effect the three principle design features have on pressure.
2. To understand if there is a difference in the effect of outsole design on people with diabetes and healthy participants
3. To understand biomechanical effects of the different design features

Objectives

1. a. Quantify the main effect of the principle design features on peak plantar pressure.
   b. Quantify the inter-subject variability between the optimal designs.
2. Quantify potential differences in response to varying design features between people with diabetes and healthy participants groups.
3. Investigate how loading under the foot changes with the three different design features by using centre of pressure measurements.

3.4 Design

A repeated measures between-within design was chosen for this current study. Also known as, a mixed design, a repeated measures design uses the same subjects for every condition. Therefore, in this current study, all the participants walked in all the different shoe conditions. The between groups part of the design allows to compare the effect between the people with diabetes and healthy groups, by comparing the mean peak plantar pressures as well as interaction. The interaction between the groups compares the effect of the outsole designs between the groups.

3.5 Participants

Only people who were categorised as having low risk diabetes (type I and II) were recruited for the study. It was not possible to recruit people with diabetes who were high risk due to ethical considerations. Within the shoe design specification were some “extreme” rocker sole designs which may have been hazardous for persons with severe neuropathy to walk in, therefore, ethically testing neuropathic participants was not possible. For example, rocker angles >20° have heel heights of 4-5 cm, which have been shown to be perceived as unstable (Nawoczenski et al., 1988). Limiting the experimental work to low-risk patients with diabetes reduces the conclusions of the findings. Nevertheless, it was felt that this study would provide insight into the general principles of footwear design which could be incorporated into future footwear studies developed for high risk patients. Therefore, this current study is a good initial step towards a comprehensive understanding, which would benefit future studies including both high and low risk patients.

A total of 24 people with diabetes and 24 healthy participants were recruited at two sites, the University of Salford (UK) and the German Sport University (Cologne, Germany). Each University provided twelve healthy participants and twelve people with diabetes. Before people were able to participate in the study they underwent a screening process; this was in place to avoid the recruitment of high risk people with diabetes. The first part of the process took place in conversation between the researcher and the participant via a phone call. Participants were initially selected on shoe size (Eu 43 for male and 39 for women), they also had to state that they would be able to walk unaided for a period of 45 minutes because the walking phases of the testing protocol would likely accumulate to approximately this length of time. Participants also had to state they had no current form of ulceration on their feet or major foot deformity which prevented them from wearing off-the-shelf footwear. Exclusions from the study resulted if individuals stated they had any other health issues such as arthritis, leg amputation, heart conditions or breathing problems which would be exacerbated by walking. Following a positive responses to these questions a qualified podiatrist visited the participant to carry out a physical foot examination.

The foot examination, carried out by the podiatrist, consisted of looking for breaks in the skin, callus or signs of athletes-foot between the toes. The podiatrist also carried out assessment of sensory perception in the feet to identify if the participant had evidence of neuropathy. The neurological status of the patients with diabetes was assessed by using a 10g monofilament at 6 sites on the plantar aspect of the foot (Feng et al., 2009). If patients were unable to detect more than one site then they were classed as having neuropathy and not recruited for the study. If the podiatrist deemed the person suitable they would then be included in the study. Vibration perception and Achilles tendon reflex tests were also carried out by the researcher at the University prior to testing.

The healthy participants also underwent a test of sensation for neuropathy prior to testing. If they had a foot problem they were unaware of, they would have been referred to a doctor and excluded from the study. However, there were no cases of this during this study. Healthy participants recruited were matched, as far as possible, by weight to the participants with diabetes because body weight has an effect on plantar pressure results (Rosenbaum et al., 1994, Segal et al., 2004). Participants with diabetes had a mean (SD) age of 57(8), a mean weight of 86.0(12.4) Kg and a mean height of 1.71 (0.09) m Healthy participants had a mean (SD) age of 49(15), a mean weight of 79.8(11.9) Kg and a mean height of 1.75(0.09) m. There was no significant difference between the diabetes and healthy groups for the mean weights, however, age was significantly different.

3.6 Methods

Ethics

Ethical approval was obtained from the University of Salford ethics committee (School of Health Science) and National Health Service (IRAS 10/H1013/32) (Appendix 1-4).

3.6.1 Footwear interventions

Participants were asked to walk in a total of twelve pairs of rocker shoes plus a flexible control shoe. The shoes were specifically manufactured by Duna®, Italy; who are a specialist orthopaedic shoe company. For the rocker soles the outsole was constructed from micro cellular rubber and incorporated a 5mm thick piece of folex which created a very stiff outsole which did not flex. The male and female shoes were made with separate lasts but both had a soft leather upper and same lacing design. For consistency, the control shoe was made with the same last as the rocker shoes. Micro cellular rubber was also used for the outsole (without the 5mm folex) creating a bending stiffness similar to a running shoe. Furthermore, as this study was carried out on people with diabetes, it was important that the control shoes were manufactured using the same last and upper material typical of those used to manufacture therapeutic shoes for people with diabetes. These designs have no seams or areas where the shoe could rub and cause a blister. Other similar studies used an oxford style shoe as a control, however, these studies did not evaluate the effect of footwear on people with diabetes (van Schie et al., 2000). With our approach the outsole was the only variable which was manipulated (Cavanagh et al., 1996).

The focus of this study was to understand the effect of varying the three principle design features on plantar pressure (Figure 3. 1). However, it was not possible to cover all different combinations of apex angle (AA), apex position (AP) and rocker angle (RA). For example, if five levels were chosen for each of the three design features the a total of 125 pairs of shoes (5x5x5) it would be required. This is infeasible number of shoes to test in an experimental setting. Therefore, a typical curved rocker outsole design with an apex angle of 80°, an apex position of 60% of shoe length, and a rocker angle of 20° was used a central or reference shoe. From this reference set of design configurations, the apex angle was varied using a set of four rocker shoes with apex angles of 70, 80, 90 and 100°. With this set of four shoes the apex position and rocker were fixed at 60% and 20° respectively. A second set of five shoes consisting of apex positions of 50, 55, 60, 65, and 70% of shoe length and an apex angle of 80° and rocker angle of 20°. The final set of 5 shoes had rocker angles of 10, 15, 20, 25, and 30°, an apex angle of 80° and an apex position of 60% of shoe length. Although the shoe with apex position at 60%, rocker angle 20°, and apex angle 80° was included three times in the data analysis (

Table 3. 1**,** it was only necessary to measure this shoe once. CAD CAM technology was used by the orthopaedic shoe manufacturers, DUNA, to create the different rocker shoe configurations.

Table 3. 1: Rocker sole configurations evaluated in Study 1. The shoes are grouped by the principle design features. AA = apex angle, AP = apex position, and RA = rocker angle.

Shoe	Apex angle (°)	Apex position (% shoe length)	Rocker angle (°)
1. Control	NA	NA	NA (heel height)
2. AA1	70	60	20 (3cm)
3. Ref	80	60	20 (3cm)
4. AA3	R	60	20 (3cm)
5. AA4	100	60	20 (3cm)
6. AP1	80	50	20 (3cm)
7. AP2	80	55	20 (3cm)
8. Ref	80	60	20 (3cm)
9. AP4	80	65	20 (3cm)
10. AP5	80	70	20 (3cm)
11. RA1	80	60	10 (1cm)
12. RA2	80	60	15 (2cm)
13. Ref	80	60	20 (3cm)
14. RA4	80	60	25 (4cm)
15. RA5	80	60	30 (5cm)

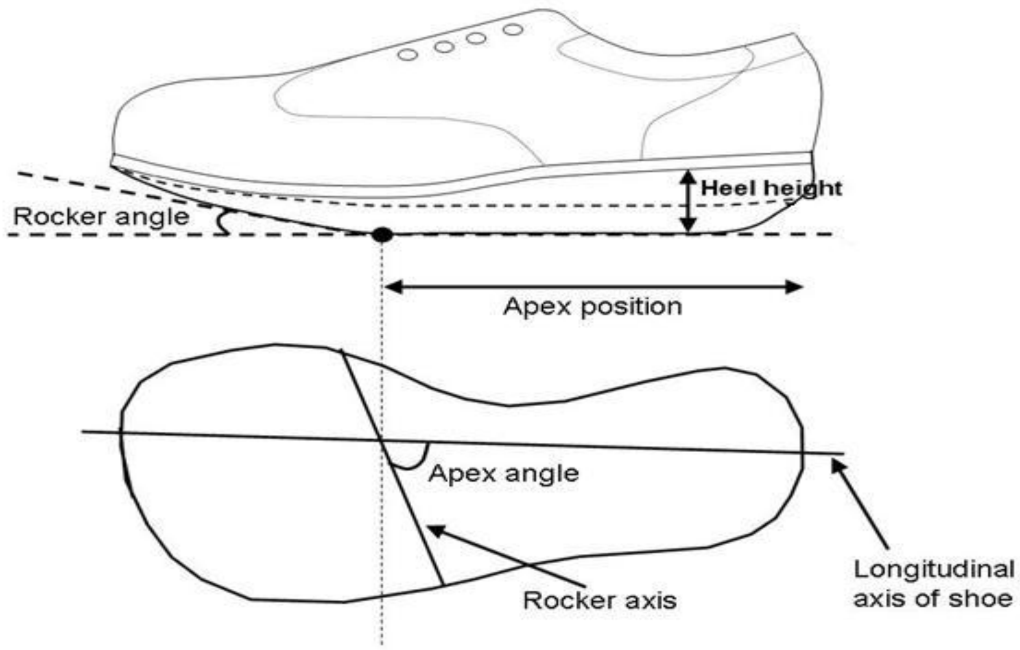

Figure 3. 1: Definition of the rocker outsole design features (rocker angles, apex position and, apex angle).

3.6.2 Protocol

Following the informed consent and sensation tests, the participants had their foot scanned using a 3D foot-scanner which was provided by INESCOP, Spain. The foot scan data was collected in order to express the apex angle and position relative to the foot anatomy in addition to the long axis and percentage of shoe length respectively. (Details of these calculations are explained below) Measurements were taken during bipedal standing.

In shoe plantar pressure was collected as participants walked at 1m/s ± 10% along a 20m walkway. Habitual walking velocity of people with type II diabetes, with a mean BMI of 33.4, has been shown to be 0.92m/s (Johnson et al., 2005). Participant mean BMI in this study was slightly lower (29.4) than the study by Johnson et al (2005), therefore because the participants in this study are likely to be more active, a velocity of 1m/s is more appropriate. Furthermore, in the study reported by van Schie et al (2000), healthy participants also walked at 1m/s ± 10%. Therefore, in order to compare results between studies, a 1m/s walking velocity was chosen.

In this study, 24 of the participants were able to walk at 1m/s ±5%, however the remaining 24 participants were only able to walk at 1 ± 10%. Analysis of the peak plantar pressures, using a paired t-test, showed that there was no difference between the participants who walked at 1m/s ±5% and the participants who walked at 1m/s ±10% (p=>0.5) for any of the shoe conditions. Additionally, there was also no significant differences for the stance times between any of the shoe conditions for the participants walking at ±5% compared to the participants walking at ±10%. Therefore, it can be confidently stated that the peak plantar pressure data collected using the ±10% range will provided valid results.

A Brower (Utah, USA) TC timing system (light gaits), was used to guarantee the participants walked within the defined velocity window. Shoe order was randomised within the set of design specifications prior to testing. For example, a participant would walk in the set of shoes varying apex angle first followed by rocker angle and then apex position. Order of the group of design features was also randomised for each participant. Randomisation was carried out using a custom Matlab programme. Participants were provided with thin nylon socks prior to the in-shoe pressure measurements. Shoes were fastened according to the participants' perception of tightness and feel. Each participant underwent an familiarisation period of approximately 45 steps in each shoe prior to in-shoe pressure data being recorded. This allowed participants to acclimatise to the velocity as well as the shoe condition. A study, currently in review (Gait and Posture (April 2014)), carried out at the Salford University by JM Melvin, sought to understand how long the acclimatisation period should be whilst wearing a rocker soled shoe. Participants walked for 400 meters in a rocker soled shoe and windows of different numbers of steps were compared to the final 100 steps. It was concluded that one minute of walking is needed in order for the plantar pressure variability between steps to stabilise (Manuscript under review in Gait and Posture (April 2014)).

In-shoe plantar pressure data was collected using a Novel Pedar-X system at 50Hz with the pressure sensitive insole attached on top of a 3mm poron (Algeos) insole. Each participant was asked to walk up and down the walkway at a constant velocity with a short pause at each end. A total of three trials at the correct velocity were recorded which gave a total of 25-35 steps for each shoe condition. Pressure data was exported in an ascii file format ready for processing.

An in-shoe pressure system must produce reliable measurements when evaluating the effect of a number of different outsole configurations. In recent years there has been a large number of footwear comparison papers published using the Pedar system(Carl et al., 2006, Payne et al., 2001, Stewart et al., 2007), however, it is only recently that the repeatability and accuracy of the system has been evaluated. In order for the device to be viable for experimental use it must meet a satisfactory level of repeatability and accuracy. Repeatability or reliability is the ability of a measure (plantar pressure) to produce consistent values when used to quantify plantar pressure on two separate occasions.

Repeatability of the Pedar system was reported by Ramanathan et al (2009). In their study, in-shoe pressure was collected at 50Hz on twenty seven healthy participants who walked in a neutral trainer on two occasions approximately one week apart. Coefficient of variation was then used to quantify repeatability. Pressure values under the heel and metatarsal heads reported the highest repeatability and the 3rd to 5th toe regions were least repeatable. All of the forefoot regions had CV values <15, which is considered to be low for in-shoe pressure data (Ramanathan et al., 2009). Therefore, it can be concluded that the Pedar system is a reliable plantar pressure measurement tool for this particular group of participants and shoe condition.

Throughout dynamic pressure application, a pressure insole must be able to detect a range of pressure levels (Hsiao et al., 2002). During walking the load is not evenly distributed to all the sensors, indeed some sensors can experience loads up to several hundred kPa, whereas others will only have small plantar pressure applied or no load at all. Therefore, it is crucial that a system can measure pressure across a large dynamic range. Accuracy of the Pedar and F-Scan systems were evaluated by Hsiao et al (2002) (Hsiao et al., 2002). Accuracy is defined by the percentage error calculated when comparing the measured load to the actual load (Hsiao et al., 2002). The Pedar system produced the greatest accuracy across a range of pressure measurements, error measurements ranged from -0.6-2.7% compared to 1.3 ± 5.8% which were produced using the F-Scan system. This research demonstrates the Pedar system is potentially the most reliable method for quantifying foot pressures and therefore an appropriate measurement instrument to use in footwear comparison studies.

The accuracy of a pressure measurement system can be optimised in a number of ways. Increasing the accuracy of the Pedar system was also explored by Hsaio et al (2002) (Hsiao et al., 2002). The accuracy of the Pedar system can be increased by using a new insole compared to a used insole. Hsaio et al (2002) reported that an insole which had been subject to approximately 200 hours of data collection had considerably lower accuracy than a new insole. Therefore, to ensure high accuracy during pressure measurements the insoles need to be replaced or repaired before 200 hours of testing has been reached. This study also found accuracy increased when insoles had been calibrated using the extended method specified by the manufacturer. Therefore, to ensure accurate measurements throughout this project new insoles were purchased prior to the project commencing and they were regularly serviced and calibrated using the extended method. For this current study, the same Pedar system and insoles were used to record the data.

3.6.3 Defining the steps

A custom Matlab programme was written which processed the plantar pressure data. This programme was written by myself because the University did not possess the Novel analysis software and it allowed for the data to be manipulated specifically for this study. For instance, all of the trials were collected in one measurement, the Matlab software allowed for the trials to be sub-divided. Additionally, storing the date in structures also made it easier to interpret the results. Data files corresponding to each shoe condition consisted of a minimum of three trials (minimum depending on extra trials due to a trial being performed at an incorrect velocity) which were separated out into 3 “blocks” of steps (9-12 steps per block approximately). Trials outside the velocity window were removed (Figure 3. 2). Each trial was then sub divided into steps by setting a threshold and the first and last two steps were removed from each trial because these represented gait initiation and termination. Following this process, the trial and step division information was saved in a mat file format. The mat file contained: the indexes of the defined steps (heel strike and toe off), the pressure data and the sampling frequency information.

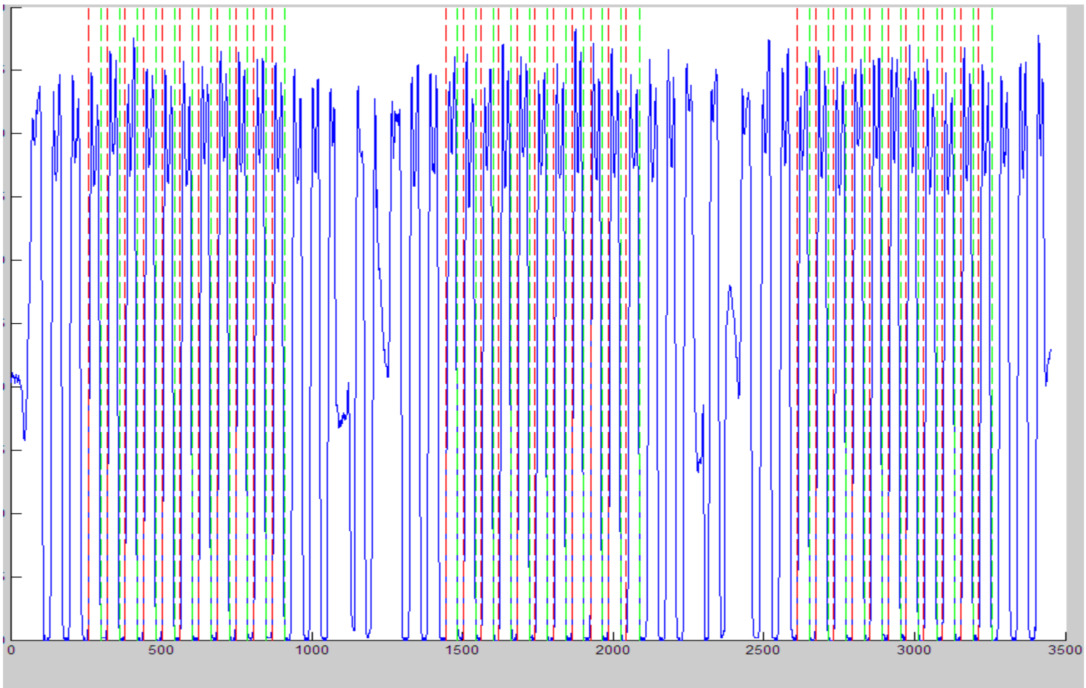

Figure 3. 2 Three trials of 10-12 steps were defined by dividing the trial into three "blocks" then selecting the individual steps using the residual threshold

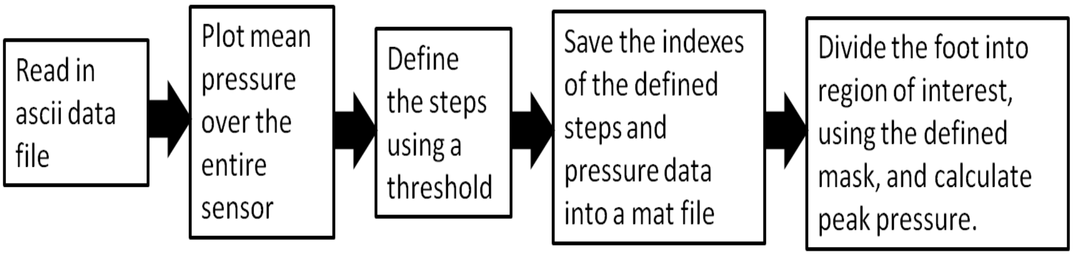

Figure 3. 3: Flow chart representing the code used to process and analyse the pressure data.

.

Once the steps were identified, a number of different variables were calculated in order to answer the four research questions. As stated in section 2.1.6 peak plantar pressure is the most common variable reported in studies comparing footwear for people with diabetes (Bus and Waaijman, 2012). Increased levels of peak pressure in people with diabetes has been long associated with plantar ulceration (Frykberg, 1998). Furthermore, peak plantar pressure provides the most value when comparing footwear for people with diabetes and the addition of reporting the pressure time integral is not needed because the differences in outcomes between these parameters does not give additional information (Bus and Waaijman, 2012). Therefore, in this current study, peak plantar pressure was used to evaluate the mean effect between the two groups and within the different design features. It was also used to quantify the inter-subject variability. In addition to relating the design features to the length of shoe or long axis, the design features were also expressed relative to the metatarsal head break. This was achieved by using the 3D footscan images and calculating the position of anatomical regions (see details below). Finally, the CoP was the calculated in order to understand how the different design features may alter the plantar loading.

3.6.4 Quantifying plantar pressure

Peak plantar pressure during the stance phase of walking was used to characterise the effect of varying the design features. This outcome was calculated for the 1st MTP joint, 2-4th MTH, the hallux, 5th MTH, and the heel regions. Regions of interest were define using the same method described in section 2.1.6 using the sensor numbers of the insoles. Peak plantar pressure was then calculated for each region and then averaged across all steps to give a single value for each region. This process was repeated for every shoe across all participants.

Throughout this project the following mask was used. The regions of interest were defined using percentages of insole length and width (Bontrager et al., 1997) (Figure 3. 5). Sensor numbers were then used to define each region-of-interest within the mask (Figure 3. 5). Using a schematic diagram of the insole with 1:1 ratio, the insole length and width was measured meaning the region of interest borders could be placed where appropriate. However, because half sensors could not be used, the borders were placed to the nearest whole sensor.

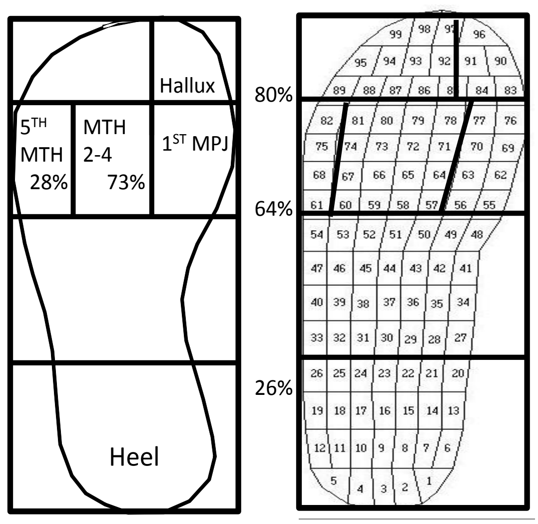

Figure 3. 4: Pedar insole layout with mask applied (Bontrager et al., 1997).

Using the defined sensor numbers for the regions-of-interest, peak pressure could then be calculated. For each subject and shoe/walking condition, the mean peak pressure across all the steps was calculated for each region-of-interest using the sensors defined the mask. Subsequently, mean peak pressure values were then calculated for each subject and for all the shoe and walking conditions (see below).

Mean peak pressure = mean(peak pressure all steps)

The mask used throughout this PhD project has been used in a number of other in-shoe pressure analysis studies (Bontrager et al., 1997, Nawoczenski et al., 1988, van Schie et al., 2000). Furthermore, the aim of this project is to reduce pressure at specific regions of the foot which have been shown to be susceptible to ulcers (Cavanagh et al., 2000, Kosiak, 1961, Veves et al., 1992). Therefore, this project will continue to use the regional analysis method because it is known that ulcers occur in these specific regions of the foot.

3.6.5 Expressing apex angle and apex positions relative to foot anatomy

To ensure that differences between individuals were not simply due to differences in the position of the foot within the shoe, footwear features were also expressed relative to the anatomy of the foot. Apex angle and position were expressed relative to the MTH break using the 3D footscan data. During data collection a 70 mm mark, measured from the heel of the shoe, was made on the long axis on the reference rocker shoe (Figure 3. 5). The distance was measured using a calliper whilst the participant was stood upright . During the analysis phase, the following specific anatomical measurements were extracted from the footscan data (Figure 3. 5 a, b, c and d).

a) Distance of the 5th MTH from the most posterior heel point
b) Distance of the 1st MTP from the posterior heel point
c) Foot width, distance between the 1st MTP and 5th MTH.
d) Distance of the lateral malleoli from the heel

- Apex position was represented as a distance from the centre of the MTH break for the 5 different configurations (50, 55, 60, 65 and 70%), these values were normalised to shoe length.

- To calculate this distance, the position of the foot on the long axis of the shoe was calculated (Figure 3. 5 g), and this value was added to the MTH centre position (Figure 3. 5 e).
- Apex angle in relation to the foot, was represented as an angle between the MTH break of the foot and the apex angle of the shoe, which was defined as a rotation from the long axis of the shoe. (Figure 3. 5 and Figure 3. 6).
- The angle of the MTH break was calculated using the foot width and the distances of the 1st MTP and 5th MTH (Figure 3. 5 and Figure 3. 6).

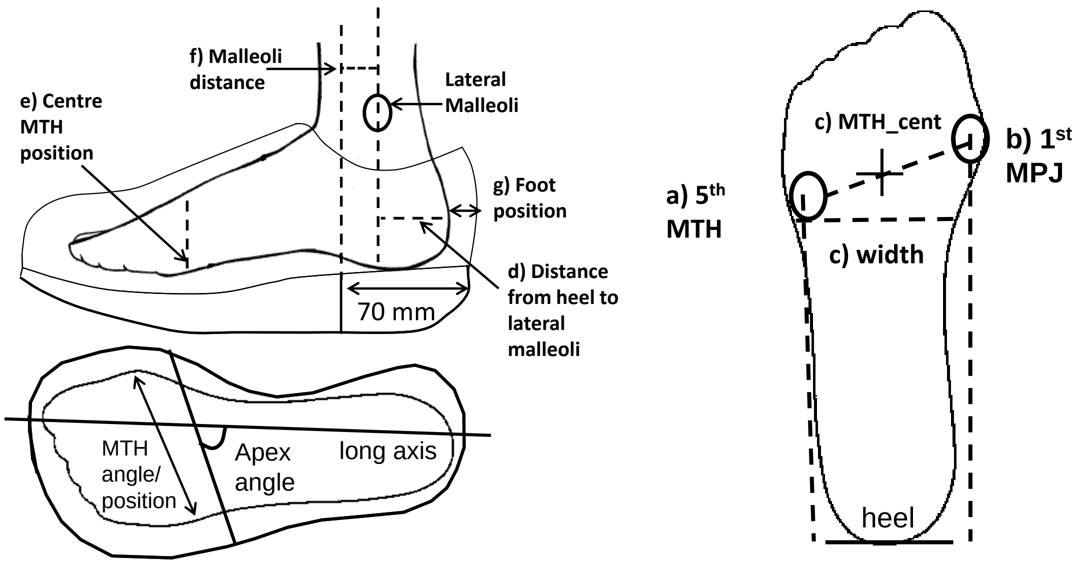

Figure 3. 5: Calculation of the foot position inside the shoe and definition of the anatomical landmarks

a) 5th MTH position (5th_pos) = distance from heel to 5th MTH

b) 1st MTP position (1st_pos) = distance from heel to 1st MPJ

c) Foot width (width) = distance between 1st_pos and 5th_pos

d) Lateral malleoli position (mall _pos) = distance from heel to lateral malleoli

e) MTH centre position (MTH_cent) = (5th_pos+ 1st_pos)/2

f) Malleoli distance (mall_dist) = 70 - mall _pos

g) Position of the foot on the shoe long axis (foot_pos) = 70 + mall_dist - mall _pos

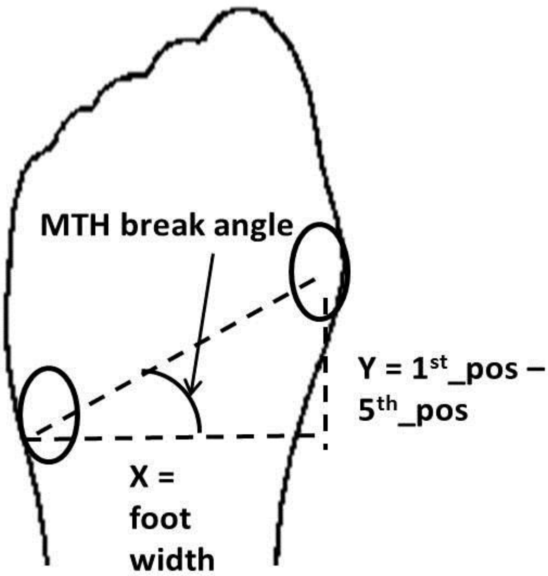

Figure 3. 6: Calculation of the MTH break angle

3.6.6 Calculating the centre of pressure

There have been a number of studies which have shown that altering the geometry of the outsole will affect the centre of pressure (Khoury et al., 2013, Xu et al., 1999). In this current study, it is possible that varying each of the three design features could influence centre of pressure in the anterior-posterior and medial-lateral domain. van Schie et al (2000) stated, "walking in the rigid shoe is possible because the shoe "tips" forward when the centre of pressure moves distal to the rocker fulcrum". Following this idea, it is possible that adjusting the location of the apex position or rocker angle size may affect the displacement or velocity of the centre of pressure in the anterior-posterior direction. Further, systematically varying the apex angle may affect the centre of pressure in the medial-lateral direction. Finally, there also may be a relationship between the centre of pressure variables and the peak plantar pressure because it has been reported that rocker soles alter the load distribution under the foot (Hutchins et al., 2009).

Centre of pressure (CoP) is defined by the average location of all the forces acting between the plantar surface of the foot and the shoe during stance phase. It is a theoretical point under the foot and is often misinterpreted as a measure of pressure (Richards, 2008). The CoP in this study was calculated by using data from the Pedar system In order to implement these calculations, a coordinate system for each Pedar insole was created by defining the most medial and posterior sensors to be the origin (zero). All X and Y coordinates were normalised (%) to the maximum width and length of the insole respectively

(Figure 3. 7). CoP for the X and Y coordinate was then calculated for all steps by multiplying each plantar pressure sample (50Hz) by the corresponding insole coordinate. An ensemble average for each subject and shoe condition was then created for analysis. A similar method to calculate the CoP using a Pedar insole sensor was reported in a study by Mao et al (2006).

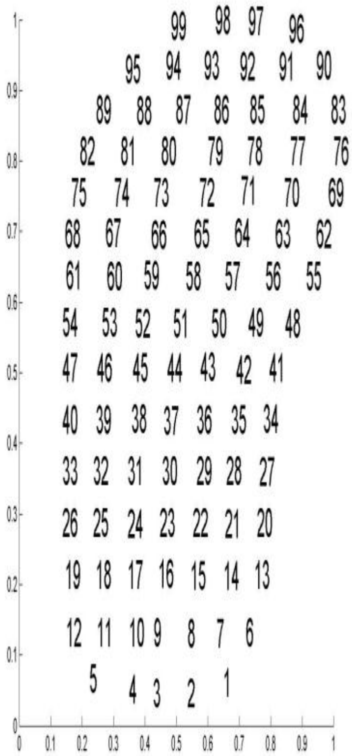

Figure 3. 7: Left side Pedar insole. Sensor number shown on the plot and corresponding x and y co-ordinates are given by the axes.

During walking the centre of pressure moves in an anterior-posterior direction (Y component) and a medial-lateral direction (X component) under each foot. By plotting the path of the CoP it is possible to gain insight into the forward progression and velocity of the progression during stance.

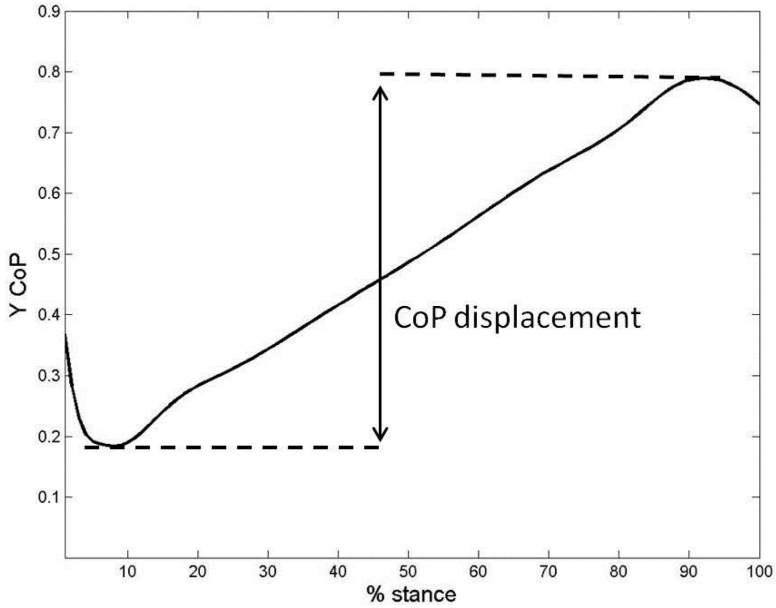

Figure 3. 8: An example plot of the CoP in the anterior-posterior direction (y component) and the calculation of the displacement.

A plot of the individual CoP components can be used to characterise the smoothness of the progression of the force during the stance phase. Specific features of these curves can be used to understand how the plantar load is distributed during walking. For example, a rapid movement of the anterior-posterior CoP from initial contact to midstance suggests an increased load over the MTH because the heel has lifted from the ground too early (Richards, 2008). In relation to rocker sole design, the anterior posterior positioning of the apex position or the size of the rocker angle may affect this component of the CoP . By comparing the anterior-posterior component of the CoP between rocker sole designs, it is possible to gain more insight into the optimal design for by comparing the CoP variables between the different shoe designs. Likewise, the medial-lateral component of the CoP may also be influenced the apex angle and this could affect the medial loading under the forefoot. In order to quantify these effects, the maximum displacements of the in CoP between the different outsole designs were compared. The CoP displacement is simply defined as the range of the curve along the y axis (Figure 3. 8).

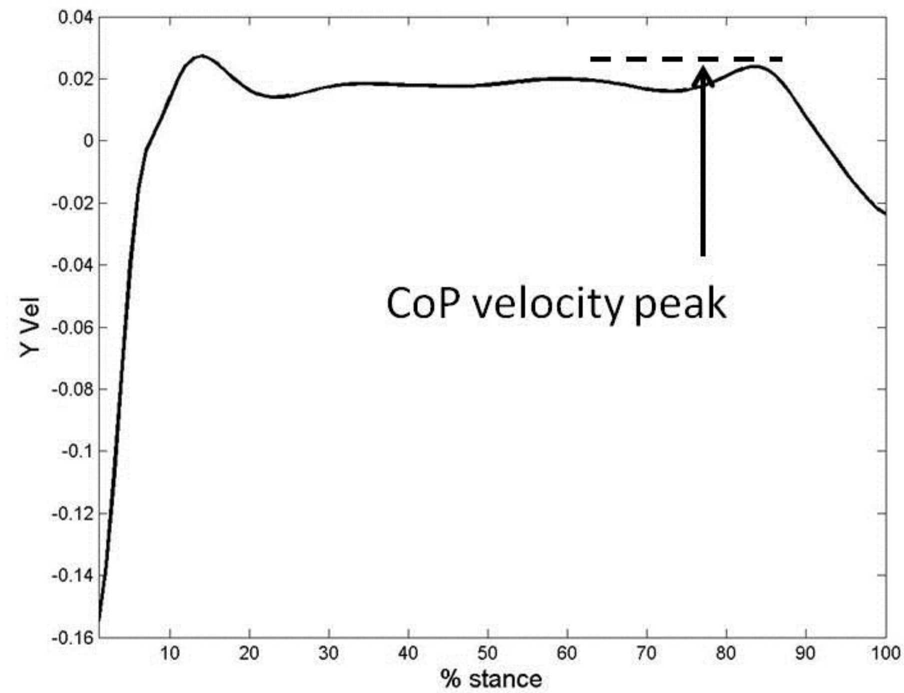

Figure 3. 9: An example plot of the CoP velocity in the anterior-posterior direction (y component) and the definition of the peak.

In addition to the CoP displacements, the velocity of the CoP was also analysed. Previous studies have shown that altering the footwear can have an effect on the CoP velocity (Cornwall and McPoil, 2000). Grundy et al (1975) reported that rigid soled shoes increase the CoP velocity under the metatarsal heads. Therefore, the CoP velocity in this study is of interest because different outsole designs may affect the CoP velocity during the last 50% of stance. The CoP velocity was calculated by calculating the gradient of the CoP between each of the samples recorded and then interpolated across the stance phase of the gait cycle. Following this, the CoP velocity during the second half of stance was used as the outcome measure (Figure 3. 9).

3.6.7 Statistical analysis

Peak pressure

ANOVA methods were used to analyse the data in this study. A between-within factors design with repeated measured was used because there was two groups, people with diabetes and healthy participants, and the within factors of the shoe conditions. A two-way repeated-measures ANOVA was used to understand mean effects, between the conditions. Separate ANOVA tests were conducted for each of the design features (containing the flexible control shoe) for each anatomical region (Table 3. 2). A significance level of p=0.05 was adjusted using a Bonferroni correction. Bonferroni, corrects the p-value by dividing it by the number of variable pairs, producing a new p value for each specific pairwise comparison test.

In order to quantify inter-subject variability, the apex angle which gave the minimum peak pressure was identified for each participant in each of the four anatomical regions. This data was then used to calculate the distribution of optimal apex angles (across individuals) for each anatomical region. This analysis was repeated for apex position and rocker angle.

Table 3. 2: Groups of shoes for the ANOVA tests

Shoes varying apex angle	**Shoes varying apex position**	**Shoes varying rocker angle**
AA1	AP1	RA1
Ref	AP2	RA2
AA3	Ref	Ref
AA4	AP4	RA4
Control	AP5	RA5
	Control	Control

Centre of pressure

The same repeated measures ANOVA method was used to analyse the CoP displacements and velocities (see above). In addition, to understand whether there was an association between CoP variables and peak plantar pressure correlation analysis were carried out between the two CoP variables and peak plantar pressure.

3.7 Results

3.7.1 Main effect for footwear design features on peak plantar pressure

There were a number of significant main effects for footwear design features. When apex angle was increased from 70° to 100° there was a corresponding reduction in pressure under the 1st MTP joint (Figure 3. 10 a), with a maximum pressure reduction of 26.29 kPa (100° apex angle) in comparison to the control shoe. However, only minimal differences were observed in the 2-4th MTH and hallux regions (Figure 3. 10 b-c) between the shoes with differing apex angles. The biggest reduction in pressure relative to the control shoe (89.10 kPa) was observed in the 2-4th MTH region (80° apex angle condition) and minimal reductions were observed in the hallux and 5th MTH regions. In contrast to the other regions, pressures increased in the heel relative to the control shoe, but again there was little change across the different apex angles. Significant main effects for design features are identified in Figure 3. 10 with significant differences between the control shoe and the individual rocker shoes reported in Table 3. 3.

Table 3. 3: Mean reductions (kPa) and significant differences between rocker sole shoes and control shoe. "R" denotes significant reduction, "I" denotes significant increase.

		1st MPJ	2nd – 4th MTH	Hallux	5th MTH	Heel
Apex angle	70°	8.47	-78.40 (R)	-1.52	-7.41 (R)	18.17 (I)
	80°	-0.28	-89.10 (R)	1.70	-10.44 (R)	22.06 (I)
	90°	-18.07 (R)	-79.83 (R)	-21.10 (R)	-0.46	27.01 (I)
	100°	-26.29 (R)	-76.77 (R)	-7.82	0.79	19.38 (I)
Apex position	50%	2.76	-79.03 (R)	9.29	-14.41 (R)	19.19 (I)
	55%	-6.38	-86.72 (R)	1.81	-14.14 (R)	19.08 (I)
	60%	-0.28	-89.10 (R)	1.70	-10.44 (R)	22.06 (I)
	65%	1.66	-69.54 (R)	-1.58	-1.85	12.33
	70%	16.63	-43.83 (R)	26.54 (I)	2.69	6.72
Rocker angle	10°	15.91	-40.40 (R)	39.93 (I)	0.56	7.12
	15°	8.11	-54.91 (R)	24.85 (I)	-1.38	9.84
	20°	-0.28	-89.10 (R)	1.70	-10.44 (R)	22.06 (I)
	25°	-4.03	-86.20 (R)	-7.59	-12.84 (R)	18.95 (I)
	30°	1.16	-87.03 (R)	-1.41	-16.07 (R)	25.72 (I)

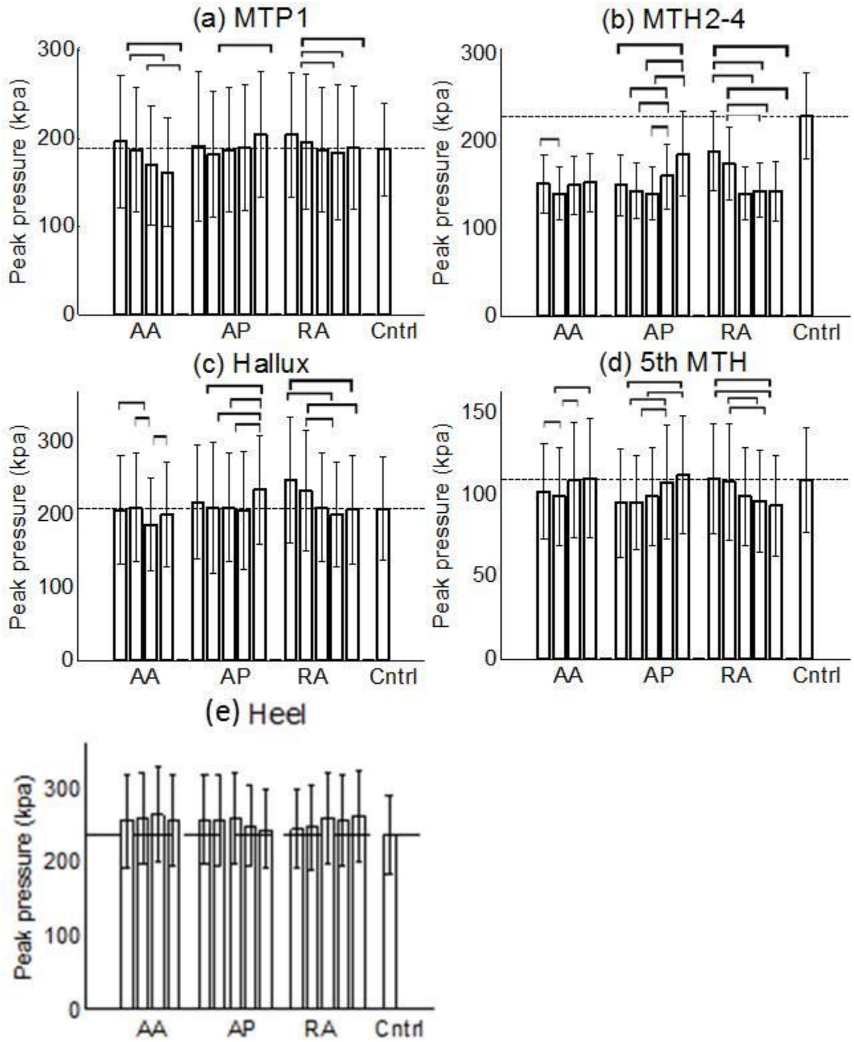

Figure 3. 10: Histograms to show mean peak pressure for varying apex angle (AA=70, 80, 90 & 100° from left to right), apex position (AP=50, 55, 60, 65 & 70%) and rocker angle (10, 15, 20, 25 & 30°) for each of the different anatomical regions (a-d). The horizontal dotted line represents the pressure from the control shoe. The horizontal lines indicating pairings on each graph indicate significant differences between footwear conditions (P<0.05 with Bonferroni correction).

When apex position was increased from 50-70% there was no main effect on peak pressure for the 1st MTP region (Figure 3.8). However, in the 2-4th MTH, hallux and 5th MTH regions, pressures were observed to be higher for the shoes with apex positions further forward in the shoe (Figure 3.8 b-d). In comparison to the control shoe, a maximum pressure reduction of 14.41 kPa was observed under the 5th MTH, however an 89.10 kPa reduction was observed under the 2-4th MTH but there was no difference in peak pressure in the hallux region between the control and any of the shoes with varying apex position (Table 3.8). In the heel region, shoes with an apex position located more posteriorly were observed to significantly increase peak pressure relative to the control shoe (Figure 3. 10 & Table 3. 3).

As rocker angle was increased from 10-30° there was a decrease in peak pressure under the 5th MTH and an initial decrease followed by a plateau under the 2-4th MTH (Figure 3.8). However, although a similar trend was observed under the 1st MTP joint, the differences between the different rocker angles were relatively small. In the hallux regions the lower angle designs actually increased pressure relative to the control shoe (Figure 3. 10 & Table 3. 3). Peak pressures were again observed to increase in the heel region when rocker angle was increased.

3.7.2 Main effect for group on peak plantar pressure

The diabetes group had increased pressures compared to the healthy group under the 2nd-4th MTH region (Figure 3. 11). However, this was only observed for the shoes varying apex angle. Increased peak plantar pressure was also shown when varying apex position and rocker angle under the 1st MTP and heel region. Furthermore, there was no main effects of group for peak plantar for the remaining regions and design features.

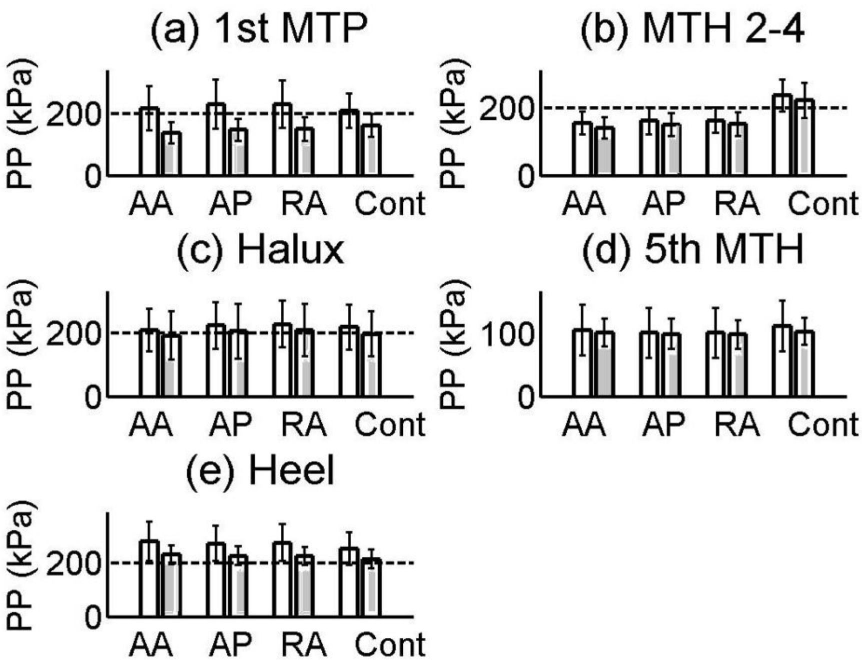

Figure 3. 11: Mean effect for group by design feature (shaded bars represent the healthy participants)

3.7.3 Group by footwear design features interaction for peak plantar pressure

Apex angle under the hallux region, was the only footwear feature to show a group by footwear feature interaction. Apart from this one interaction, the effect of varying the footwear features had the same effect for the participants with diabetes and the healthy participants (Figure 3. 12-12). For instance, the shoes varying apex angle in 1st MTP region, the lines are almost parallel because of decrease in pressure when apex angle is increased. For the 2nd -4th MTH region, there is a more complex relationship, but this is seen in both the healthy participants and people with diabetes which suggests the effect is the same between the two groups.

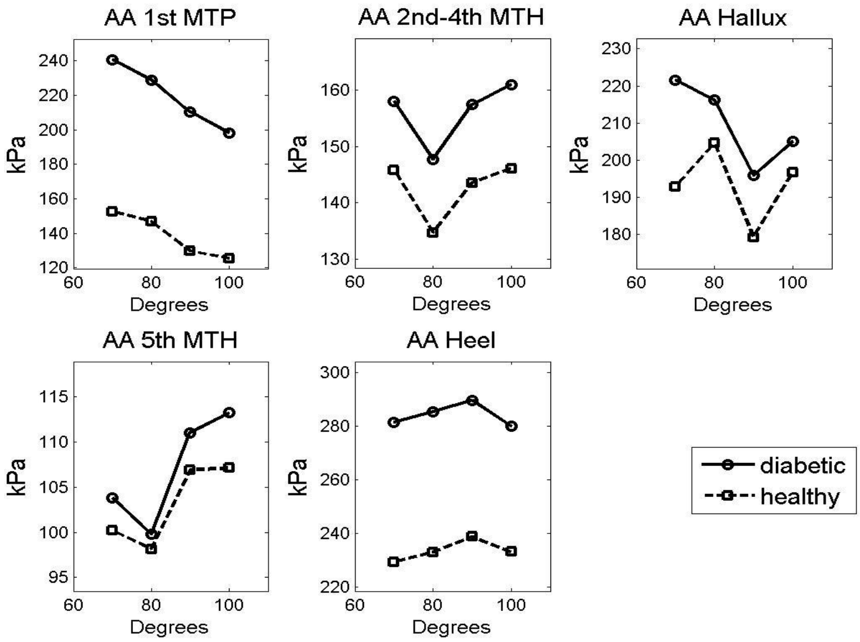

Figure 3. 12: Group by footwear feature interaction plots for the shoes varying apex angle.

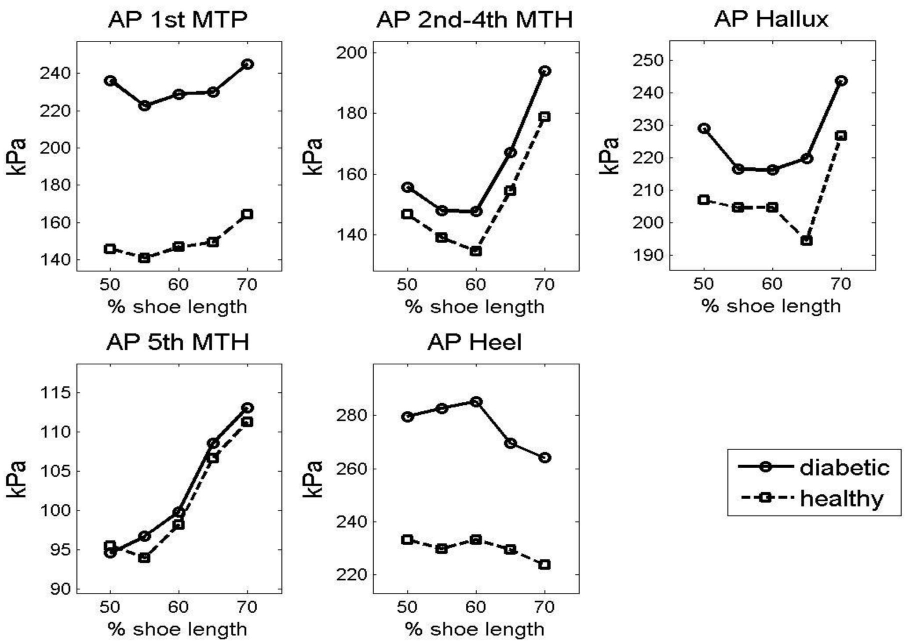

Figure 3. 13: Group by footwear feature interaction plots for the shoes varying apex position.

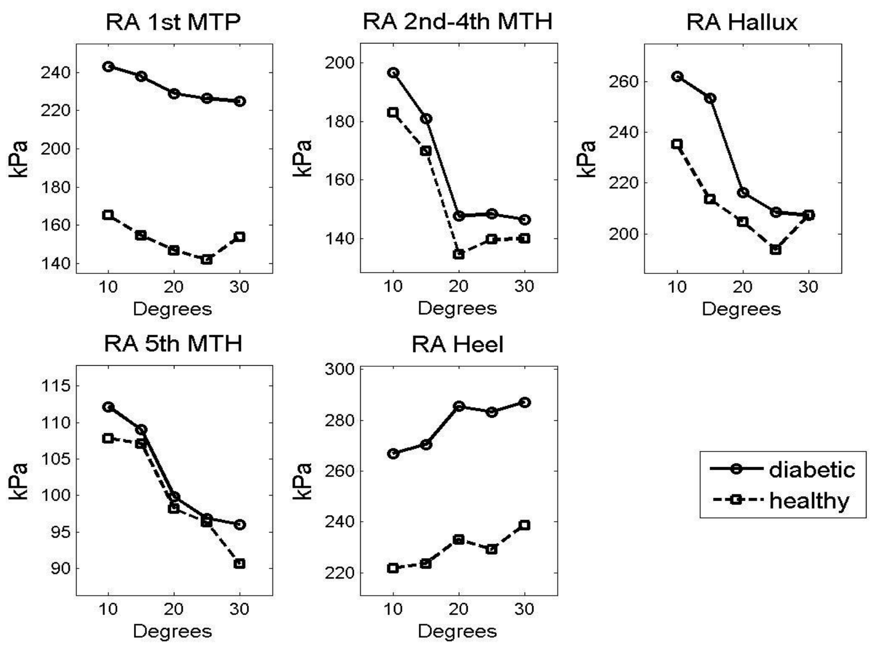

Figure 3. 14: Group by footwear feature interaction plots for the shoes varying rocker angle.

3.7.4 Inter-subject variability between different rocker sole designs

The inter-subject variability analysis was completed using a combined diabetes and healthy group because there was few group by footwear feature interactions (3.7.3). A large degree of inter-subject variability in optimal design characteristics was found across the five different anatomical regions (Figure 3. 15 a). Higher values on each figure can be used to identify the best design for apex angle, apex position and rocker angle. For the first MTP joint, the optimal apex angle was found to be either 90° or 100° for over 90% of participants (Figure 3. 15a). However, there was an equal spread of optimal apex positions. Rocker angles of 20° and above were optimal for over 80% of participants but there was no single optimal value. Optimal apex angles showed similar levels of variability when expressed relative to the foot or to the shoe (

Table 3. **4**), however, greater variability in the optimal apex position was observed when these values were expressed relative to the foot (

Table 3. **4**).

For the 2-4th MTHs, there was a clear optimal apex angle of 80° (Figure 3. 15 b). The best apex position was 60% of shoe length, however 50% and 55% were also found to be optimal in a relatively large proportion of participants studied. Optimal rocker angles were found to be either 20° or 30° with no participants having an optimal angle of 10°. Similar trends to the 1st MTP joint were observed in the relative levels of inter-subject variability for the apex angle and apex position.

The data presented in

Table 3. **4** showed that many of the rocker shoe designs actually increased pressure under the hallux and heel in comparison to a flexible control shoe. The results demonstrated that there was a relatively even distribution of optimal values for the three footwear features across these two anatomical regions (Figure 3. 15 c and d).

Optimal design values for the 5th MTH followed very similar trends to the 2-4th MTH with an optimal apex angle of 80° (Figure 3. 15 d) and optimal apex position of 50-60% for most participants. Again, rocker angles of less than 20° rarely performed well (Figure 3. 15 d). As with the previous anatomical regions, there was a similar level of variability in the optimal apex angle when expressed either relative to the shoe or to the foot. There was also slightly greater variability in the optimal apex position when this was expressed relative to the shoe (

Table 3. **4**). Finally, an apex position of 70% of shoe length and a lower rocker angle did appear to minimise the increase in pressure in the heel region.

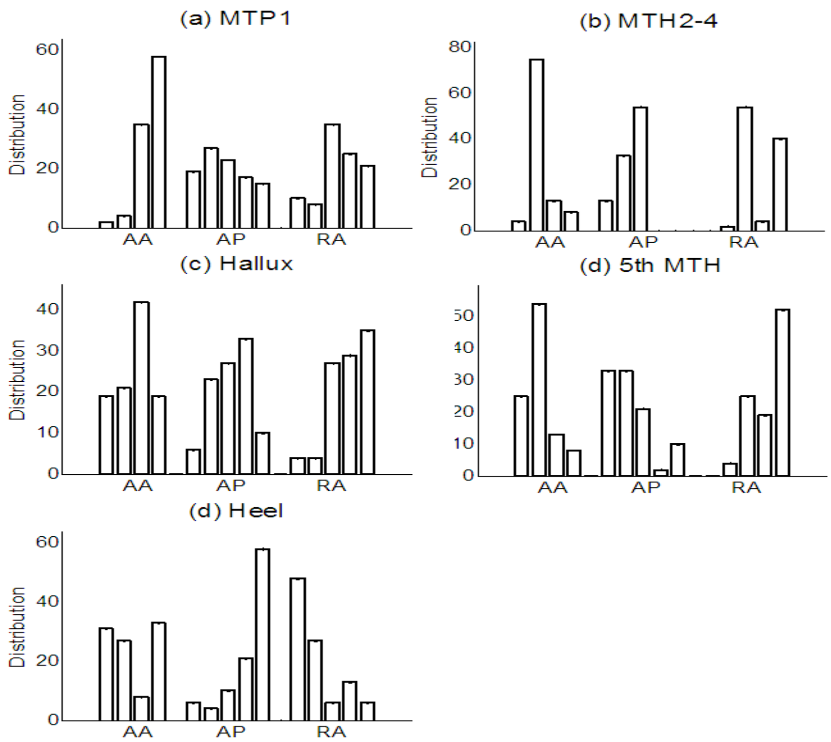

Figure 3. 15 Histograms to show the relative distribution (%) across all 48 participants of optimal apex angle (AA=70, 80, 90 & 100° from left to right), optimal apex position (AP=50, 55, 60, 65 & 70%) and optimal rocker angle (10, 15, 20, 25 & 30°) for each of the different anatomical regions (a-e).

Table 3. 4: Mean (SD) optimal values for apex angle (AA), apex position (AP) and rocker angle (RA), expressed both relative to the shoe and relative to the foot.

	1st MTP	2-4 MTH	Hallux	5th MTH	Heel
Optimal AA: rotated from long axis of shoe (degrees)	95(6.8)	82.5(6.7)	86(10.1)	80.4(8.5)	84.4(12.5)
Optimal AA: rotation from the MTH break (degrees)	18.8(6.2)	5.5(7.6)	9.8(9.4)	3.6(9.3)	7.8(14)
Optimal AP: % shoe length	59.1(6.7)	57.1(3.5)	60.9(5.5)	56.1(6.2)	66(5.9)
Optimal AP: distance from the median of the MTH break (mm/shoe length).	-17.5(25.8)	-22.7(24.7)	-11.7(29.3)	-25.3(31.2)	3.3(27.2)
Optimal RA: (degrees)	21.9(6.1)	24.1(5)	24.4(5.4)	25.9(4.8)	15.1(6.4)

3.7.5 Main effects for footwear features on CoP

Mean effect of different rocker sole designs on CoP displacements

Figure 3. 16 illustrates the medal-lateral displacement for the CoP between the shoe designs. There were a number of significant differences between the shoe designs for the maximum medial-lateral CoP displacement (X component). When apex angle was increased, there was a significant reduction in the displacement once a 90° apex angle was reached (Figure 3. 15). However, there were no significant findings when varying apex position from 50-70% of shoe length for medial-lateral displacement. However, all of the shoes displacements were significantly higher than the control shoe. When rocker angle was increased the only shoe differing from the other configurations was the shoe with a 25° angle.

Figure 3. 16 also shows how the anterior-posterior displacement for the CoP differed between the shoe designs. Increasing apex angle from 70-100° did not have any effect on the anterior-posterior displacement. In contrast, the shoes varying apex position produced significant differences when the apex position was greater than 65% of shoe length. Varying rocker angle also produced some significant findings between the different configurations. The two smaller angles of 10 and 15° showed greater maximum displacements compared to the other configurations.

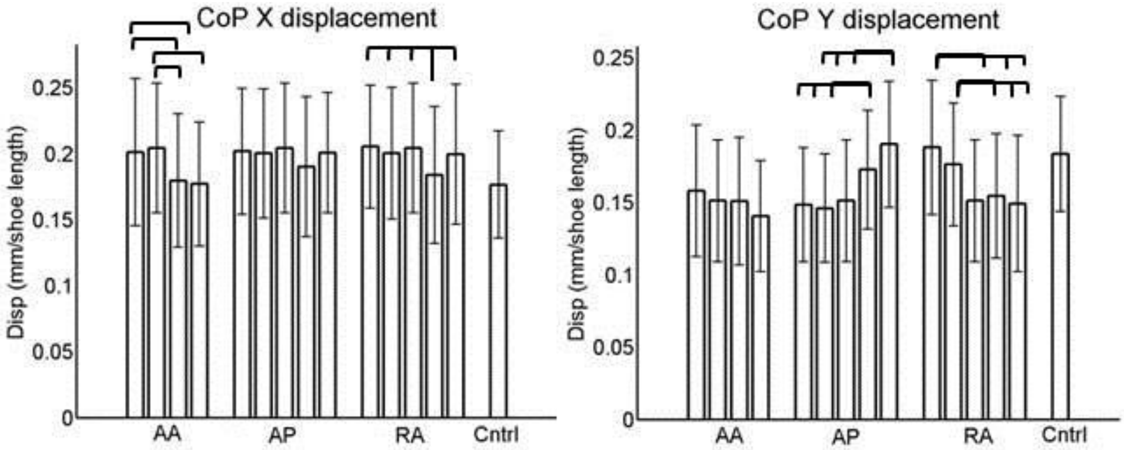

Figure 3. 16: CoP displacements for the medial-lateral (X) and anterior-posterior (Y) directions.

Mean effect of different rocker sole designs on CoP maximum velocity

Figure 3. 17 displays the maximum CoP velocities for the medial-lateral direction. Results showed significant differences between the shoe designs and the maximum CoP velocity. For the medial-lateral component, all the rocker shoes varying apex angle produced a significantly greater maximum velocity compared to the control shoe. However, there was no differences between the rocker sole configurations. In contrast, the shoes varying apex position showed differences between the rocker sole configurations. The CoP velocity for the shoes with apex positions of 65 and 70% of shoe length, were significantly smaller than the other configuration (Figure 3. 17). Finally, all of the rocker angle configurations produced maximum velocities significantly greater than the control shoe. Furthermore, the shoe with the 20° rocker angle was also significantly greater to the other rocker angle configurations.

Figure 3. 17 also illustrates the maximum CoP velocity for anterior-posterior direction. Increasing the apex angle did not have any effect on the CoP velocity, however, once again

all the rocker configurations were significantly higher than the control shoe. When apex position was varied, increasing the apex position past 65% of shoe length significantly reduced CoP velocity. Finally, increasing the rocker angle to 20° caused a mean increase in anterior-posterior velocity, however, there was no further increase seen for the 25 and 30° configurations.

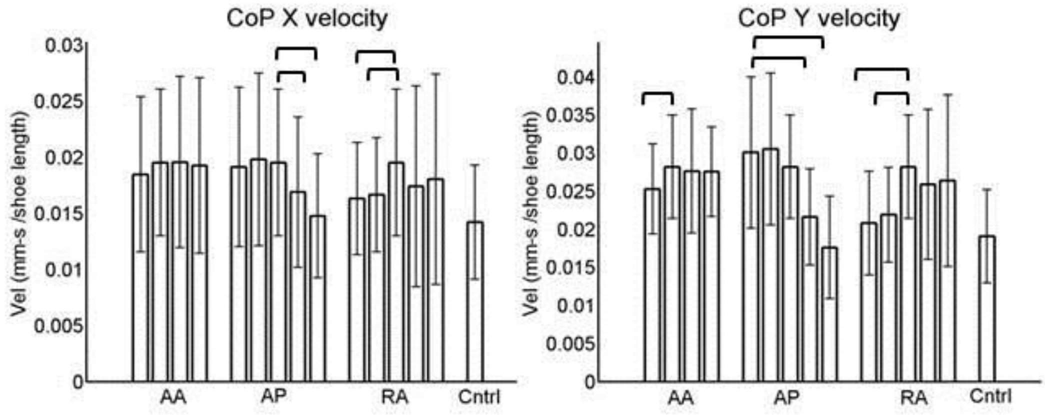

Figure 3. 17: CoP velocity for the medial-lateral (X) and anterior-posterior (Y) directions.

3.7.6 Group by footwear design features interaction for CoP

Figure 3. 18 illustrates the group by footwear features interaction plots for CoP. There was no group by footwear feature interactions for either of the CoP variables, showing that varying the different design features had a similar effect on the people with diabetes and healthy participants.

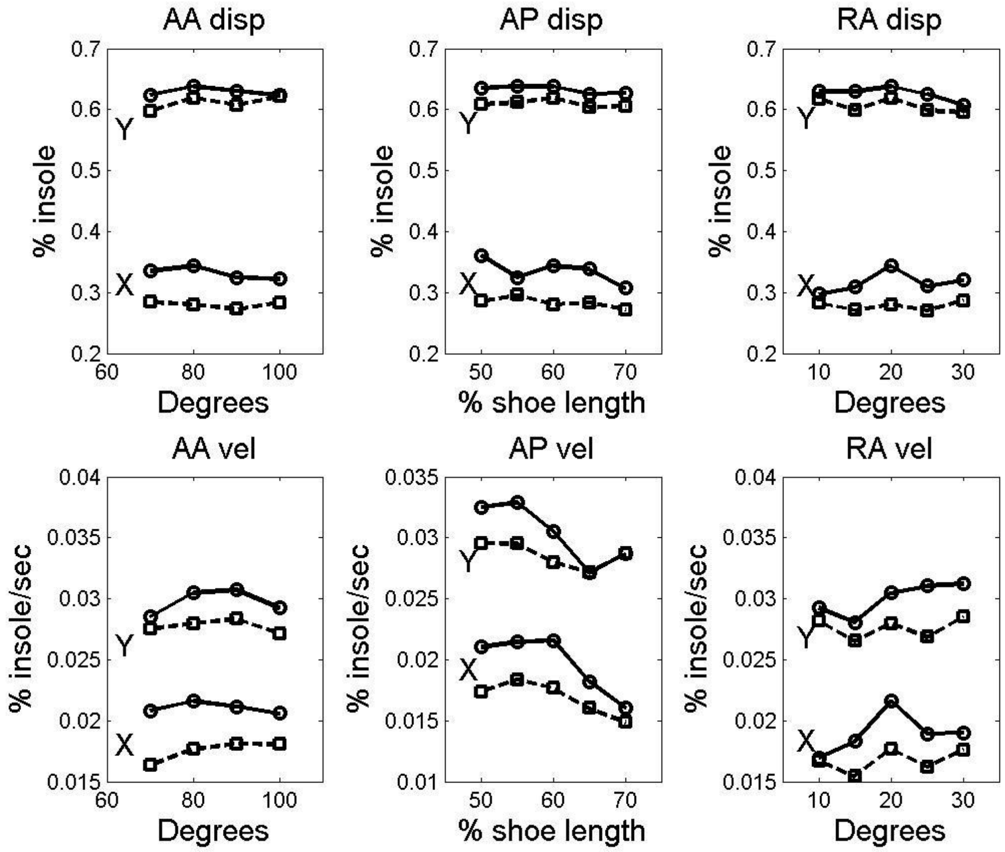

Figure 3. 18: Group by footwear feature interaction plots for the CoP variables (displacement (disp) and velocity (vel)) Diabetes = ___ , Healthy = - - - -

3.7.7 Correlation coefficient between CoP and peak plantar pressure

There were no correlations between the CoP displacement and the peak plantar pressure for any of the design features. Table 3. 5 shows the r-values for the correlation analysis between the CoP maximum velocity and peak plantar pressure. The results showed stronger a correlation between maximum velocity and peak plantar pressure under the hallux region (Table 3. 5). For the hallux region, both the medial-lateral and anterior posterior direction showed r-values above 0.5 for the 50 and 55% apex positions. Furthermore, there were also r-values >0.5 for the shoes varying rocker angle. In the medial-lateral direction, the shoe with a 25° rocker angle was the only configuration with an r-value >0.5. However, for the anterior-posterior direction the configurations of 10 and 15° both showed r-values >0.5.

Table 3. 5: R-values for CoP velocity and peak plantar pressure under the four forefoot regions

	CoP velocity X													
	Apex angle (r values)				**Apex position (r values)**					**Rocker angle (r values)**				
	70	**80**	**90**	**100**	**50**	**55**	**60**	**65**	**70**	**10**	**15**	**20**	**25**	**30**
1st MTP	0.18	0.06	0.03	0.09	0.18	0.10	0.06	0.16	0.01	0.17	0.28	0.06	0.17	0.19
2nd-4th MTH	0.02	-0.08	-0.07	-0.09	-0.11	-0.12	-0.08	0.03	-0.19	-0.12	-0.08	-0.08	-0.11	-0.16
Hallux	0.34	0.28	0.29	0.16	**0.51**	**0.54**	0.28	0.49	0.33	0.31	0.49	0.28	**0.50**	0.29
5th MTH	0.05	0.05	0.06	0.09	-0.21	-0.10	0.05	-0.09	0.00	0.00	-0.08	0.05	-0.14	-0.23
	CoP velocity Y													
1st MTP	-0.01	0.02	0.06	0.07	0.23	0.21	0.02	-0.06	-0.13	0.23	0.21	0.02	-0.06	-0.13
2nd-4th MTH	-0.09	-0.07	-0.12	-0.06	-0.22	-0.14	-0.07	-0.26	-0.28	-0.22	-0.14	-0.07	-0.26	-0.28
Hallux	0.20	0.15	0.48	0.23	**0.52**	**0.50**	0.15	0.26	0.20	**0.52**	**0.50**	0.15	0.26	0.20
5th MTH	0.03	-0.14	-0.12	-0.06	-0.45	-0.33	-0.14	-0.35	-0.17	-0.45	-0.33	-0.14	-0.35	-0.17

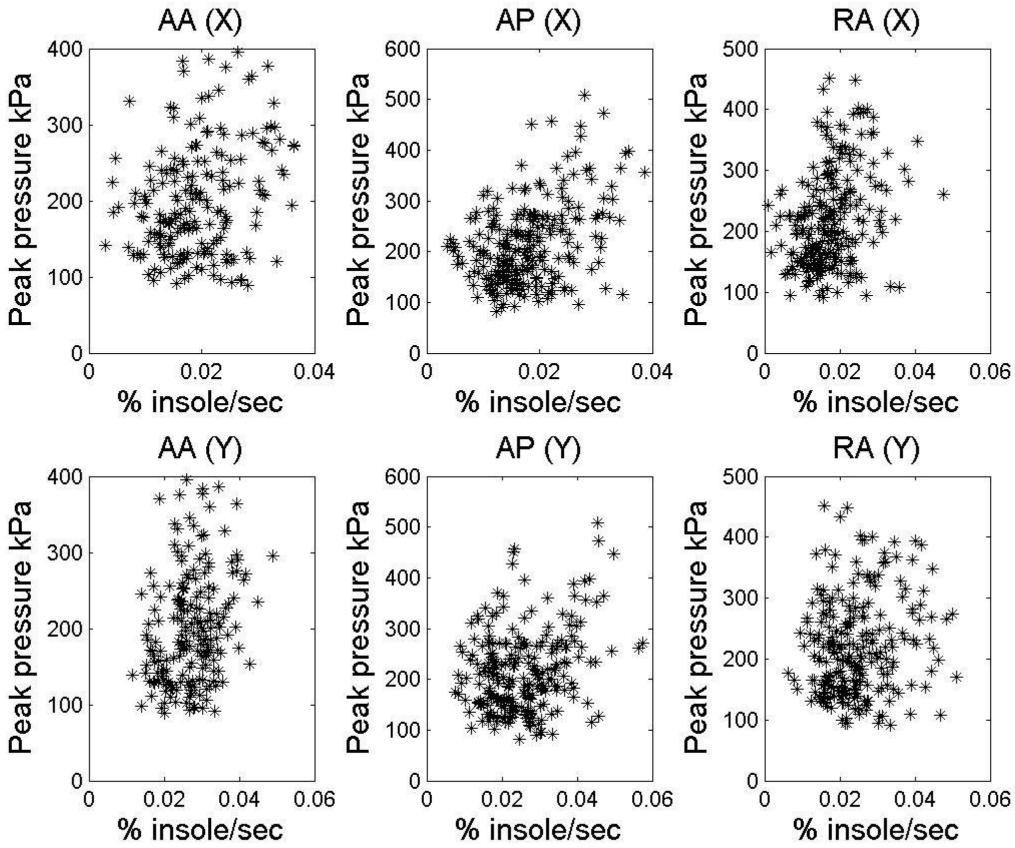

Figure 3. 19: CoP velocity scatter plot for the shoes varying apex angle (AA), apex position (AP), and rocker angle (RA).

3.8 Discussion

The aim of the study was to understand the independent effect of varying apex angle, apex position and rocker angle on plantar pressure in the curved rocker shoe. The study was designed to understand the mean effect of varying these three parameters in a cohort of low risk patients with diabetes, and to establish whether the same effects would be observed in a healthy population. The study was also designed to provide insight into whether a specific combination of the three design features would be optimal for all individuals or whether different combinations may be required for different patients. This was addressed by describing inter-subject variability for the optimal value for each of three design features. Finally, the CoP in each of the shoe conditions was analysed in order to understand how the different outsole designs alters the loading under the foot. This was achieved by comparing the CoP displacements and velocities, correlations were also performed between the CoP variables and peak plantar pressure.

The first section of the discussion will draw together the findings of the main effect of varying the design features and the inter-subject variability. Each of the three principle design features will be discussed in turn and the findings compared to current literature. Following this, the findings of the potential differences in the response to varying design features between people with diabetes and healthy participants will be presented. The implications for the future design of rocker soles will then be discussed and a brief summary presented on the recommendations for outsole designs which need further investigation (Study 2). Finally, implications of the differences in loading patterns under the foot caused by the different design features will be discussed and related to other studies which have investigated the biomechanical effects of rocker soles.

3.8.1 Understanding the effect the three principle design features have on pressure.

The first aim of Study 1 was to quantify the independent effect of each of the three principle design features which characterise a curved rocker sole. To accomplish this aim, two objectives were defined, a) quantify the main effect of the principle design features on peak plantar pressure and b) quantify the inter-subject variability between the optimal designs. Both of these results are now discussed in detail for each of the different design features in each of the different forefoot regions. The effects in heel region are also discussed after the forefoot.

Apex angle

This was the first study to investigate the effects of varying apex angle on pressure. The results showed that there was a differing effect of varying apex between the different regions of the foot. An apex angle greater than 90° will cause a significant reduction in pressure in the 1st MTP and hallux regions. The two values greater >90° were the only configuration to cause a significant reduction compared to the control shoe. Under the 2nd-4th MTH region there was a different effect because an 80° apex angle caused a significant mean reduction in pressure. However, all of the rocker configurations caused a significant reduction in pressure compared to the control shoe. This suggests that the positioning of the apex angle may not be critical in the 2^{nd}-4^{th} MTH region. For example, there was only a 10 kPa difference for the reduction of the shoe with an 80° angle, compared to the shoe with a 90° angle. The same effect was also seen in the 5th MTH region where an 80° apex angle caused a significant reduction in pressure. Overall, the pressures under the 5th MTH were much smaller compared to the other forefoot regions suggesting it may be at less risk of a plantar ulcer. This is supported by Waaijam et al (2012) who reported only 13% of ulcers occur in this region.

The inter-subject variability in optimal design also showed a different effect between the anatomical regions. Each of the forefoot regions had a large proportion of participants distributed over one of the values (Figure 3. 15). The sole with a 70° apex angle did not have a large proportion of people for which it was optimal in any of the forefoot regions, suggesting an apex angle would need to be selected between the remaining three values for optimal offloading. In the 1st MTP region, a large proportion of participants had lowest pressures for an apex angle of 100°, suggesting this would be optimal and almost all of the participants were distributed between the 90 and 100° angle. In contrast, nearly 80% of the population had the lowest pressure with an 80° angle and over 40% had the lowest pressure for the shoe with a 90° apex angle for the 2nd-4th region and hallux respectively. These results suggest that the apex angle may need to be tailored depending on the region of highest pressure. However, the mean results showed that there was an average of reduction of 74 kPa for the rocker configurations in the 2nd-4th MTH. This may be clinically sufficient in order to avoid tailoring the apex angle for this region. Very few ulcers occur in the 5th MTH but nearly half occur between 1st MTP and hallux. Significant reductions were shown once the apex angle was increased past 90° in both of the 1st MTP and hallux region, therefore, it may be possible to define a single apex angle for both of these regions.

As stated above this was the first study to evaluate the effect of varying apex angle on pressure. The majority of previous rocker sole studies use the currently prescribed configuration of 80° but a study by Kavros et al (2011) evaluated the effect of a rocker sole compared to a flat sole using an apex angle perpendicular to the long axis (90°) (Kavros et al., 2011). The results showed significant reductions in pressure between the flat sole and rocker sole for the hallux and metatarsal heads. Results from Kavros et al (2011) are similar to Study 1 because reductions in the medial forefoot were only seen in the shoes with an apex angle >90°. Another study compared the curved rocker to a control shoe using a 100° apex angle and did not report a significant reduction for the medial forefoot (Hsi et al., 2004). Hsi et al (2004) incorporated a small rocker angle (8°), however, Kavros et al (2011) incorporated a rocker angle of 5° so it is unclear why both studies did not report significant reductions for the medial forefoot. The shoe used by Kavros et al (2011) was a post-operative design, meaning it had different upper design to the shoe the conventional shoe used by Hsi et al (2004). This may explain the difference in findings.

Apex position

The results showed there was no clear optimal apex position for any of the regions. Only a minimal change was observed in pressure between the different apex position configurations under the 1st MTP (Figure 3. 10). Similar effects were seen in the other regions, however, increases in pressure were always shown in at least one of the configurations. For example, under the 1st MTP and hallux region there was a large increase in pressure with the most anterior apex position of 70% . Similarly, under the 2-4th and 5th MTH regions there was an increase in pressure when the apex position was increased past 60%. This suggests that, for the forefoot regions, there may be a mean worst apex position and to achieve an optimal pressure reduction the apex position would need to be adjusted for each individual patient. Furthermore, expressing the apex position relative to the foot did not reduce the overall inter-subject variability. The results showed that there was no mean optimal distance from the metatarsal break, suggesting that differences between subjects was not due to a different position of the foot inside the shoe. Instead, structural, such as tissue thickness (Cavanagh et al., 1997), or biomechanical variations, such as joint kinematics (Morag and Cavanagh, 1999), may account for these differences.

A number of other studies have investigated the ability of rocker shoes to reduce pressure at different anatomical points during normal walking (Brown et al., 2004, Nawoczenski et al., 1988, Praet and Louwerens, 2003, van Schie et al., 2000). Van Schie et al (2000) obtained similar findings to this study, showing that apex position may need to be adjusted on an individual by individual basis for optimal results. However, van Schie et al (2000) carried out their study on young healthy participants, and therefore because this current study reported only one group by footwear feature interaction, the results between the studies are generalizable. The study by Nawoczenski et al (1988) also evaluated the rocker outsole using a curved design. They also came to the conclusion that apex position is a major contributing factor to forefoot pressure reduction by showing it is a design feature which may need to be adjusted for each individual to achieve optimal offloading. However, in the study report by Nawoczenski et al (1988), only two values (50 and 60%) were evaluated, making comparisons with this study limited.

Rocker angle

Rocker angle was the only design feature to show a similar trend across the different regions of the forefoot. A large decrease in pressure was observed when the rocker angle was increased to 20°, however, under the 1st MTP joint the effect was smaller compared to the other forefoot regions. Furthermore, increasing the rocker angle past 20° did not reduce the peak plantar pressure. In contrast, the van Schie study (van Schie et al., 2000), reported a further reductions in pressure with rocker angles greater than 20˚, which are not prescribed in clinical practice. van Schie et al (2000) also stated that increasing rocker angle had an significant reduction in peak plantar pressure despite the position of the apex, which suggests that rocker angle has a significant effect on plantar pressure. The difference in findings may be due to the use of a curved outsole in this study compared to the traditional design which was used in the van Schie study. Furthermore, because van Schie et al (2000) only used rocker angles ranging from 20-30˚, this study provides a better understanding of varying rocker angle because smaller angles of 10 and 15˚ were also evaluated along with angles greater than 20˚. Finally, the study by Nawoczenski et al (1988) evaluated the effect degree of curvature, using a single rocker angle (20˚). However, a smaller degree of curvature (60 or

75% of shoe length) performed better than the larger radius (125%) as it delays the end of the shoe coming into contact the ground, a similar mechanism to that of a large rocker angle (Hutchins et al., 2009).

As stated in section 2.2.5, rocker angle is the only design feature will strongly influence a patient's perception of the shoe aesthetics. To increase the size of the rocker angle it is necessary to increase the height of heel, e.g. a rocker shoe with a 30° rocker angle will need a heel height of approximately 5cm (Figure 3. 20). Our findings , along with other studies, demonstrate that larger rocker angles (>20°) significantly reduce forefoot plantar pressure (Chapman et al., 2013, van Schie et al., 2000). However, people with diabetes regularly make choices about footwear based on aesthetic judgement (Nawoczenski et al., 1988) (Knowles and Boulton, 1996) and may not accept a shoe with a thick outsole. It is therefore very important to understand how to design shoes and maintain aesthetic appeal. This is especially true for those who would be considered low risk and who may be using the footwear in a preventative capacity. Results from this current study showed that there was no mean difference between rocker angles greater than 20°. However, there was a significant reduction between the sole with a 15° angle and the sole with a 20° angle (1st MTP region). In this study, only a small number of apex angle and apex position combinations were investigated. Given this, it is not known whether a sufficient amount of reduction can be achieved using a 15° rocker angle. These finding suggest that it may not be necessary to evaluate rocker angles greater than 20° further. However, rocker angles of 15 and 20° require additional investigation.

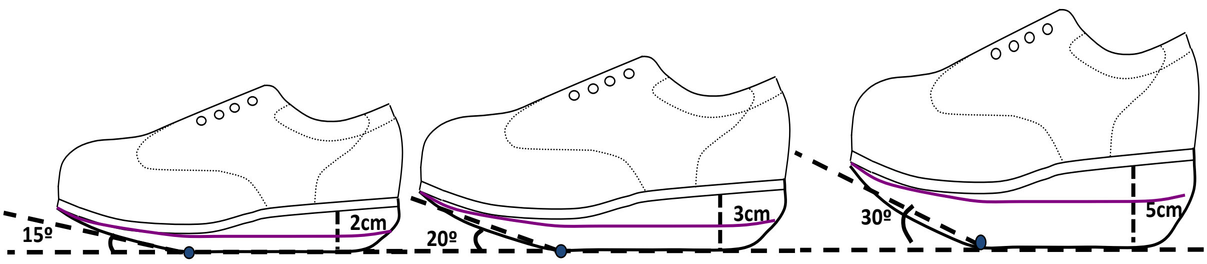

Figure 3. 20: The increase in heel height caused by increasing the rocker angle.

The reductions in pressure between the rocker shoes and the control shoe were not as large in this current study compared to the results by van Schie et al (2000). This finding may also be associated by this study using a curved design sole compared to a traditional style rocker sole used in the study by van Schie et al (2000). A traditional rocker outsole has been shown to be more effective at reducing forefoot pressures compared to the curved rocker sole (Nawoczenski et al., 1988). Additionally, other studies have compared the rocker soles to an oxford-style shoe (Brown et al., 2004, Praet and Louwerens, 2003, van Schie et al., 2000), which is known to create larger pressures than a flexible shoe (Perry et al., 1995). It is already known that trainers are more effective at reducing peak plantar pressure compared to oxford-style shoes (Lavery et al., 1997). In this study we used a control shoe with a flexible sole (similar to a trainer) in order to test whether the curved rocker design could perform better than a simple flexible shoe. However, our results demonstrate that, provided that design features are chosen correctly, the curved rocker design can significantly reduce pressures in comparison to a flexible shoe.

Heel region for all the design features

There was very little difference between the plantar pressures for any of the rocker shoes for the heel region. This was seen across all of the design features. The only noticeable difference was there was an increase in pressure between eight of the rocker soles and the control shoe. This may be associated with the basic mechanism of the rocker sole redistributing the force under the foot away from the forefoot to the heel. The inter-subject variability for this region showed that the worst configurations for apex position and rocker angle for the forefoot regions were shown to be optimal for a large proportion of the participants. This could also be associated with the pressures being increased in the heel region compared to forefoot regions.

3.8.2 The difference in the effect of outsole design on people with diabetes and healthy participants

The results from this study showed that the effect of varying the three design features was the same for healthy participants and people with diabetes. This suggests that results from previous studies, which have tested outsole configurations using healthy participants, such as van Schie et al (2000) and Nawoczenski et al (1988), may be extrapolated and used to inform design choices for shoes for people with diabetes. However, the people with diabetes in Study 1 were classed as low risk (diagnosed with diabetes but no evidence of neuropathy).

Therefore, healthy pressure data can only be used to guide on the design for this specific population. It is well known that factors associated with diabetes, such as tissue changes, reduced joint motion, and neuropathy are more common in people who have suffered from diabetes for a longer duration of time (Oyibo et al., 2001a). Therefore, results from healthy data cannot yet be applied to people with evidence of neuropathy because the outsole may have a different effect due to these factors.

3.8.3 Implications for the future design of the curved rocker sole

Study 1 was the first phase of a two phase approach, to improve the design of the rocker soled shoe. Implications with regards to the independent effect of each of the design features could be made in Study 1, however, it was not possible to cover all the possible combinations of design features because of the sheer number of shoes this would require. The results of Study 1 were used to inform the choice of rocker sole designs used in the subsequent study (Study 2, Chapter 4). The aim of this study was to investigate both the independent effect and the interactions between rocker design features and therefore it was necessary to focus on a limited range of design features.

Apex angle

From the literature, it is evident that plantar ulcers are more common in the 1st MTP and hallux regions (Waaijman et al., 2012). Study 1 supported this by reporting higher pressures in these regions compared to the 5th MTH. Studies have shown that very few plantar ulcers occur at the 5th MTH, therefore it is may not be as important to select features to minimise pressure under this region (Waaijman et al., 2012). This study also showed that varying the apex angle had very little effect in the 2nd-4th MTH region. However, each of the rocker configurations with varying apex angle did result in a significant reduction in pressure compared to the control shoe. These results suggest that it may not crucial to adjust the apex angle in this region. Instead, apex angle could be selected to minimise pressure in the other forefoot regions..

The results showed that, in both the 1st MTP and hallux regions, apex angles of 90° and 100° lead to the lowest pressures [fig ref]. However, although in the 1st MTP region, the absolute minimum pressure was observed with the 100° angle, under the hallux, pressure was at a minimum with the 90° apex angle. Taken together these results show that apex angle should be 90° or above to reduce pressure under these two region. However, it is also feasible that a 95° apex angle would be an appropriate compromise which would lead to reduced pressures in both regions.

As stated in section 2.1.1, current evidence suggests that if footwear can be used to reduce pressures below 200 kPa, then this may lead to a reduced chance of developing an ulcer. As explain above, the results of this study suggest that an apex angle of 95° may lead to reduced pressures. However, definite recommendations on this apex angle cannot be made until it has been tested with other apex positions and rocker angles. This idea is explored further in Study 2. However, the results from this study suggest that the traditional apex angle of 80° will lead to pressures similar to that of a flexible a control shoe in the 1st MTP and hallux region. Thus further work is essential to confirm the efficacy of rocker shoes incorporating apex angles of 90° or greater.

Apex position

The results of this study show that it is possible to reduce pressure under the high risk forefoot regions (1st MTP and hallux) with one apex angle (95°). Furthermore, it may be appropriate to fix the apex angle for all individuals to achieve optimal offloading. However, the results of this study suggest that it may not be possible to achieve optimal offloading across all participants using fixed values for the remaining two footwear features (apex position and rocker angle).

The next stage of the investigation (Study 2) focused on evaluating different apex positions and rocker angles with the proposed apex angle of 95°. It is clear from the previous literature, and from this study, that apex position is a design feature which can results in a large amount of inter-subject variability in pressure (Chapman et al., 2013, van Schie et al., 2000). Biomechanically, there are a number of hypothesis why this may be the case. However, both of the studies by van Schie et al (2000) and Nawoczenski et al (1988), and this current study have only evaluated the effect of apex position in combination with one apex angle (80°). Therefore, it is still not clear if it may be possible to reduce pressure sufficiently using an appropriately selected apex position in conjunctions with an optimal apex angle.. This Study was able to define a range of apex positions which may prove effective with the proposed apex angle of 95° and this range is evaluated further in Study 2 (Chapter 4).

Rocker angle

Results from this study show that rocker angle also needs further investigation. In this current study, rocker angle was only evaluated using one apex position (60%). Apex position has been established as the design feature with the most inter-subject variability. Therefore a large proportion of the participants did not walk in the shoes with 15° and 20° rocker angles in combination with their optimal apex position. Additionally, all shoes with 10, 15, 25 and 30° rocker angles had an apex angle of 80°, which has been shown to be the poorest configuration for the medial forefoot regions. It is possible that, by selecting a more appropriate apex angle and apex position, it may be possible to achieve acceptable offloading with a 15° rocker angle with. As explained above, this would have significant implications for the footwear design sector, as the smaller rocker angle of 15° would more acceptable to patients, because the heel height is approximately 1cm less compared to a shoe with a 20° angle (Figure 3. 20). Therefore, the combined effect of apex position and rocker angle needs further investigation, and is the focus in Study 2.

The overall findings suggested that rocker soles may need to be individually adjusted for optimal offloading. Large reductions compared to the control shoe were shown for all the rocker configurations under the 2nd-4th MTH. This suggests that under this region, the basic mechanism of a rocker sole is sufficient to reduce pressure and adjusting the position of the apex only results in a minimal improvement in offloading. However, for the 1st MTP and hallux regions, there were fewer reductions between the rocker conditions and the control shoe. The hallux region even showed increases for some of the configurations. Therefore, a rocker sole may need to be tailored for these two regions because most configurations appears to reduce pressure in the 2nd – 4th MTH region.

Future research for rocker soled shoes

There are a number of ways this study could influence future research. No research to date has examined the effectiveness of footwear to prevent ulceration (Healy et al., 2013). A future study could use a rocker sole with the new apex angle and evaluate its effectiveness to prevent ulceration using a prospective design. However, this type of prospective study can be difficult to design and implement. The population of people with diabetes must be selected carefully. It may not be practically feasible to follow someone from initial diagnosis until they developed an ulcer. Therefore, patients who have risk factors including neuropathy and a long duration of the illness, would need to be recruited. Prior to a prospective study being undertaken, the effect of rocker outsole configuration needs to be evaluated on people with diabetes with evidence of neuropathy in a laboratory setting.

Future research could also measure in-shoe plantar pressure during daily life activities. Study 1 evaluated the effect of rocker outsole design in a laboratory setting, walking in a straight line over level ground. To evaluate the effect of different design configurations, this method is used because all other factors, such as walking velocity and surface, need to be controlled. However, it has been questioned whether these types of data represent plantar pressures during everyday activities (Guldemond et al., 2007a). It would be of interest to collect pressure data in a non-laboratory setting. This could be achieved in two ways. Firstly in-shoe pressure could be collected in a controlled environment whilst the participants performed tasks other than walking in a straight line including tasks such as walking on an incline of decline, walking on different surfaces, and a Up and Go test (Guldemond et al., 2007a).

In-shoe pressures could also be collected outside the laboratory. Technology now exists which allows for plantar pressure to be measured during daily activities and can allow 20 hours of measurement (Saito et al., 2011, AbuFaraj et al., 1997). Furthermore, these devices can be inserted into the shoe by the participant and have a wireless transmission which allows for normal gait. Once the design of the rocker soled shoe has been fully explored and optimised, it would be interesting to understand whether the outsole design had the same effect in a non-laboratory setting. Before such a study could be undertaken, the rocker sole needs further evaluation. Study 1 has identified that it may be appropriate to fix apex angle for all individuals to achieve acceptable offloading. However, different combinations of rocker angle and apex position need to evaluated to confirm if a one-design-suits-all approach can be adopted, or if the configuration needs to be adjusted for each individual. This issue is explored further in Study 2.

3.8.4 Plantar loading when varying the three different design features

A number of studies have evaluated the effect of rocker sole design on different biomechanical variables (Long et al., 2007, Myers et al., 2006, Van Bogart et al., 2005, Wu et al., 2004). However, the majority of these studies only used a single rocker sole design which limits the comparisons with this current study. Temporal parameters such as step length have been shown to be reduced due to the addition of rocker soles (Mueller et al., 1994). For example Mueller et al reported an 11% reduction in step length with the addition of a rocker sole.

Hypotheses for CoP

The function of the rocker sole is to rock the foot from heel strike to toe-off, this alters the motion and force distribution patterns (Hutchins et al., 2009). Furthermore, the rocking action occurs when the CoP passes over the rocker axis of the shoe (apex position) (van Schie et al., 2000). Given this mechanism a number of hypothesises were made with regards to the effect of specific design features on CoP variables. Firstly, it was hypothesised that apex angle would affect the CoP displacement and velocity in the medial-lateral direction. Secondly, it was also hypothesised that varying the apex position and rocker angle would affect the CoP displacement and velocity in the anterior-posterior direction.

Findings for CoP in relation to sole design

Medial/lateral

The results showed that there was a decrease in the medial-lateral displacement when apex angle was increased. Increasing the apex angle to 90˚ caused a significant reduction in the medial-lateral displacement. The main effects of medial-lateral displacement was similar to the trend reported for apex angle and peak plantar pressure. Choosing an apex angle which shifts the CoP to a more lateral position prior to toe off may be associated with increased plantar pressure under the 1st MTP and hallux. However, the correlation analysis between the peak plantar pressure and the maximum displacements for the medial-lateral direction was weak. The weak correlations may have been associated with other factors which affect peak plantar pressure which were not measured. For example, Morag et al (1999) reported that tissue thickness, gastrocnemius muscle activity, and specific joint motions can affect peak plantar pressure (Morag and Cavanagh, 1999). Increasing apex position and rocker angle had a minimal effect on the medial-lateral displacement which supports the hypothesis.

Increasing the apex angle did not have an effect on the medial-lateral velocity, which does not support our proposed hypothesis. However, there was a significant effect when increasing the apex position. This suggests that the positioning of the apex heavily influences the velocity at which the forces move under the foot, irrespective of the direction. Furthermore, rocker angle also has a similar association with the CoP velocity. Increasing the rocker angle produced a significant increase in the velocity for the medial-lateral direction. Both of these findings do not support the hypothesis that only the apex angle would influence the CoP in the medial-lateral direction.

Anterior/posterior

Increasing the apex angle had no effect on either of the CoP variables in the anterior-posterior direction. However, increasing apex position and rocker angle both caused an increase in the displacement. Therefore, increasing apex position and rocker angle can be associated with the manipulation of the force in the anterior-posterior direction. However, once again there was not a strong correlation for either apex position or rocker angle and displacement.

The apex position and rocker angle also appears to change the velocity at which the force moves posteriorly during walking. Results showed a significant decrease in CoP velocity when apex position increased. This decrease in velocity maybe associated with apex position being in front of the MTH break which delays the rocking motion. van Schie et al (2000) reported a similar finding for a shoe with a 65% apex position. An example for two subjects showed that some people will continue to rock forward from heel strike to toe off, while others "dwell" once the shoe is horizontal to the ground. It is the latter concept which may be associated with a reduction in the CoP velocity. When rocker angle was increased there was an increase in the CoP velocity, therefore, a larger rocker angle may cause a continuing rocking action from heel strike to toe-off, increasing the maximum CoP velocity.

Much stronger correlations values were shown between the peak pressure and the CoP velocity compared the pressure and displacement. However, the highest of these correlations was only 0.54 which would only be described as a moderate correlation (Taylor, 1990). As explained above, the same conclusion can be drawn that there are other factors that affect peak plantar pressure which were not measured in this current study.

This is the only known study to analyse CoP and rocker shoe design systematically therefore, a comparison of literature is limited. However, similar studies have also shown that footwear can manipulate the CoP through footwear geometry (Grundy et al., 1975, Khoury et al., 2013, Lidtke et al., 2010). Grundy et al (1975) reported that rigid soles increased the CoP under the metatarsal heads. Similarly, this current study showed that some of the rocker soled shoes produce an increase in CoP velocity compared to the control shoe.

The use of CoP variables in Study 1 did not fully explain the mechanism of the different rocker sole designs. Therefore, it would be of interest to investigate the effect different designs have on foot kinematics. It is not fully known how the foot is moving when walking in a rocker soled shoe. Other studies have used modelling techniques to quantify the movement of the foot inside different types of footwear (Arnold and Bishop, 2012, Genova and Gross, 2000). Similar techniques could be applied in a rocker sole study. However, such a study would need to model the 1st MTP joint because rocker soles are designed to reduce the movement of this joint. The 1st MTP may be affected differently by different rocker sole designs (e.g. positioning of the apex).

3.8.5 Limitations

There are three limitations to Study 1. Firstly, in order to test the relatively large numbers of shoes used in this study, participants were only able to spend a few minutes to become accustomed to each of the different designs. However, work carried out in the laboratory showed that peak pressures in a range of different shoes stabilised after a very short amount of time (Melvin et al 2014, manuscript in review)). Therefore, we believe the data collected is a valid representation of plantar pressure patterns.

The second limitation is that we did not study the interaction between the different design features. For example, our study quantified the effect of varying apex angle when apex position was fixed at 60% and rocker angle is fixed at 20°. However, we did not study this effect for a range of different apex positions and rocker angles. In order to study all possible interactions it would be necessary to use a very large number of shoes and therefore experimentally impractical. Furthermore, because the results from this study suggest apex angle can be fixed for all individuals, Study 2 was required to evaluate different combinations of apex position and rocker angle to continue to develop the understanding of rocker soles.

Finally, low risk patients with diabetes were recruited for this study who did not have foot deformity or serious neuropathy.This group of patients with diabetes were selected because the focus of the project is to improve footwear for people in the early stages of diabetes. However, it would also be clinically relevant to evaluate the effectiveness of the curved rocker outsole on people with neuropathy.

3.8.6 Conclusions

This study has provided a thorough understanding of the effect of the three principle design features on pressure. The results of this study have been used to make a small number of recommendations for specific values for the design features of the curved rocker shoes. Interpretation of the data suggests that, in order to minimise pressure at the high risk anatomical locations, apex position should be chosen on an individual by individual basis. However, the results also suggest that apex angle can be fixed at 95° in order to achieve offloading across the high-risk forefoot regions. The findings with regards to rocker angle showed that there was no further improvement when the angle was increased past 20°. Furthermore, there was a decrease in pressure when the rocker angle was increased from 15 to 20°. Therefore, because an outsole with a smaller rocker angle would be more acceptable to people with diabetes, more investigation is required into the combine effect of different apex positions, in shoes with an apex angle of 95° and rocker angles of 15° and 20.

Finally, despite significant differences being reported between the CoP velocity variables, there was not a strong correlation between these and the design features. Therefore, CoP variables do not fully explain the mechanism of a rocker soled shoe and varying the design features which suggests that kinematic and kinetic analysis is needed in order to fully understand the mechanism of different rocker sole designs.

Chapter 4: (Study 2) The effect of varying rocker angle and apex position in rocker soled shoes

4.1 Introduction

Study 1 investigated the independent effect each of the three design features which characterise a rocker sole (Chapman et al., 2013). This was accomplished by using a systematic approach which evaluated a range of values for each design feature, whilst the other two design features remained constant. For instance, apex position was only varied using one rocker angle and vice-versa. With this approach, it was not possible to quantify the effect of varying more than one design feature at a time on plantar pressure. For example, it is not known what the effect of varying both the apex position and rocker angle would have on plantar pressure. Therefore, Study 2 was designed to address this issue.

The results presented in Study 1 provided important insight into the effect of individually varying each of the three principal design features (Chapman et al., 2013). Although the study did not quantify the interactions between the different design features, the results showed very consistent pressure reductions in the forefoot regions in shoes with an apex angle of 90° and 100°. Varying the apex angle had very little effect in the 2nd-4th MTH region. However, most of the rocker configurations in Study 1 showed a significant reduction in pressure when compared to the control shoe. These finding suggest that any apex angle 70°, 80°, 90° or 100° would provide sufficient offloading in the 2-4th MTH region and therefore an apex angle could be chosen to optimise offloading in other high risk regions. In the 1st MTP region the largest mean reduction in pressure was observed with the 100°. In contrast the best position was 90° for the hallux. Therefore to achieve a compromise for these two regions, it was suggested that this study (Study 2) should focus on rocker outsole designed with a 95° apex angle.

Study 1 showed that there was no single best apex position which minimised pressure across all subjects. This suggests that it may be necessary to adjust the apex position on an individual-by-individual basis. In Study 2, a range of four apex positions were chosen and evaluated in combination with different rocker angles. The range of apex positions was reduced slightly from Study 1 because the results showed that, in the medial forefoot regions, there was an increase in pressure for the shoe with a 70% apex position. The results also showed a slight increase in pressure for the shoe with a 50% apex position. Therefore, the apex positions chosen for this study (Study 2), ranged between 52% and 67% of shoe length.

Study 1 also showed that there was a consistent effect of increasing rocker angle from 15° to 20°. This design feature can negatively influence a patient's perception of footwear design because of the increase in heel height required to increase the rocker angle (Nawoczenski et al., 1988). Therefore, it is important to keep the rocker angle as low as possible, whilst maintaining the pressure reducing effects of the shoe. In the previous study, rocker angles greater than 20° showed no further improvement over the 20° condition. However, there was a significant increase in pressure between a 15° and 20° rocker angle. Furthermore, the rocker configurations tested in Study 1 were only evaluated using an 80° apex angle. Given this apparent threshold between a 15° and 20° rocker angle and the lack of testing of lower rocker angles with varying apex positions, further comparisons between shoes with 15° and 20° rocker angles incorporating a range of different apex positions is required. This will allow us to understand if sufficient offloading can be achieved in footwear which would be aesthetically acceptable to patients.

This study (Study 2) also sought to develop a prescription method using in-shoe plantar pressure measurements. Before such a method can be defined, it must be established whether a one-design-suits all approach can be adopted. The results of Study 1 demonstrated a large degree of inter-subject variability in optimal rocker shoe design. Therefore it may be necessary for people to try on a large range of different designs in order to identify the optimal design. This approach is unlikely to be feasible in a shop/clinic due to the time consuming nature of pressure measurements. It is important to understand how the use of a mean optimal design (best compromise between individuals) compares to an individually chosen design, across a cohort of individuals with diabetes. A recent study suggested that people who exhibit plantar pressures below a specific threshold (200 kPa) are less likely to develop an ulcer (Owings et al., 2009a). Given this important information, a 200 kPa threshold was used to quantify how many people would be at risk of ulceration in a mean optimal shoe compared to their individually optimised design.

4.2 Study 2 research question

What is the effect of varying rocker angle in combination with apex position?

4.3 Study 2 aims and objectives

Aims

1. Establish whether the effects of the two footwear design features are the same for patients with diabetes and healthy participants.
2. Understand the effect of varying apex position in combination with rocker angle
3. Understand whether a pre-defined rocker sole can be used for all participants or does each person need an individual design.

Objectives

1. Evaluate the group interaction for patients with diabetes and healthy participants and evaluate the difference in peak pressures.
2. Quantify the effect of varying apex position (52-67% of shoe length) and rocker angle (15° and 20°).
3. a) Quantify the difference in pressure of the rocker designs with a flexible control shoe.
   b) Identify the mean optimal design, (combination of rocker angle and apex position)
   c) Establish the proportion of individuals for which there is acceptable pressure offloading with the, control shoe, mean optimal rocker sole design, and individual optimal rocker sole design.
   d) Establish the proportion of individuals for which the 15° rocker angle would give sufficient pressure offloading.

4.4 Design

A repeated measures design was chosen for this study, and due to the design of this study, the analysis was altered depending on the research question. For instance, a two-way within-factors design was chosen to understand the effect rocker angle and apex position, with a three way, between-groups-within-factors analysis, being chosen to establish whether the effects of the two footwear design features were the same for patients with diabetes and healthy participants.

4.5 Participants

The same population of low risk people with diabetes were recruited for this study. Once again, people with diabetes and healthy participants were recruited at two sites, the University of Salford (UK) and the German Sport University (Cologne, Germany) (Table 4. 1). Identical, to the recruitment process used in the previous study, participants underwent a screening procedure using the same exclusion criteria (Section 3.5). The only difference to the exclusion criteria being the foot size as, for this study, a total of eight shoe sizes were available, 37-40 for women and 41-44 for men. Firstly, a phone conversation between the researcher and the participant was conducted and following this, a foot examination from a podiatrist or foot specialist. The neuropathy classification used the same foot examination procedure reported in Study 1 and once again participants with peripheral neuropathy were not recruited. Participants were deemed to be neuropathic using the same criteria used in Study 1 by evaluating six sites on the plantar foot using a 10 g monofilament (Section 3.5).

Table 4. 1: Participant demographic characteristics. Mean (Standard deviation). Variables in bold were significantly different between the two groups (p = <0.051)

People with diabetes (n = 87) 45 from Salford 42 from Cologne		Healthy participants (n = 76) 31 from Salford 45 from Cologne	
Height	1.69 (0.09)	Height	1.69 (0.09)
Weight	**85.3 (15.9)**	**Weight**	**72.6 (14.1)**
Age	**57.2 (8.8)**	**Age**	**49.5 (13.6)**
Male	44	Male	46
Female	43	Female	30

4.6 Methods

Ethics

Ethical approval was obtained from the University of Salford ethics committee for the school of Health Science and National Health Service (IRAS 10/H1013/32) (Appendix 1-4).

4.6.1 Footwear interventions

Participants walked in a total of eight rocker shoes containing different combinations of rocker angle and apex position. For all shoes, apex angle was fixed at 95°. As with the previous study, the footwear manufacturer Duna®, Italy, provided the shoes for this study. The lasts were manufactured by Duna® using the scan data from ninety people with diabetes which were collected at the University of Salford and the German Sport University, Cologne during Study 1. The scan results showed the width of the female lasts had to be increased slightly, but the rocker soles were constructed using the same method reported in the previous study. Micro cellular rubber was used for the outsole and it incorporated a 5mm thick piece of folex giving the shoe a completely stiff outsole.

An adjustment to the upper design was made because of fitting problems in the previous study which caused a small number of participants to be excluded. The upper of the shoes in the previous study had a lacing design where by the laces were very close together

(Figure 4. 1 A). Fitting became a problem if the participants foot was too large for the size of the upper because there was very little room to tighten the laces and secure the foot, hence participants were lost due to poor fit, so to solve this problem, a Velcro strapping system was used instead of a lacing system (Figure 4. 1 B), allowing the shoe to be adjusted to fit the foot more easily.

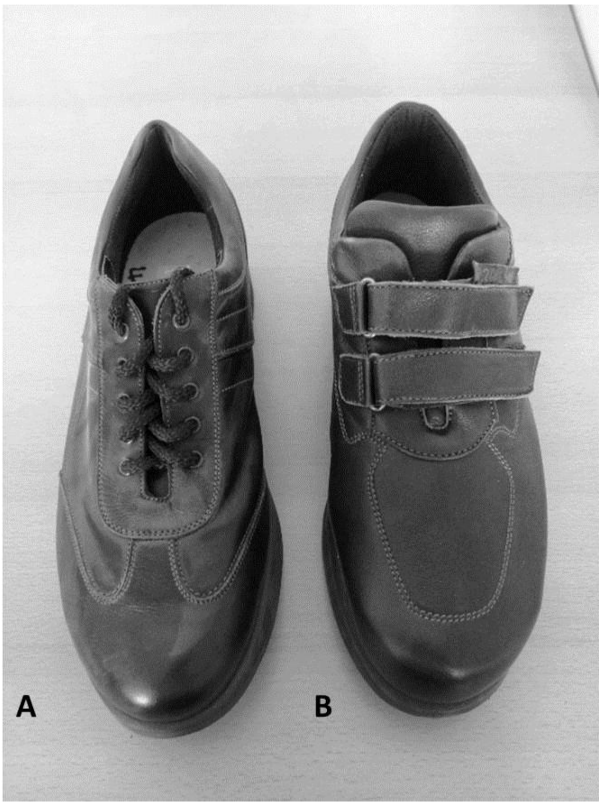

Figure 4. 1: Shoe A: the upper design used in chapter 4. Shoe B: the upper design used in chapter 5 with the new fastening system.

Using the results from the Study 1 it was possible to define a smaller range of design features which could be evaluated in combination with each other. A total of eight different rocker outsoles were defined using two different rocker angles, four different apex positions, and a fixed apex angle of 95° (Table 4. 2 (No 1-8)). Also the same flexible shoe used in the previous study was also included, but this shoe also had a Velcro fastening system like the rocker shoes.

Table 4. 2: Rocker sole configurations evaluated in this study. A total of eight rocker soles with different combinations of rocker angle and apex position were chosen.

A1 = 52% apex position **R1 = 15° rocker angle**

A2 = 57% apex position **R2 = 20° rocker angle**

A3 = 62% apex position

A4 = 67% apex position

Shoe	Apex angle (°)	Apex position (shoe length)	Rocker angle (°)	Heel height
1. R1 A1	95°	52%	15°	2cm
2. R1 A2	95°	57%	15°	2cm
3. R1 A3	95°	62%	15°	2cm
4. R1 A4	95°	67%	15°	2cm
5. R2 A1	95°	52%	20°	3cm
6. R2 A2	95°	57%	20°	3cm
7. R2 A3	95°	62%	20°	3cm
8. R2 A4	95°	67%	20°	3cm
9. Control	NA	NA	NA	2cm

4.6.2 Protocol

Participants were then asked to wear thin nylon socks and the in-shoe plantar pressure was again collected along a 20m walkway with the participants walking at 1m/s $\pm$ 10%. Shoe order was randomised between all of the nine shoes, with randomisation order determined using a customised Matlab programme (3.6.3).

The same in-shoe pressure protocol was used in Study 1 was also used in this Study For each shoe, participants completed a familiarisation period of two-three minutes (approximately 45 steps) prior to in-shoe pressure being recorded, with the Novel Pedar-X system being used to collect the in-shoe plantar pressure data (50Hz). As with the previous experiment, pressure sensitive insoles were placed on top of 3mm thick Poron which were cut to cover the entire plantar aspect of the internal area of the shoe (Table 4. 2). As eight different shoe sizes were used in this study a number of different pressure sensitive insole sizes also had to be used (Table 4. 2). A total of three trials at the correct speed were recorded, again giving a total of 25-35 steps for each shoe condition with the data then being exported in an ASCII file format and imported into Matlab for further processing.

Table 4. 3: Male/female shoe sizes and corresponding Pedar insole size.

Male shoe size	Pedar Insole	Female shoe size	Pedar Insole
41	X	37	V
42	Y	38	W
43	Y	39	W
44	Z	40	X

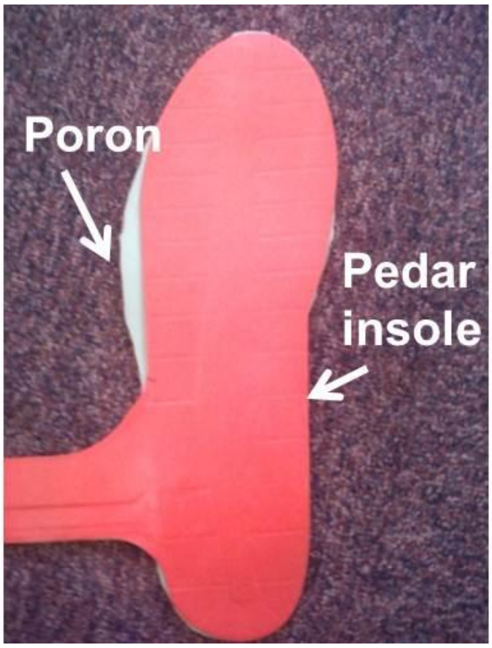

Figure 4. 2: Pedar pressure sensitive insole attached to the top of the custom made poron insole.

4.6.3 Statistical analysis for the objectives

Different statistical methods were used in order to accomplish the aims and objectives. Data from the healthy participant were only used to understand the effect of group by footwear design features (Research question 2). For the remaining research questions, only data from the people with diabetes results were used.

1. **Establish whether the effects of the two footwear design features are the same for patients with diabetes and healthy participants.**

The first aim of this study was to compare the peak plantar pressure between people with diabetes and the healthy groups. To accomplish this, a between (groups)-within factors (three way) ANOVA was chosen. A comparison of peak plantar pressure between the groups as well as the interaction is presented in the results section.

2. **Understand the effect of varying apex position (52-67% of shoe length) and rocker angle (15° and 20°) and to compare the different rocker designs with a flexible control shoe.**

A within-within (two way) ANOVA design, with repeated measures was chosen to understand the effects of rocker angle in combination with apex position. Separate ANOVA tests were conducted for each for each anatomical regions and a significance level of p=0.05 was chosen and adjusted using a Bonferroni correction for multiple comparisons. To quantify the mean effect of the rocker soled shoes in comparison to a control shoe two separate one-way ANOVA (with repeated measures) tests were used. The first of these tests compared the mean of the shoes with a 15° rocker angle plus the controls and the second compared the mean of the shoes with a 20° rocker angle plus the control. As explained earlier, this analysis was only carried out on the group with diabetes.

3. **a) Identify the mean optimal design, (combination of rocker angle and apex position)**

The third aim sought to identify a mean optimal shoe. The inter-subject variability in response to the different rocker designs was chosen to define this shoe. Specifically, the inter-subject variability was quantified by identifying which shoe gave the minimum peak pressure value for each participant. This data was then used to calculate the distribution of optimal shoes across individuals and the mean optimal design identified.

b) Establish the proportion of individuals for which there is acceptable pressure offloading with the, control shoe, mean optimal rocker sole design, and individual optimal rocker sole design.

One of these objectives to accomplish the third aim was to compare the proportion of individuals for which there is sufficient offloading with the control shoe, mean optimal design and individual optimal design. Sufficient offloading was defined as a peak pressure below the 200 KPa threshold recommended by Owings et al (2012) (Section 2.1.3). This threshold-based analysis was carried out for the control shoe, the mean rocker shoe design and finally for an individual's optimal rocker shoe design. With this approach it was possible to quantify the proportion of individuals with diabetes receiving sufficient offloading in these different design choices.

c) Establish the proportion of individuals for which the 15° rocker angle would give sufficient pressure offloading

The final objective was to establish the proportion of individuals for which the 15° rocker angle would give adequate pressure offloading. This analysis was also based on the 200 kPa threshold (Owings et al., 2009b). If pressure can be reduced 200 kPa it has been shown that people with diabetes did not re-ulcerate. Therefore, it is appropriate to apply in this study as a goal for pressure reduction to prevent the first instance of ulceration.

4.7 Results

4.7.1 Group by footwear feature interactions

Peak plantar pressures in the 1st MTP and 2nd-4th MTH regions were significantly lower in healthy participants compared to people with diabetes (Table 4. 4). Under the Hallux and 5th MTH there was no significant differences between the diabetes and healthy groups, however, for heel region the diabetes group had significantly higher peak plantar pressures (Table 4. 4).

Table 4. 4: Difference in peak pressure between the healthy and people with diabetes groups. A negative difference indicates that pressures were lower in the health group. The significant differences are highlighted in bold.

	R1A1	R1A2	R1A3	R1A4	R2A1	R2A2	R2A3	R2A4
1st MTP	**-49.51**	**-48.67**	**-42.98**	**-46.34**	**-45.92**	**-44.50**	**-39.24**	**-42.86**
2nd-4th MTH	**-31.00**	**-32.91**	**-40.08**	**-35.60**	**-26.46**	**-32.74**	**-38.16**	**-38.74**
Hallux	-8.74	-6.18	-4.63	-5.29	-3.98	-5.78	-3.30	2.02
5th MTH	-7.69	-5.85	-8.72	-6.35	-6.85	-6.34	-11.61	-9.07
Heel	**-23.55**	**-25.97**	**-25.58**	**-26.06**	**-29.09**	**-23.57**	**-25.80**	**-23.65**

Despite the significant difference in peak plantar pressure, there was no interaction for rocker angle or apex position between the two groups for any of the regions (Figure 4. 3 and Figure 4. 4). Therefore, it can be concluded that varying the two design features in healthy and the diabetes group has the same effect on pressure. For instance, both groups showed a decrease in pressure when rocker angle was increased.

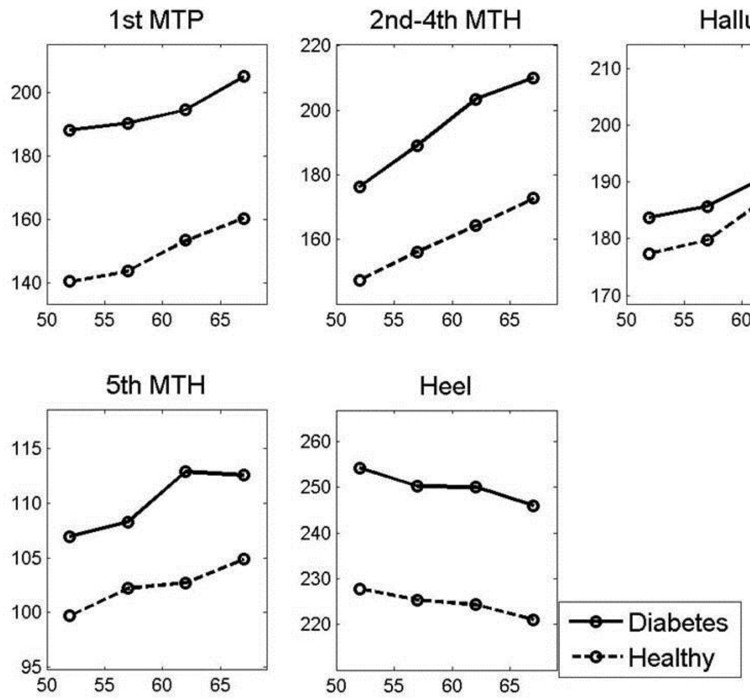

Figure 4. 3: Group by footwear interaction plots for apex position.

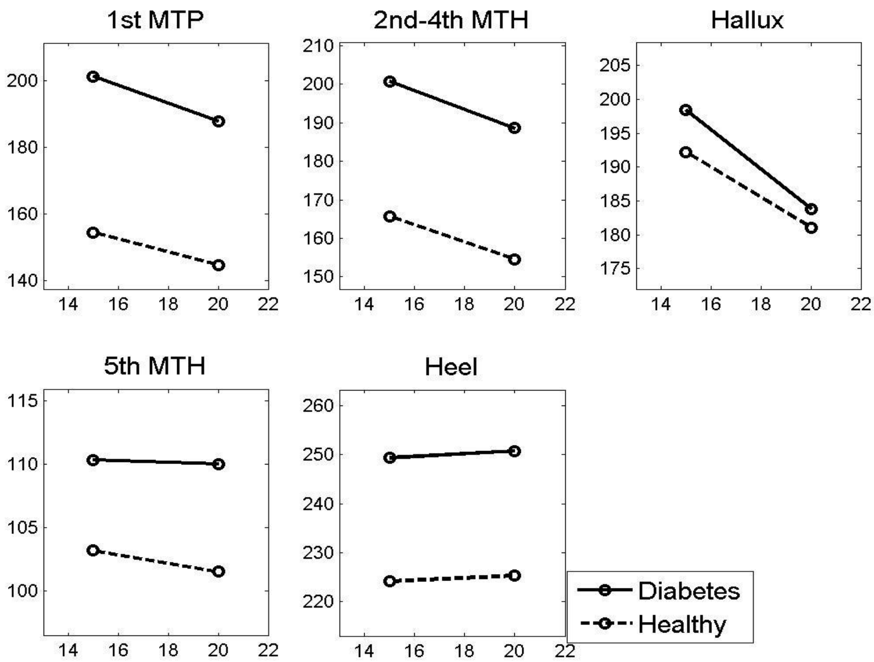

Figure 4. 4: Group by footwear interaction plots for rocker angle

4.7.2 Main effects and interaction of rocker angle and apex position for the participants with diabetes

1st MTP (Figure 4. 5): For this region, there was a significant decrease in peak plantar pressure when rocker angle was increased to 20° (p = <0.05). In this current study, apex position was varied using the following configurations 52, 57, 62 and 67% of shoe length. There was a significant increase in peak plantar pressure when the apex position was increased from 62 to 67% of shoe length (p = <0.05). The effect of increasing the apex from 52 to 62% of shoe length had very little effect on the peak plantar pressure. There was no interaction between the two design features (p = >0.05).

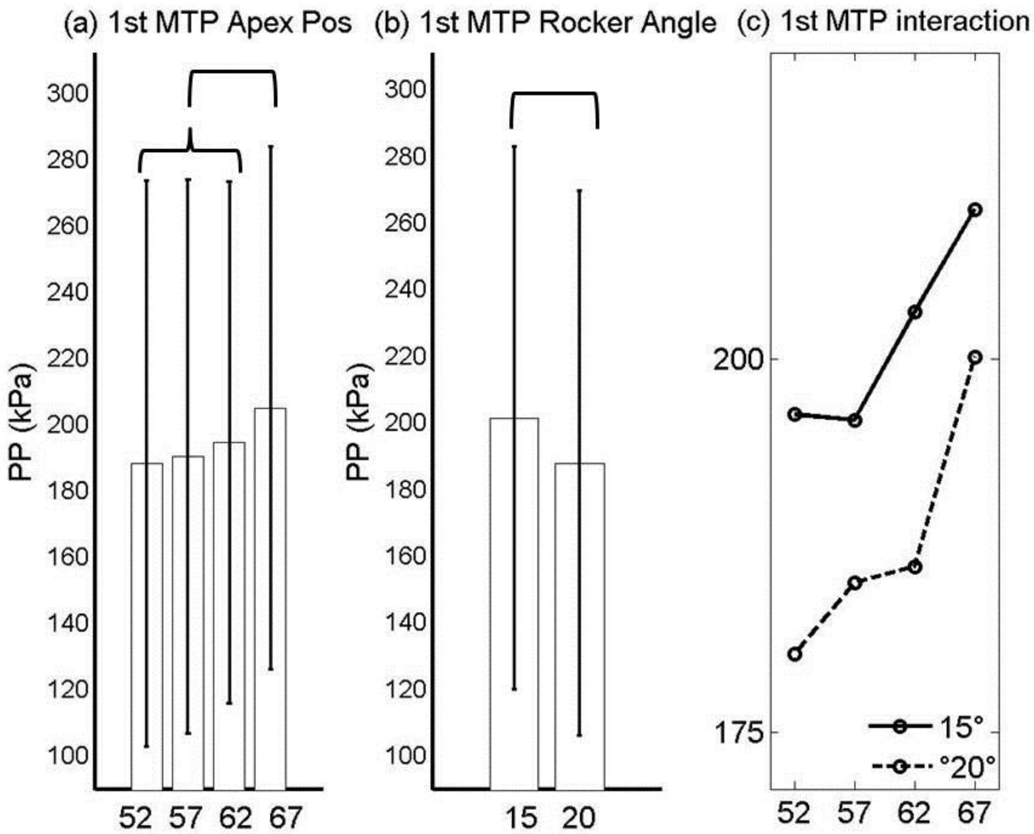

Figure 4. 5: 1st MTP: Mean effect of apex position (a), rocker angle (b), and the interaction between the apex position and rocker angle (c).

2^{nd}-4^{th} **MTH (Figure 4. 6):** In this region, increasing the rocker angle from 15 to 20° produced a significant decrease in peak plantar pressure (p = <0.05). Significant increases in mean peak plantar pressure were observed between all of the apex configurations (p = <0.05). However, again, there was no interaction between apex position and rocker angle.

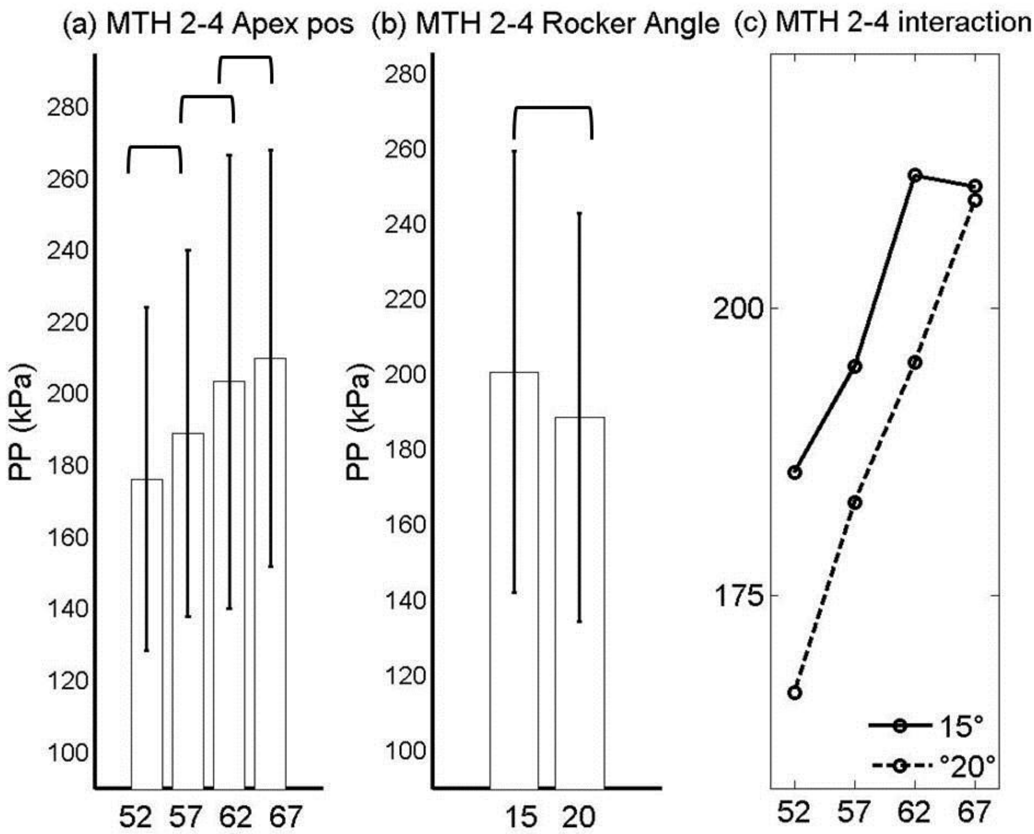

Figure 4. 6: 2nd-4th MTH: Mean effect of apex position (a), rocker angle (b), and the interaction between the apex position and rocker angle (c).

Hallux region (Figure 4. 7): For this region, there was significant differences between the two rocker angle configurations. A rocker angle of 15° significantly increased the peak plantar pressure compared to the shoes with a 20° angle (p = <0.05). Minimal effect was observed between shoes with different apex positions, however, there was a significant difference when the apex was increased from 57 to 62% and then 67% (p = <0.05). Finally, there was no interaction between the two design features.

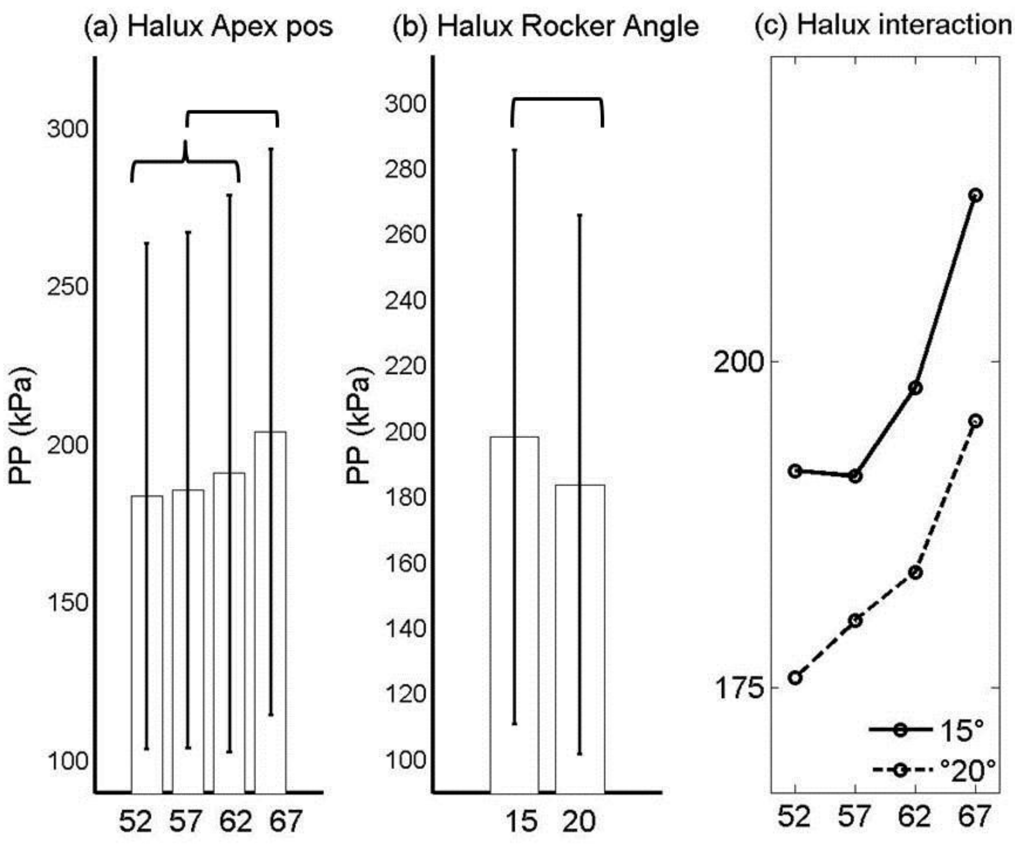

Figure 4. 7: Hallux: Mean effect of apex position (a), rocker angle (b), and the interaction between the apex position and rocker angle (c).

5th MTH (Figure 4. 8): In this region there was also a reduction in peak plantar pressure as rocker angle increased, however, a different effect of apex position was observed between the two rocker angles. Specifically, there was little effect when varying apex position for the shoes with a 15° rocker angle (p = <0.05). However, an increase in peak plantar pressure was observed when increasing the apex position in the shoes with a 20° rocker angle. In these shoes there was a significant increase in peak plantar pressure the first three configurations (52, 57 and 62%) (p = <0.05). This was the only forefoot region to show an interaction between the two design features. Figure 4. 8 shows the interaction plot between the two rocker angle conditions. It is clear that there is a different effect, as apex position is increased, between the 15 and 20° rocker angles. The 15° configuration has very little effect and the 20° configuration shows a large increase between the first three apex positions.

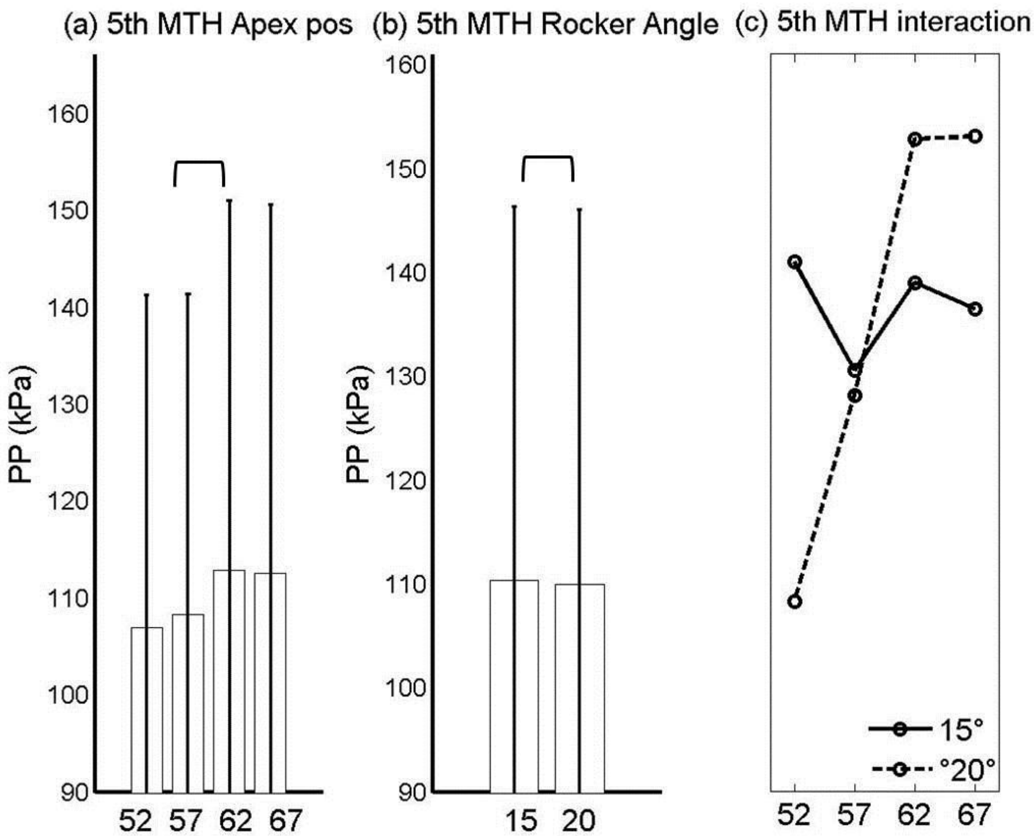

Figure 4. 8: 5th MTH: Mean effect of apex position (a), rocker angle (b), and the interaction between the apex position and rocker angle (c).

Heel (Figure 4. 9): In this region, there was minimal effect for the shoes with a 15° rocker angle, however, there was a significant decrease in peak pressure as apex position was increased. There was an interaction between the two rocker angles. Once again it is clear that there is a different effect when increasing apex position between the two rocker angle configurations.

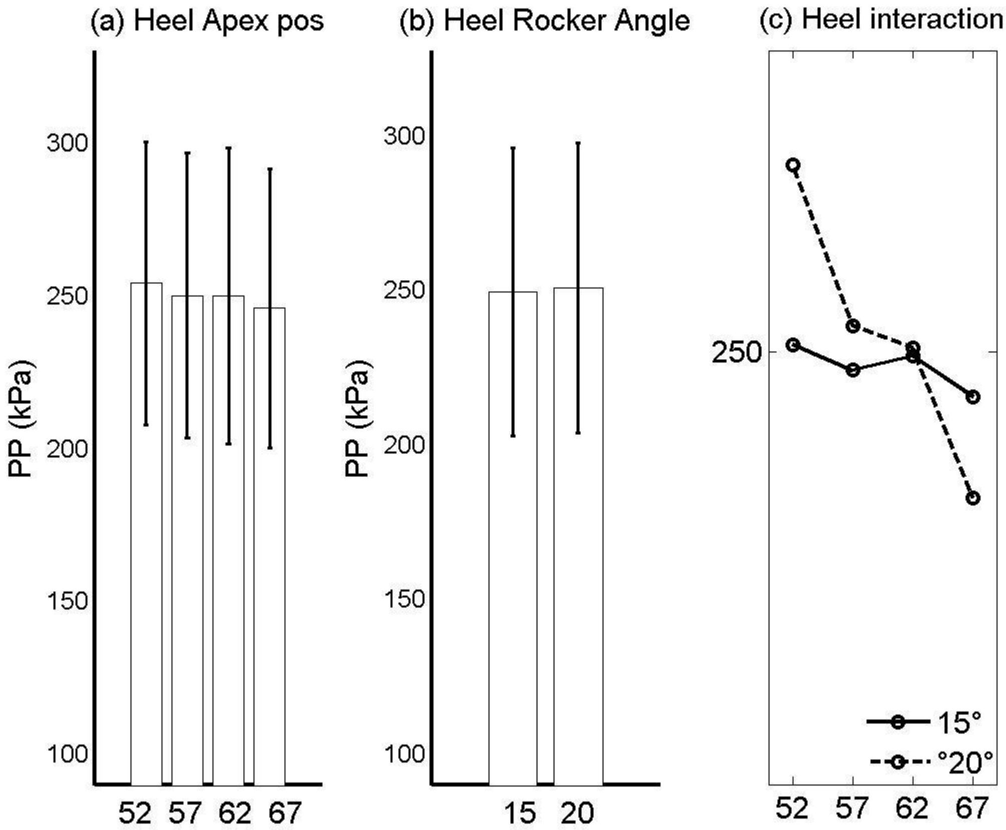

Figure 4. 9: Heel: Mean effect of apex position (a), rocker angle (b), and the interaction between the apex position and rocker angle (c).

4.7.3 Effects of rocker shoes in comparison to the control shoe

There were a number of significant differences between the rocker sole configurations and the control shoe. As explain in the statistical analysis section above, a single one way ANOVA was performed for these data.

1st MTP: For this region peak plantar pressure was significantly lower than the control shoe for all rocker designs, except the two shoes with a 67% apex position (Table 4. 5).
2nd–4th MTH: Under this region pressure was significantly lower for all of the rocker sole designs compared to the control shoe (Table 4. 5).
Hallux: For this region pressure was significantly lower for the rocker soles with 20° rocker angles in combination with the two smallest apex positions (52 & 57%) (Table 4. 5).
5th MTH: All rocker soles with a 15° rocker angle caused a significant increase in peak plantar pressure. Furthermore, the outsoles with a 20° rocker angle and apex angles of 62 and 67% of shoe length also caused a significant increase (Table 4. 5).
Heel: Finally, for the heel region there was a significant increase in pressure for all of the rocker sole configurations (Table 4. 5).

Table 4. 5 shows the mean differences for each of the rocker configurations when compared to the control shoe. The heel and the 5th MTH were the only regions to show significant increases in pressure. The 1st MTP and hallux showed significant reductions in five and two of the rocker configurations respectively. The shoe with the 67% apex did not show a reduction in both of the rocker configurations in either of these regions. Finally, there was significant reductions in all the rocker configurations in the 2nd -4th MTH region.

Table 4. 5: Mean differences (kPa) and significant differences between rocker sole shoes and control shoe. "R" denotes significant reduction, "I" denotes significant increase.

	Apes position	1st MPJ	2nd – 4th MTH	Hallux	5th MTH	Heel
15° rocker angle	52%	-18.27(R)	-79.28(R)	-8.06	10.69(I)	23.55(I)
	57%	-17.71(R)	-70.80(R)	-9.70	6.75(I)	22.38(I)
	62%	-12.42	-53.15(R)	-2.15	9.78(I)	22.93(I)
	67%	-4.01	-54.58(R)	12.18	8.27(I)	21.39(I)
20° rocker angle	52%	-33.48(R)	-98.76(R)	-24.17(R)	1.03	31.12(I)
	57%	-28.44(R)	-82.24(R)	-19.51(R)	6.14	24.32(I)
	62%	-28.22(R)	-69.67(R)	-16.41	13.57(I)	23.30(I)
	67%	-14.18	-56.02(R)	-5.07	13.28(I)	17.12(I)

4.7.4 Defining the mean optimal design

Inter-subject variability between the eight rocker configurations

The inter-subject variability between the eight different rocker designs was analysed to determine the mean optimal shoe (Figure 4. 10). Under the 1st MTP, the rocker sole with a 20° rocker angle and 52% apex position was the optimal configuration for the largest proportion (40%) of people with diabetes . This design configuration was also optimal for the 2nd-4th MTH region, with 84% of the population experiencing the most offloading with this design (Figure 4. 10). Finally, under both the hallux and 5th MTH, the shoe with a 20° rocker angle and 52% apex position was found to be the mean optimal design, with 37% and 38% of the population experiencing the largest benefit from this configuration. Given this consistency across the different regions of the foot this design configuration was taken as the mean optimal design.

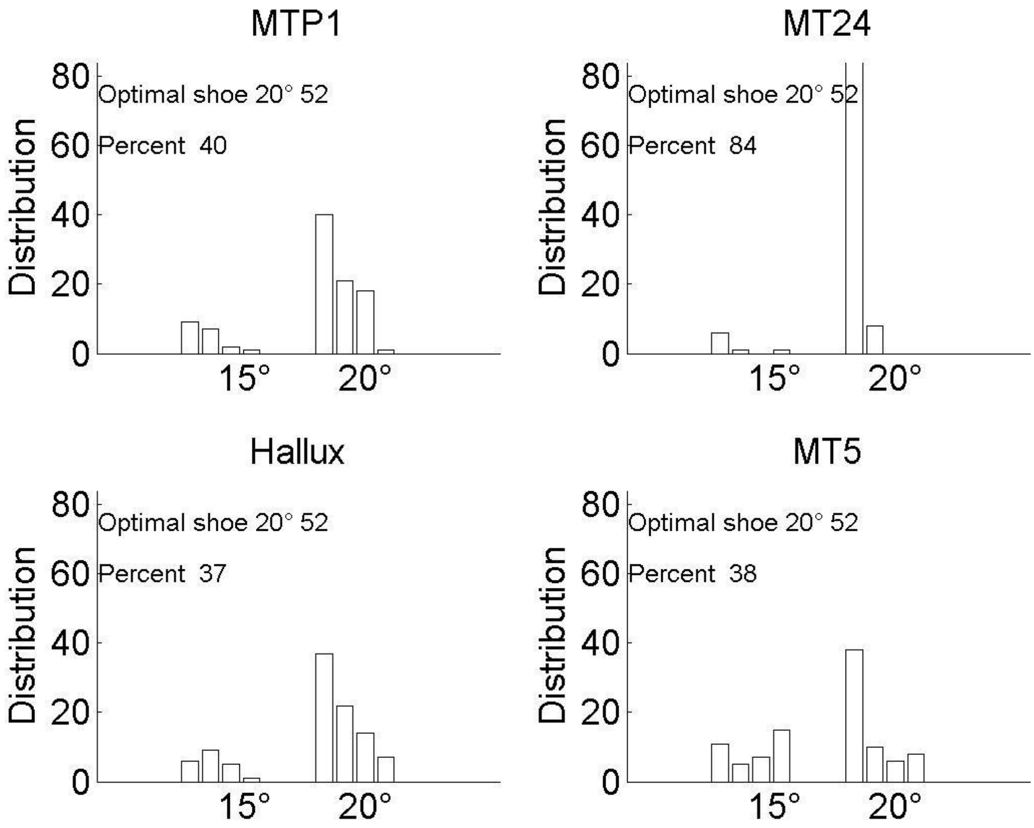

Figure 4. 10: Histograms to show the relative distribution (%) across all 87 participants with diabetes of optimal shoe configuration (15 and 20° rocker angles each consisting four apex positions of 52, 57, 62 and 67%) for each of the different anatomical forefoot regions

The ANOVA results (described in section 4.7.2) also supported the choice of the mean optimal design configuration as a 52% apex position and 20° rocker angle, Specifically, the results showed that increasing the rocker angle from 15 to 20° caused a significant reduction in pressure, in all of the forefoot regions (Figure 4. 5 -8), justifying the choice of a 20° rocker. Secondly, there was significant increase in pressure between the apex positions of 62 and 67% for all of the high risk regions (1st MTP, 2nd-4th MTH and hallux), showing that an apex angle of 67% should not be used. Interestingly, under the 1st MTP and hallux regions, there was minimal effect on pressure between apex positions 52%, 57% and 62%. However, under the 2nd-4th MTH there was a significant increase in peak pressure between all of the configurations (Figure 4. 6), providing support for the choice of an apex position of 52% of shoe length.

4.7.5 Pressure reduction between the control shoe, mean and individual optimal rocker sole design

The next stage was to quantify how many people would be able to wear a control shoe, mean optimal rocker sole, and how many would need an individually adjusted design. Owings et al (2009) recommended that in-shoe pressures should be reduced below 200 KPa in order to reduce the risk of ulceration. This target pressure was therefore used as a threshold to estimate the proportion of individuals who may be a higher risk of developing an ulcer. This analysis was performed for three types of design configuration: 1) the control shoe 2) mean optimal rocker shoe and 3) individually selected optimal rocker shoe design. Figure 4. 11 shows the mean values of the control shoe, mean optimal shoe, and the individually selected rocker sole, which was selected from all eight configurations. The results show the individually selected rocker sole produces mean pressure below the 200 kPa threshold for all of the forefoot regions (Figure 4. 11)

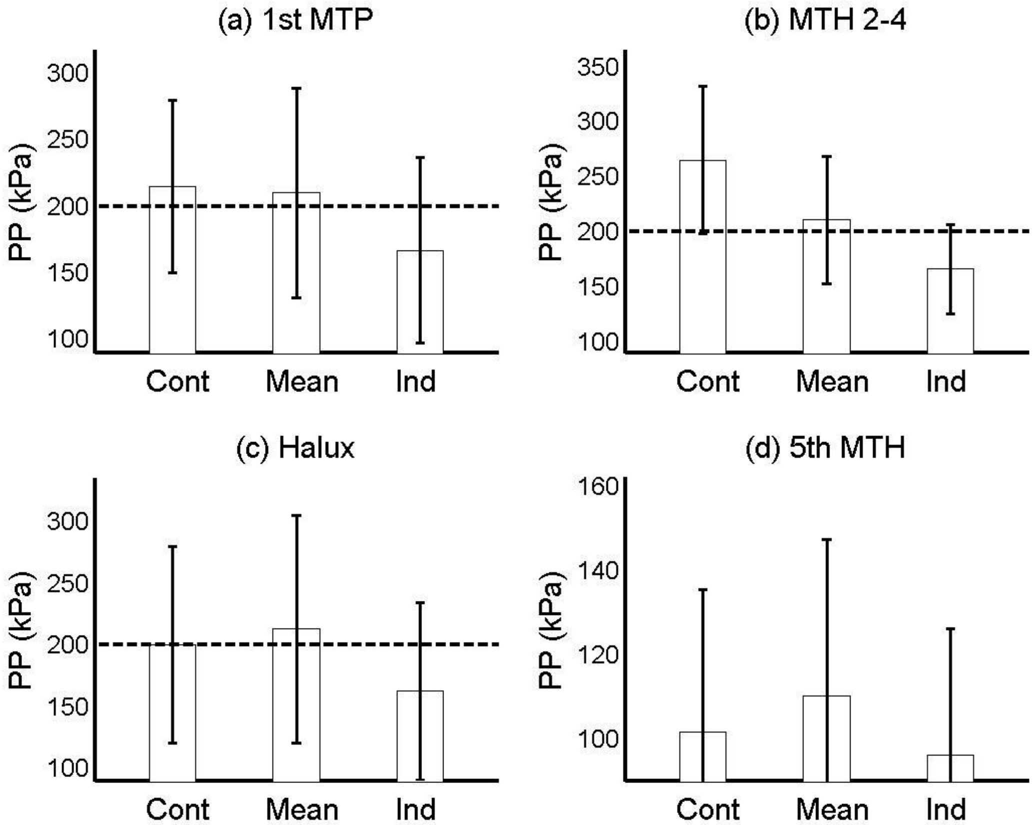

Figure 4. 11: Mean values of the control shoe (Cont), mean optimal shoe (Mean (52% apex, 20° rocker angle)), and individual rocker shoe (Ind (minima selected from all eight configurations))

The graphs below show the proportion of participants which exhibited pressure values above the threshold when walking in the control, mean optimal rocker and individually selected rocker shoe. The vertical line represents the 200 kPa threshold and the bars represents the number of the participants.

1st MTP: In this region, 55% of the population were above the 200 kPa threshold when wearing the control shoe. This was over double the number of people who were above the threshold when wearing the mean optimal rocker sole. In this condition, 74% of the population were under the 200 KPa threshold. There was a slight improvement when the individually optimal rocker sole was selected because 79% of the population were under the 200 KPa threshold.

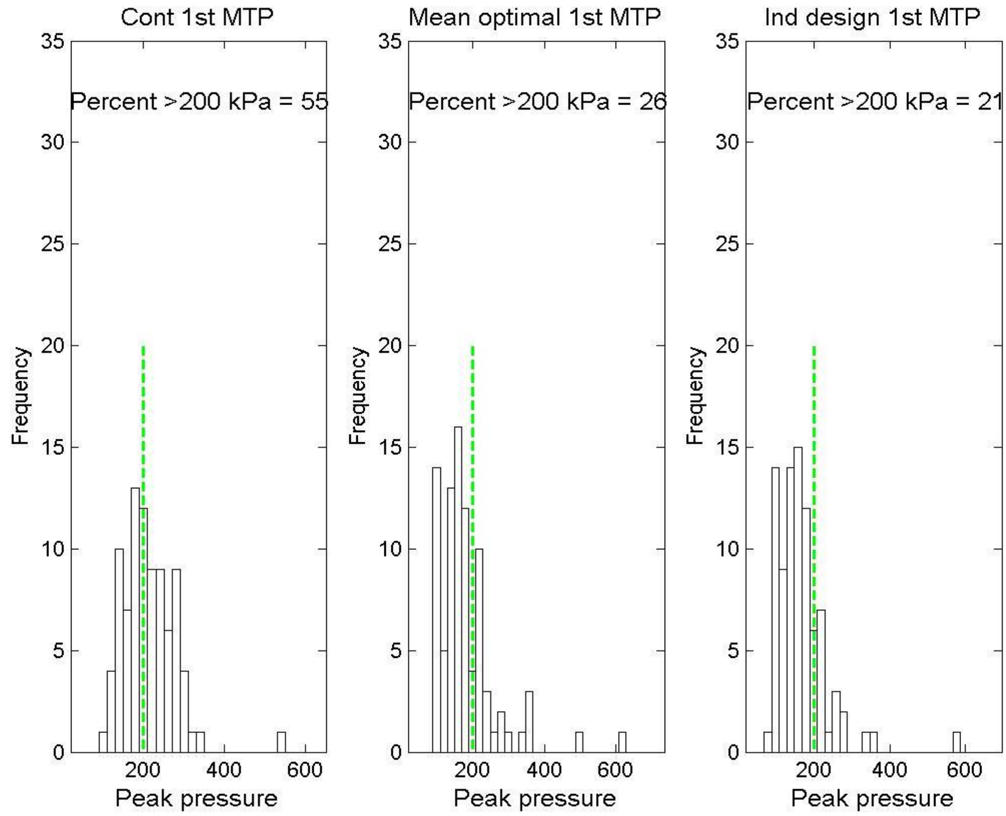

Figure 4. 12: 1st MTP: Proportion the population over the 200 kPa threshold when walking in the control shoe, ,mean optimal and individual optimal design.

2nd-4th MTH: For the control shoe, 87% of the population (which was the largest of the forefoot regions) were above the 200 kPa threshold. To reduce peak plantar pressure below 200 kPa in this region, a much greater proportion of the population (83%) were under the threshold in the mean optimal shoe. A similar number of people to the proportion for the mean optimal shoe were still above the threshold despite having an individual shoe selected (16%).

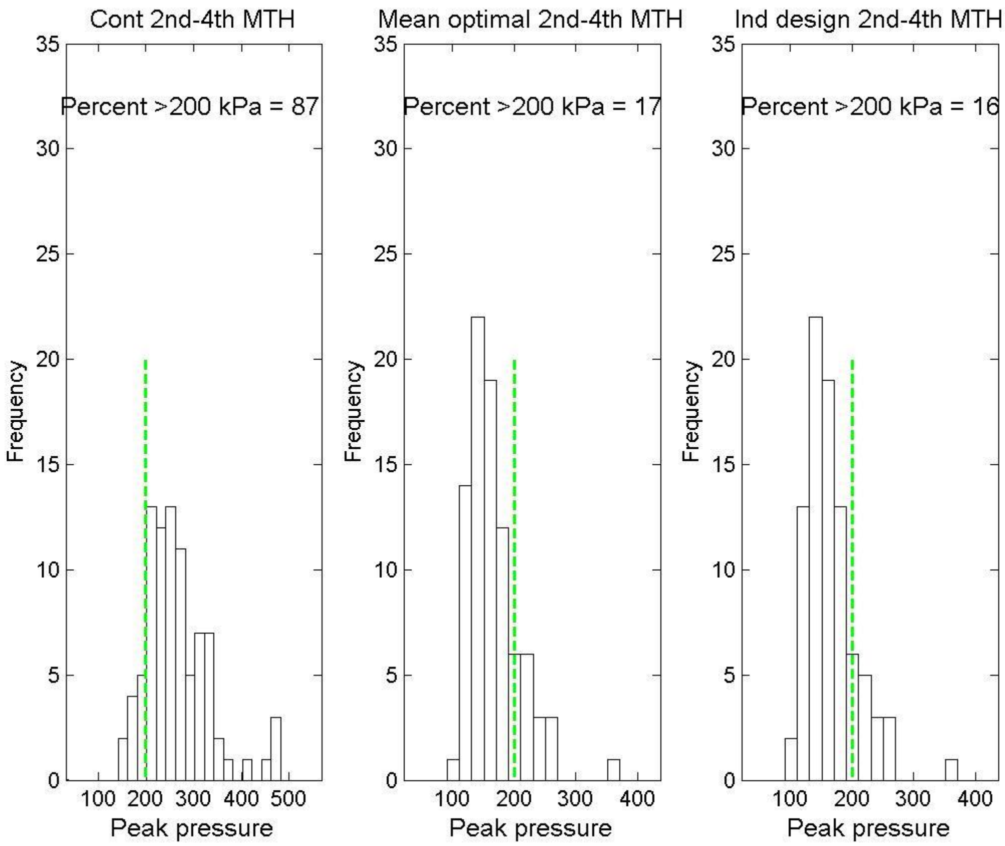

Figure 4. 13: 2nd-4th MTH: Proportion the population over the 200 kPa threshold when walking in the control shoe, ,mean optimal and individual optimal design.

Hallux: For the control shoe, 40% were above the 200 kPa threshold. For this region, only 23% were above the threshold when an individual outsole was selected. A similar proportion of participants to the 1st MTP were over the threshold in the mean optimal shoe (72%), meaning 22% of the population would require a different outsole design.

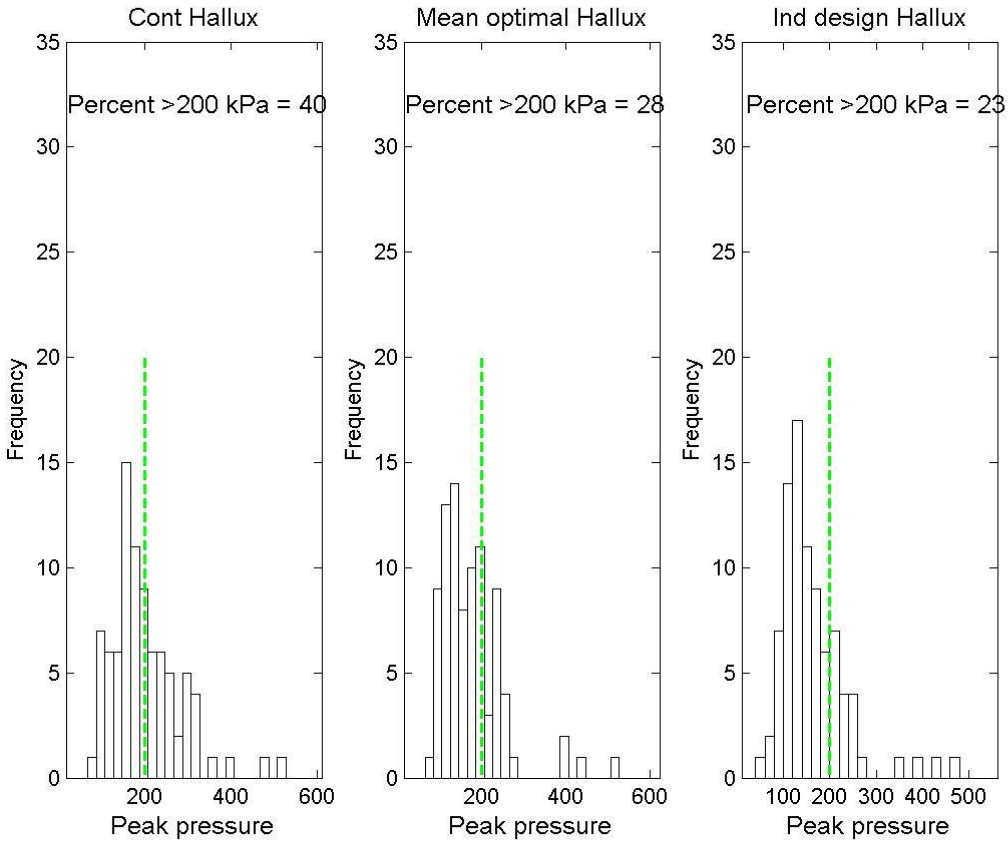

Figure 4. 14: Hallux: Proportion the population over the 200 kPa threshold when walking in the control shoe, ,mean optimal and individual optimal design.

5th MTH Region: This region had the smallest proportion of the population above the threshold for any of the conditions. For the control shoe, nearly the entire proportion of people who were below the threshold (2%). This was improved when the mean optimal and individual rocker design were selected as 1% of the population were above the threshold of 200 kPa.

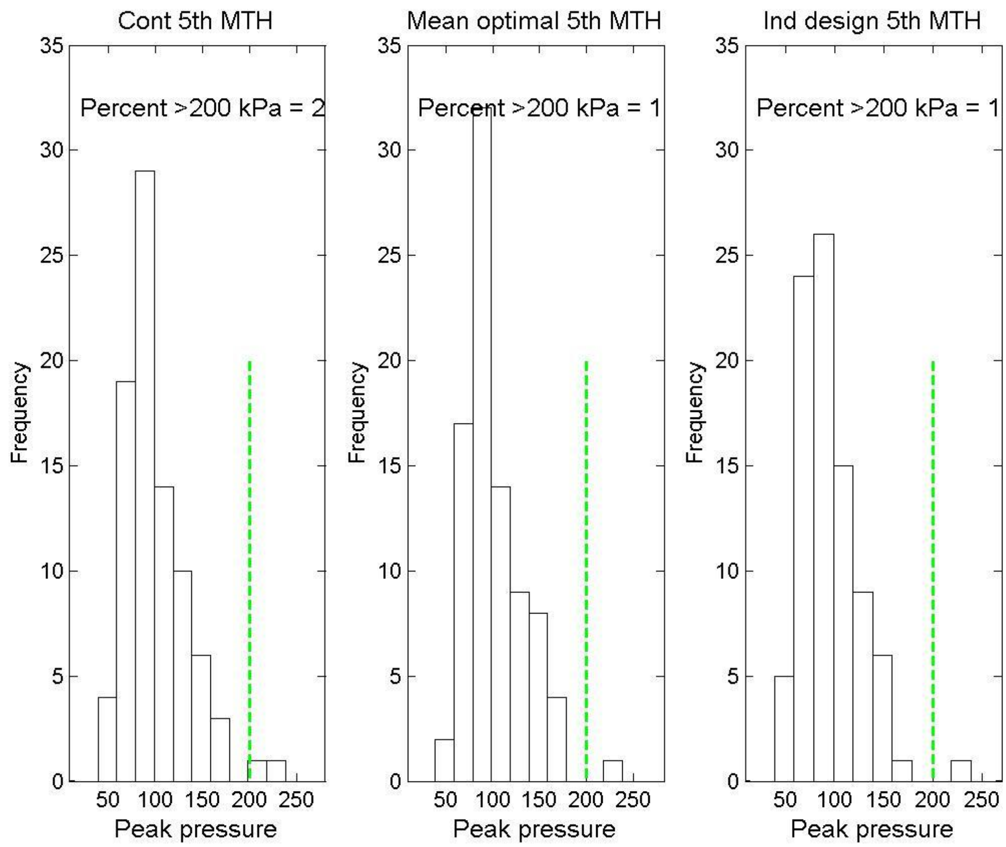

Figure 4. 15: Hallux: Proportion the population over the 200 kPa threshold when walking in the control shoe, ,mean optimal and individual optimal design.

Finally, for the proportion of participants over the 200 kPa whilst wearing the mean optimal shoe, there were some large increases in plantar pressure.

1st MTP Region: For this region, there was an average increase of 48 kPa and the mean peak pressure value increased to 296 kPa.

2nd-4th MTH Region: Under this region, there was a mean increase of 14 kPa and the mean pressure value increased to 236 kPa when wearing the mean optimal shoe.

Hallux Region: For this region, there was an average increase of 27 kPa and the mean peak pressure value increased to 274 kPa when wearing the mean optimal shoe.

5th MTH Region: Finally, under this region, there was an mean increase of 11 kPa and the mean pressure value increased to 236 kPa.

It is clear that these individuals cannot wear the mean optimal shoe to reduce the risk of ulceration.

4.7.6 Pressure reduction between a 15 and 20° rocker angle

The final aim of this study was to compare peak pressures between shoes with a 20° and a 15° rocker angle when using the individually selected rocker sole. This analysis was carried out to quantify the propitiation of individuals who would experience sufficient offloading with a 15° rocker angle. As explained in earlier, patients would be more likely to wear a shoe with a 15° rocker angle due as it has reduced outsole thickness and is therefore more aesthetically appealing.

1st MTP (Figure 4. 16): The data show that 66% of the population would be able to wear a 15° rocker angle. There was a slight improvement in the offloading when the angle was increased to 20° because only 21% of the population were above the 200 kPa threshold.

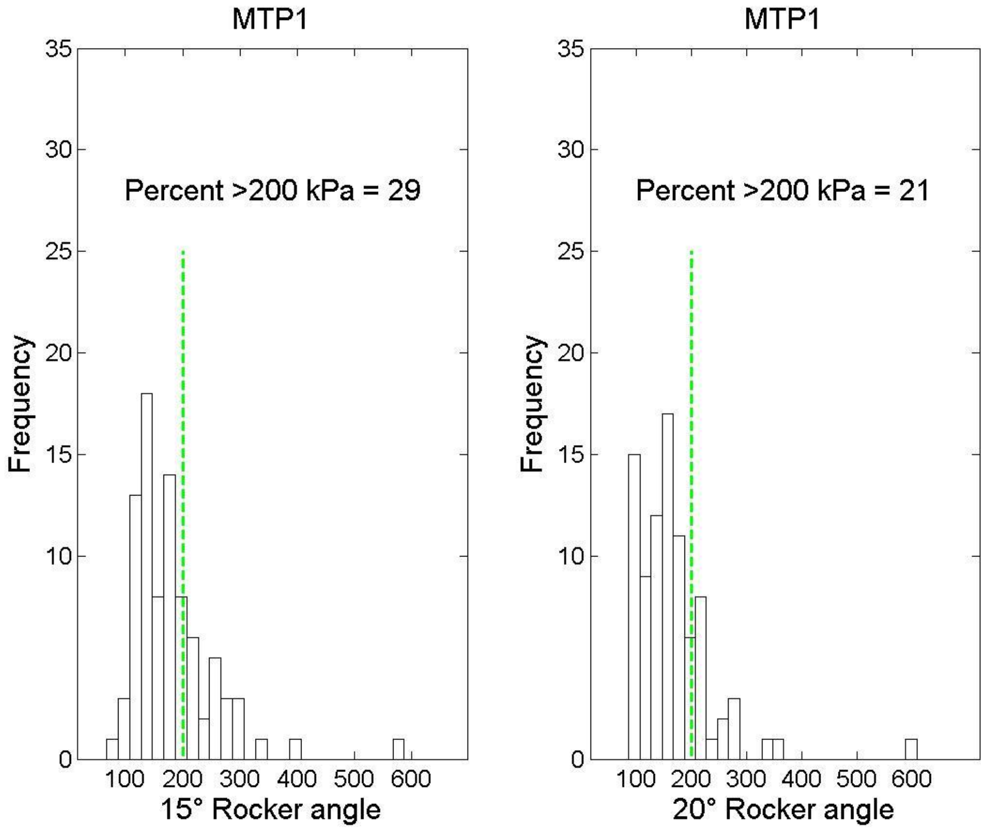

Figure 4. 16: Peak pressure distribution for the mean optimal apex position (52%) using a 15° and 20° rocker angle and the percentage of the population above the 200 kPa threshold.

2^{nd}-4^{th} MTH (Figure 4. 17): The results showed that 24% of the population would not receive sufficient offloading when wearing a 15° degree rocker angle and only 17% would not receive sufficient offloading when wearing a 20° rocker angle.

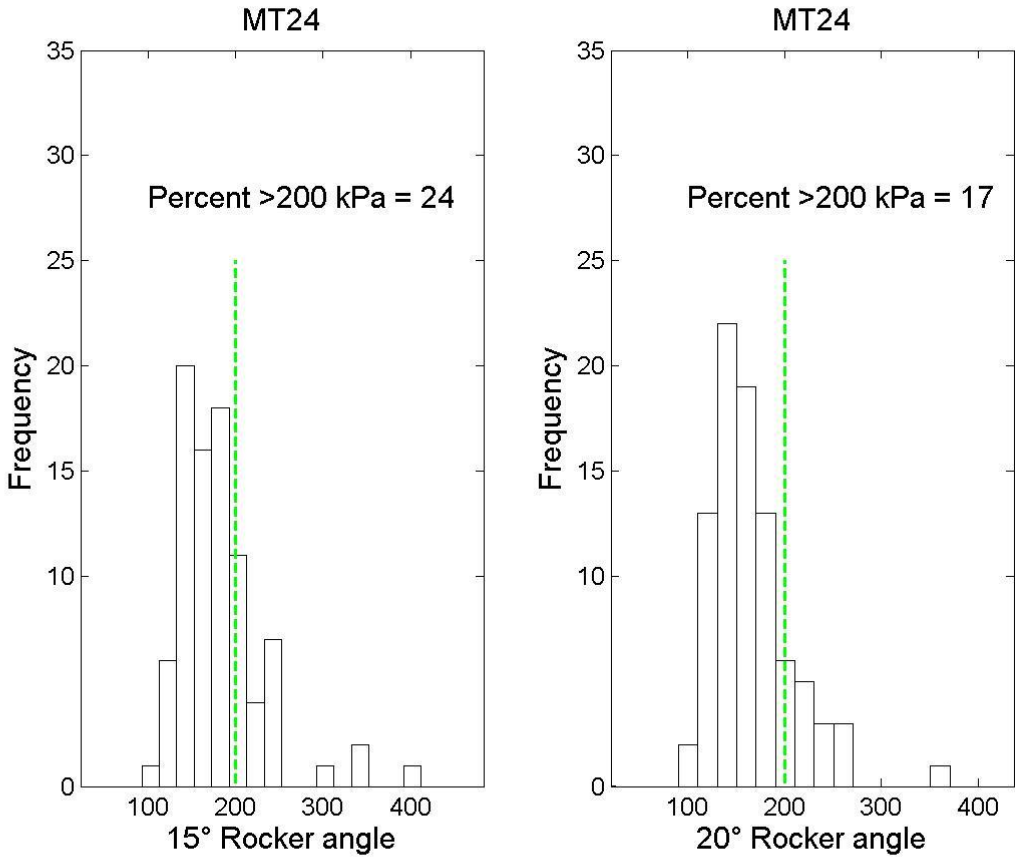

Figure 4. 17: Peak pressure distribution for the mean optimal apex position (52%) using a 15° and 20° rocker angle and the percentage of the population above the 200 kPa threshold.

Hallux (Figure 4. 18): In this region, 29% of the participants did not receive sufficient offloading when wearing the shoe with a 15° rocker angle and 23% for the shoe with a 20° rocker angle.

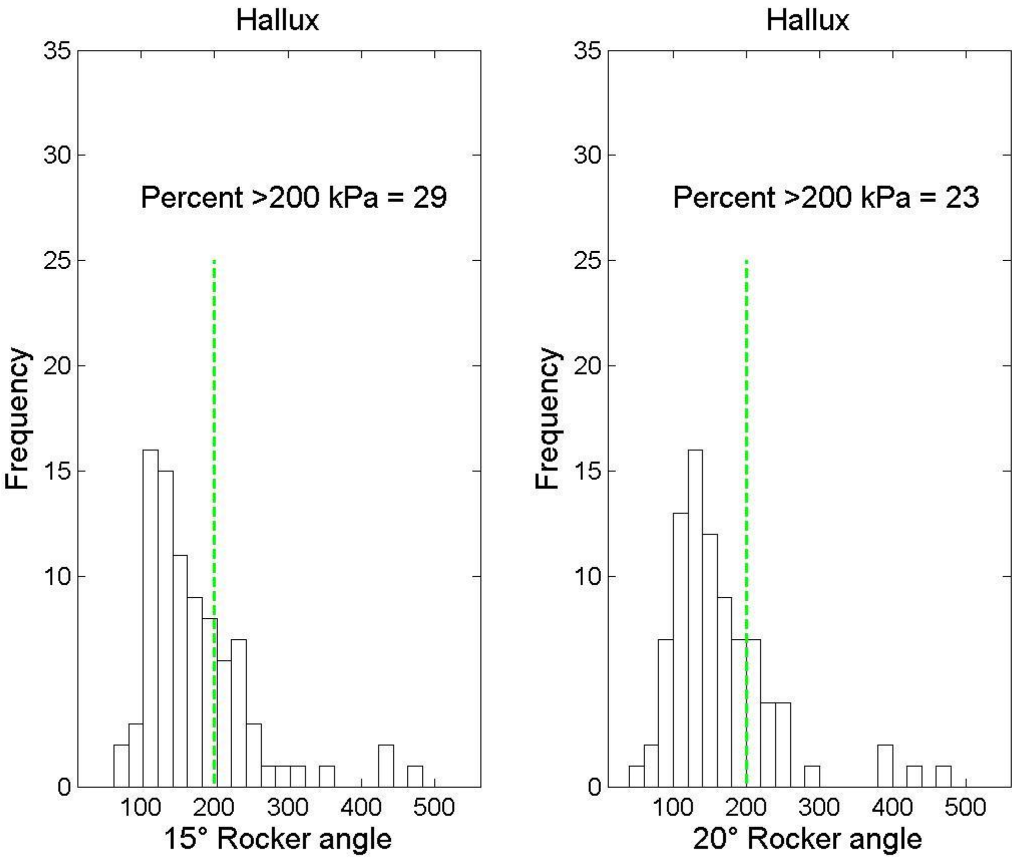

Figure 4. 18: Peak pressure distribution for the mean optimal apex position (52%) using a 15° and 20° rocker angle and the percentage of the population above the 200 kPa threshold.

5th MTH (Figure 4. 19): This region produced the smallest proportion of the population who would need a different apex position. Only 1% of the population did not receive sufficient offloading for both rocker angles.

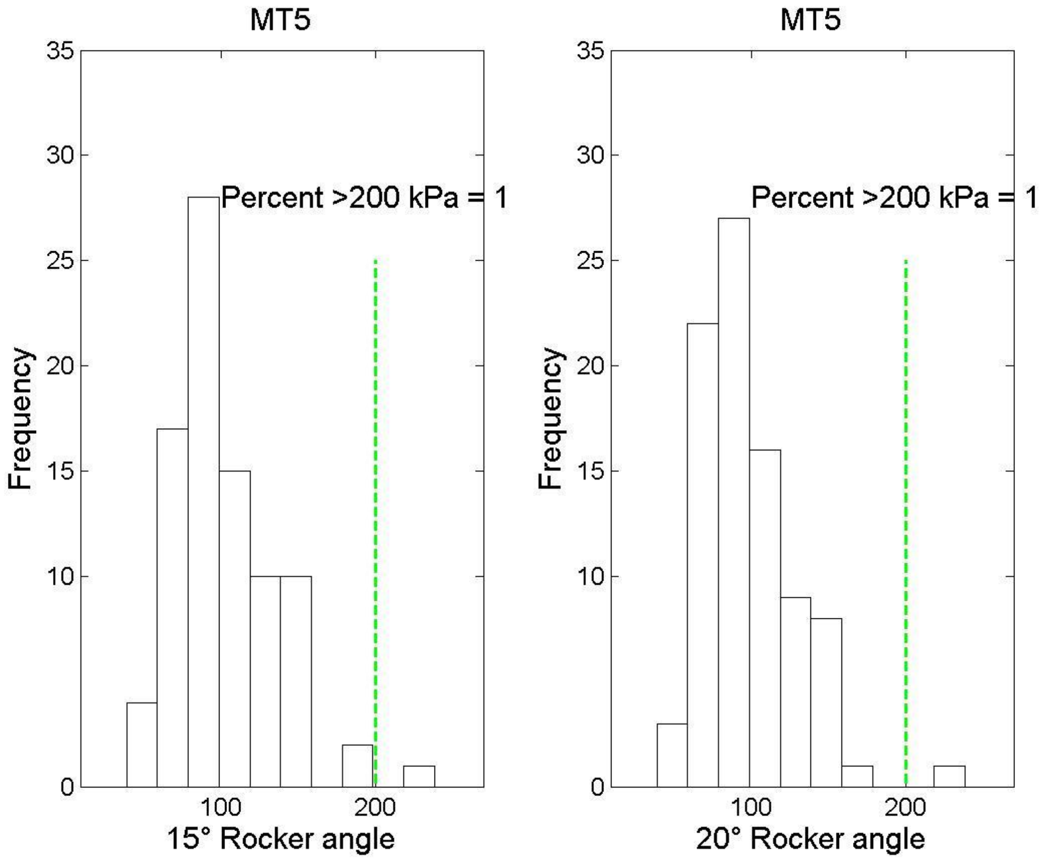

Figure 4. 19: Peak pressure distribution for the mean optimal apex position (52%) using a 15° and 20° rocker angle and the percentage of the population above the 200 kPa threshold.

4.8 Discussion

The first aim of this study was to establish whether there was a different effect of the outsole designs on healthy participants and people with diabetes. This would not only establish whether healthy pressure data can be extrapolated to make recommendations for shoes for people with diabetes who are classed as low risk but also give insight into plantar pressure differences between the two groups. Study 1 also evaluated the difference in pressures, however, Study 2 was completed using a much larger data set (n = 76 healthy, 87 people with diabetes compared to 24 in each).

The second aim of this study was to understand the effect of varying apex position in combination with rocker angle. Results from Study 1 showed that different combinations of rocker angle and apex position needed further evaluation because of the high levels of inter-subject variability (Chapman et al., 2013). Using the results from Study 1, a single apex angle, for optimal offloading was defined (95°) as well as a range of apex positions and rocker angles. The aim of evaluating the effect of different combinations of apex position and rocker angles, was to increase the understanding of the interactions between these two design which will, in future, lead to improved design of rocker soled shoes.

The third aim of this study was to establish whether a pre-defined rocker sole could provide sufficient offloading, or if the design needs to be adjusted for each individual. Clinically, this is an important question because being able to prescribe a pre-defined shoe is more time efficient, and cost-effective, than having to prescribe an individual design. The criteria for sufficient offloading was based on findings of Owings et al (2012), who proposed that a 200 kPa threshold should be adopted when prescribing footwear in order to reduce the risk of ulceration. To accomplish this aim, two objectives were defined. Firstly the mean optimal design was identified. Secondly the proportion of individuals for which there was acceptable offloading was quantified for the control shoe, mean optimal rocker sole and individual optimal rocker sole.

Finally, this one of the aims of study 2 was to develop a prescription method for rocker soled shoes. Before a method could be established, it was important to ascertain whether sufficient offloading can be achieved with a 15° rocker angle because people with diabetes are more likely to wear a shoe with a smaller rocker angle.

The discussion below firstly summarises the findings from the between groups analysis. Secondly the main effect and interaction findings for rocker angle and apex position are presented and the results compared to previous literature. Thirdly, a discussion is presented on whether all people can wear a pre-defined rocker sole and a recommendation process will be presented which could be incorporated into a clinical setting. Finally, the conclusions and limitations of Study 2 are discussed.

4.8.1 Between group peak plantar effect.

The results showed differences in peak plantar pressures between the healthy group and people with diabetes group. These differences may be associated with the people with diabetes group having a significantly greater body weight compared to the healthy group and being significantly older. It is equally possible that the differences in peak pressures may be associated with factors associated with diabetes, as it is well known that tissue mechanics are affected by diabetes and cause a subsequent increase in plantar pressure (Mueller et al., 2003). There are a number of ways by which diabetes can affect the plantar layers of the skin; changes to the density and thickness of the plantar tissue have been shown to be significantly different in people with diabetes (Mueller et al., 2003, Robertson et al., 2002). Despite the people with diabetes in this study not having neuropathy and being classed as low risk, changes in tissue mechanics are associated with the increase in plantar pressure.

This increase in planter pressure confirms the need of preventative methods for ulceration. It is known that people with diabetes are more likely to develop an ulcer if they have increased plantar pressure in combination with neuropathy (Boulton, 2013). It is evident that a significant increase in plantar pressure can occur in a patient with diabetes who does not show evidence of neuropathy. A preventive method is needed because the onset of neuropathy is a gradual process and the patient may develop skin damage before evidence of neuropathy is identified (Boulton et al., 1994, Levin and O'Neal, 1988).

There were minimal interactions between the people with diabetes and healthy group. Therefore, varying the design features of the rocker footwear has the same effect on both groups of participants. The following discussion will only focus on the results obtained from people with diabetes.

4.8.2 Main effects and interaction of rocker angle and apex position

The second aim of this study was to understand the effect of varying apex position in combination with rocker angle. This is the first study to evaluate the effect of different combinations of design features for a curved rocker sole with a 95° apex angle, with results illustrating that the effect of rocker angle in combination with apex position differed between the anatomical regions. There was a significant reduction in pressure when the rocker angle was increased from 15-20°. Despite the positioning of the apex, this effect was observed for all of the forefoot regions. It can be concluded that increasing rocker angle from 15 to 20° reduces peak plantar pressure.

A number of other studies have also shown rocker angle to have a significant effect on plantar pressure (Chapman et al., 2013, Nawoczenski et al., 1988, van Schie et al., 2000). The study by Van Schie et al (2000) also used a factorial design and found that at any apex position, an increase in rocker angle gave greater pressure relief. It was suggested this was associated with the larger rocker angle, causing a rocking action which occurs over a longer period of time during the stance phase, before the distal part of the sole comes into contact with the ground (van Schie et al., 2000). The results in the previous chapter also demonstrated a significant difference between the rocker angles of 15 and 20° (Chapman et al., 2013). However, the use of a 20° rocker angle compromises the aesthetics of the shoe, so configurations with a 15° rocker angle were also explored in this study.

The results showed a differing response when adjusting the apex position between the forefoot regions. No mean optimal position was observed for the 1st MTP, hallux or 5th MTH regions. However, the most posterior position of 67% caused a significant increase in pressure. There was still a degree of inter subject variability for these regions which suggests that apex position will need to be adjusted for optimal offloading. In contrast, for the 2nd-4th MTH region, the results showed there was a mean optimal position of 52%. Furthermore, there was little inter-subject variability for this region demonstrating that in order to reduce pressure in this region, the apex position can be fixed for all individuals. The finding of the main effect results there is a mean optimal apex position for the 2nd-4th MTH region, it suggests that increasing the apex angle past perpendicular changes the effect of the apex position under this region. This study also reported a reduction in the inter-subject variability for this region.

A number of other studies have evaluated the effect of varying apex position (Chapman et al., 2013, Nawoczenski et al., 1988, van Schie et al., 2000). Van Schie et al (2000) came to the conclusion that apex position will need to be adjusted for optimal offloading, however, van Schie did not report a mean optimal position for the 2nd-4th MTH region. The study by van Schie et al (2000) used an apex angle of 80°. Additionally, the results of Study 1 also did not show a mean optimal position for this region when using an apex angle of 80° (Chapman et al., 2013). In summary, these studies did not show an optimal apex position. This supports the finding that using an apex angle >90° changes the affect apex position has on plantar pressure in the 2nd-4th MTH region.

4.8.3 Can all participants wear a pre-defined rocker sole or does each person need an individual design?

One of the key aims of this study was to establish whether the participants could all wear a pre-defined outsole design. This is an important question because it is more efficient in practice if a clinician can prescribe a single deign for all patients. By using the criteria defined by Owings et al (2009), it was possible to quantify how many people would be at increased risk of ulceration in different footwear designs. Two studies (Owings et al., 2009a, Waaijman et al., 2012), have suggested the risk of ulceration can be minimised if peak plantar pressure is reduced below 200 kPa. This is a meaningful measure to clinicians because it provides them a target threshold when prescribing footwear. This study allowed the risk of ulceration in different footwear designs to be quantified

Firstly, it was important to compare effectiveness of rocker soled shoes to that which people with diabetes wear normally (control shoe). This would not only support the evidence for using an apex angle >90°, but also quantify the increase in risk of not wearing a rocker sole. The mean values of the control shoe, mean optimal and individual optimal rocker sole (Figure 4. 11), showed the individual rocker design was the only design which would reduce the risk of ulceration. These results suggest rocker soles are more effective than a control shoe but they will need to be individually adjusted.

The mean values from the three different shoe samples do not convey the complete effect (Figure 4. 11). In Study 2, the proportion of participants over the 200 kPa threshold for the three different shoe samples was quantified. The results showed a large proportion of the participants were at greater risk when walking in the control shoe. For example, under the 1st MTP over half of the participants were at greater risk and nearly 90% were at greater risk for the 2nd-4th MTH region. However, the results demonstrated that participants were at less risk from ulceration when walking in a rocker soled shoe. The results also showed that over two thirds of the participants would be at less risk when wearing the mean optimal rocker sole for the 1st MTP and Hallux region. Remarkably, under the 2nd-4th MTH the number of people over the threshold was reduced by 70%. This is a noteworthy finding because simply looking at the mean values suggests the only way to achieve sufficient offloading is to adjust the outsole for each individual, which is not the case.

The risk of ulceration was reduced further when the individual optimal design was selected. There was a small improvement in the proportion over the threshold between the mean optimal and individual design. The proportion of people above the threshold in the mean optimal shoe showed large increases in plantar pressure; for example, under the 1st MTP there was a mean increase of 48 kPa. When the individual design was selected the pressure was still above the threshold, however, the pressure was considerably lower than if they wore the mean optimal design. For this proportion of people, it is critical an individual design is selected in order to reduce pressure as much as possible because of the higher risk of ulceration despite the selection of footwear.

The results in Study 2 also showed a rocker sole may need to be designed for a specific region. It has been established that plantar ulcers most commonly occur under the Hallux, 1st MTP, and the medial metatarsal heads (Waaijman et al., 2012). In this study, any rocker design configuration significantly reduced pressure under the 2nd – 4th MTH compared to the control shoe. In Study 2, there was a mean reduction 71 kPa compared to 74 kPa in Study 1 (Table 4. 6). Interestingly, the similar level of reduction was achieved in Study 2 when half of the rocker configurations had a 15° rocker angle compared to 2/12 in Study 1. Despite it being shown that increasing the rocker angle from 15 to 20° causes a significant reduction in pressure, it is clear the basic rocking action is sufficient to significantly reduce pressure in this region.

A rocker sole will need to be designed specifically for two regions of the forefoot. The 5th MTH region produced pressures under 200 kPa even in the control shoe and is not at risk of ulceration. The mean reductions compared to the control shoe, under the 1st MTP and

Hallux were not as large compared to the 2nd-4th MTH, however, the mean reductions were increased compared to Study 1 (Table 4. 6). In Study 1, the apex angles <90° only produced minimal reductions for the 1st MTP and Hallux region. Study 2 shows there were significant reductions for three and two of the rocker configurations for the 1st MTP and Hallux respectively (Table 4. 6). It can be concluded that a rocker sole will need to be designed for either the 1st MTP or Hallux region, depending which has the highest pressure.

Table 4. 6: Mean reductions compared to the control for the rocker soles in Study 2 with a 20° rocker angle, the rocker soles in Study 1 which varied apex angle, and the rocker soles in Study 1 which varied apex position(* denotes significant difference).

		1st MTP	2nd – 4th MTH	Hallux
Used in Study 2 Apex position (20° rocker angle and 95° apex angle)	52%	-33.48*	-98.76*	-24.17*
	57%	-28.44*	-82.24*	-19.51*
	62%	-28.22*	-69.67*	-16.41
	67%	-14.18	-56.02*	-5.07
Used in Study 1 Apex angle (20° rocker angle and 60% apex position)	70°	8.47	-78.40*	-1.52
	80°	-0.28	-89.10*	1.7
	90°	-18.07*	-79.83*	-21.10*
	100°	-26.29*	-76.77*	-7.82
Used in Study 1 Apex position (20° rocker angle and 80° apex angle)	50%	2.76	-79.03*	9.29
	55%	-6.38	-86.72*	1.81
	60%	-0.28	-89.10*	1.7
	65%	1.66	-69.54*	-1.58
	70%	16.63	-43.83*	26.54*

4.8.4 Has the design of the rocker soled shoe been improved?

The overall aim of this PhD project was to improve the design of the rocker soled shoe. In order to establish whether this aim has been achieved, the peak pressure was compared between the shoes used in Study 2, which had a 95° apex angle, and those in the previous study, most of which had an 80° apex angle. The graphs shown in Figure 4. 20 show the mean values for all the rocker shoes in this study (top row) and the shoes investigated in the previous chapter (bottom row). The mean values from the shoes studied in the previous chapter were re-calculated using only the people with diabetes data. The exact choice of apex angle and rocker angle in the two datasets is not equivalent and therefore direct comparison is not possible. However, the data gives some indication of what happens when the apex angle is changed from 80° to 95°.

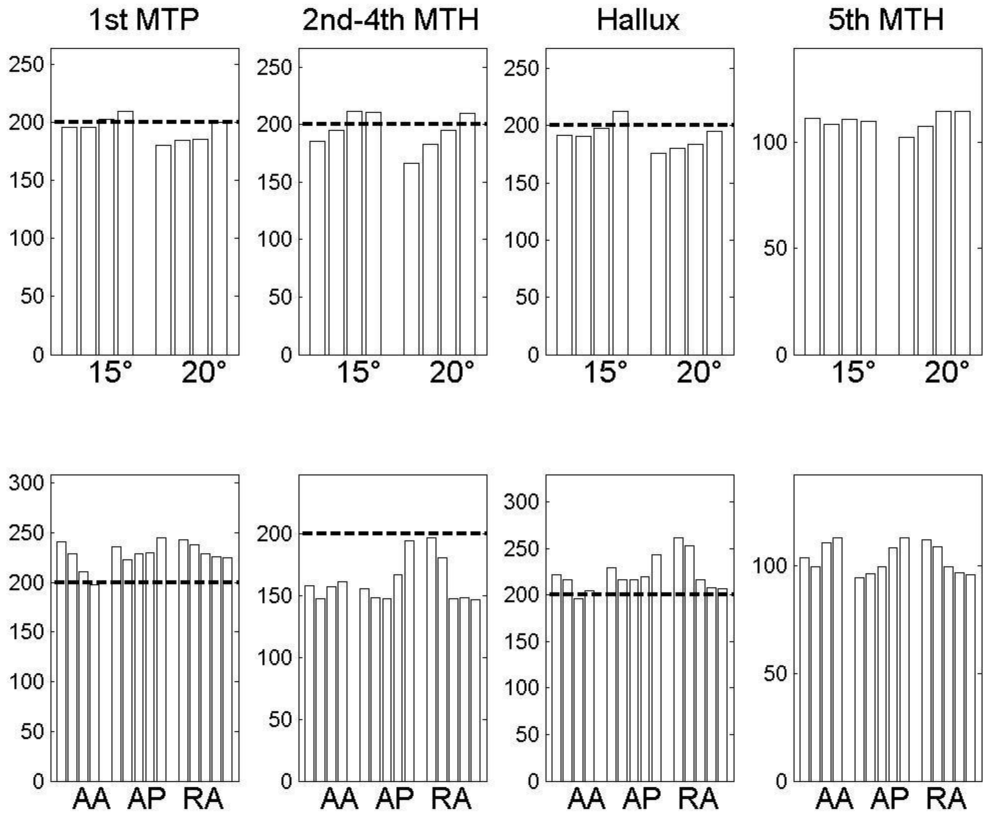

Figure 4. 20: Peak plantar pressure (kPa) for the rocker shoes from current study (top row using a 95° apex angle) in comparison to the shoes from the previous study (chapter 4) (bottom row using a 80° apex angle) for the forefoot regions (the results were recalculated using only the people with diabetes for chapter 4).

Comparing the peak plantar pressure from this current study (top row) to the pressure from the previous study (bottom row), suggests a reduction in peak plantar pressure (Figure 4. 20). For example, under the 1st MTP and hallux region, there was one shoe out of the twelve rocker conditions used in the previous study which was below the 200 kPa threshold. In the current study, three and seven out of the eight rocker soles were below the 200 kPa for the 1st MTP and hallux regions respectively (Figure 4. 20). In Study 1, the only shoe configuration which produced a pressure below 200 kPa had an apex angle of 100°. This comparison suggests that the overall improvement in the offloading, observed in this current study, can be strongly associated with the 95° apex angle. This supports the decision to fix the apex angle at 95° for all rocker configurations used in the current study. The use of this apex angle reduces the risk of ulceration and therefore, by completing Study 1 and 2 the design of the rocker soled shoe has been improved.

4.8.5 Developing a prescription method for rocker soled shoes

A secondary aim of Study 2 was to develop a prescription method for rocker soled shoes. The results of this study, in combination with the previous study, provide considerable insight into the individual effect of each of the principle design features (apex angle, apex position, and rocker angle) as well as the combined effect of apex position and rocker angle. There is sufficient information now available to develop a prescription method using in-shoe pressure as the outcome measure. The results of both these studies demonstrated the potential to improve on both a flexible shoe and on the currently used off-the-shelf design for a rocker shoe which has an 80° apex angle, 55-60% apex position and 15° rocker angle (Hutchins et al., 2009). However, despite a significant reduction in pressure, the current study still demonstrated a degree of inter-subject variability and careful considerations need to be made when prescribing a rocker soled shoe for an individual with diabetes.

Based on the understanding developed in Studies 1 and 2, a method for prescribed rocker sole shoes has been developed. This method is designed to be used in a shop/clinic with the aim of reducing the number of pairs of shoes that each individual needs to try whilst at the same time ensuring that the maximum pressure does not exceed 200 kPa in any region of the foot. The method is based around the use of a baseline shoe which is always worn first, whilst in-shoe pressure data is collected. Depending on recorded pressures and the importance of footwear aesthetics to the patient, they are either prescribed the baseline shoe or required to try other designs.

Defining the baseline shoe

Given the finding of Study 1, the baseline shoe has been defined to have an apex angle of 95°. It would also have an apex position of 52%. This study found the majority of subjects experiencing optimal offloading for this position in all three high risk regions (1^{st} MTP, 2^{nd}-4^{th} MTH and hallux). Furthermore, this position produced the greatest reductions in pressure compared to the control shoe. As explained earlier, rocker angle is the only design feature which can influence a patient's perception of the footwear. Therefore, the baseline shoe will incorporate a rocker angle of 15°. Our data demonstrated that there was only a slight improvement in the number of people below the 200 kPa threshold when the rocker angle was increased from 15 to 20°. Approximately two thirds of the population would have sufficient offloading to reduce the risk of ulceration using a 15° rocker angle.

4.8.6 How the prescription method would work in a clinic

The flow diagram (Figure 4. 21) gives a schematic illustration of how the footwear prescription algorithm would operate. A patient would first undergo in-shoe pressure measurements whilst walking in the baseline rocker design using the measurement protocol described throughout this thesis. The region of highest pressures would need to be identified from the 1^{st} MTP and Hallux region and the outsole selected accordingly. If the results demonstrated in-shoe mean peak plantar pressures below 200 kPa, then the baseline shoe would be considered to achieve sufficient offloading. If the results demonstrated in-shoe pressures above the 200 kPa threshold, then further designs would be tried, whilst in-shoe pressures are recorded.

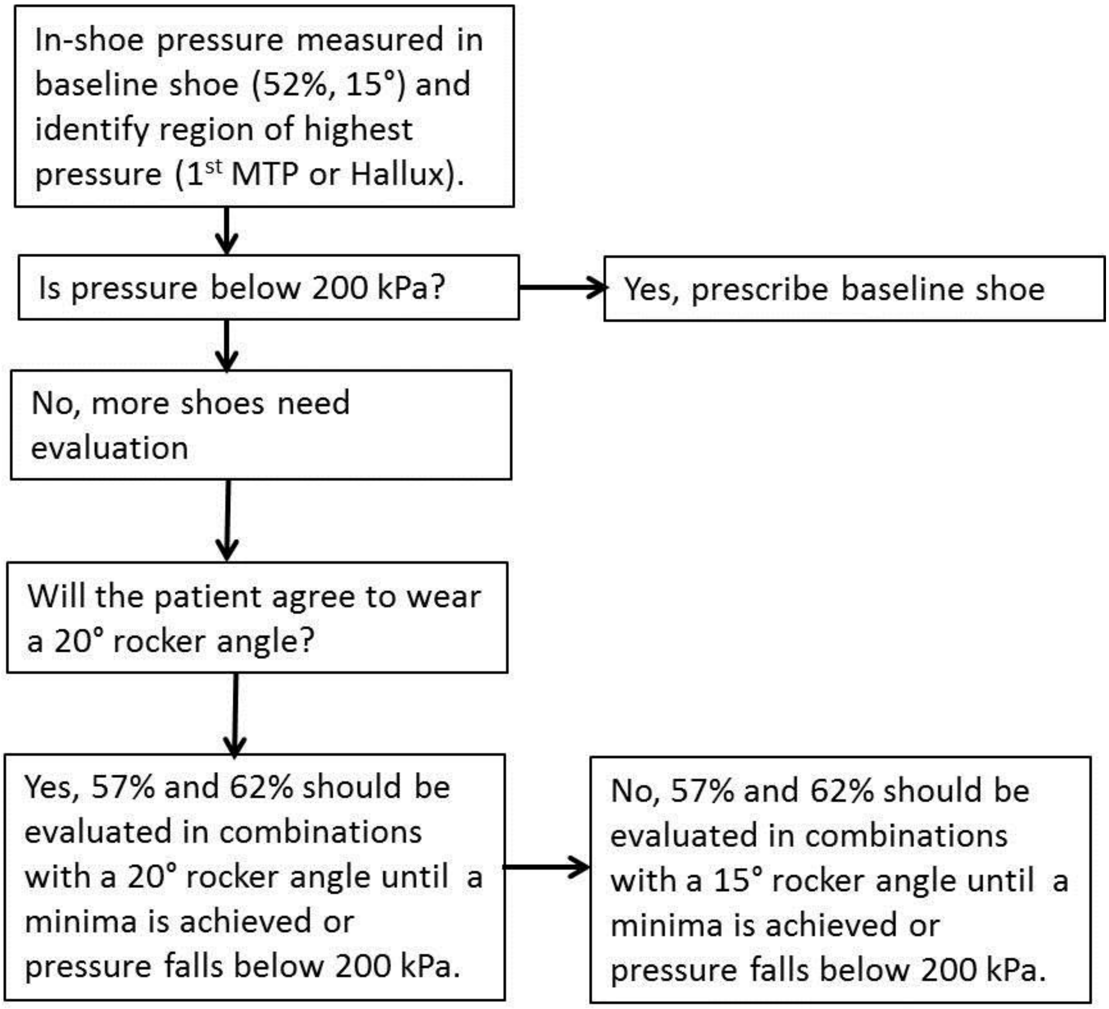

Figure 4. 21: Flow diagram of the proposed prescription method.

Individuals required to try further shoes would first be asked whether they would be willing to wear a shoe with a 20° rocker angle. Due to an increase of approximately 1 cm in the heel height of the shoe, people may not be willing to wear a 20° shoe. Those willing to wear a 20° rocker shoe would then try two additional rocker shoes designs; both with a 20° rocker angle. One shoe would have a 57% apex and the other a 62% apex position. This choice is based on the results presented in section 4.7.2, which showed that the most posterior apex position, 67% of shoe length, was rarely optimal for any of the 87 subjects. Even in cases in which the 67% configuration was found to be optimal, there was never any major difference in pressure values between this position and the second most effective. Those participants not willing to wear the larger rocker angle would be required to try two additional rocker shoes, this time with a 15° rocker angle. The same two apex positions of 57 and 62% would be incorporated with the 15° rocker angle.

4.8.7 Limitations

There are two limitations to this current study. Firstly, including more outsole designs and having smaller increments between the different apex positions would have given a better insight into the effect of this design feature on peak plantar pressure in addition to varying apex angle in combination with apex position. However, the results suggest that the range was large enough in order to select an optimal design. Secondly, this study did not include people with diabetes who also had peripheral neuropathy or were deemed at risk of ulcer development. These people were excluded because the focus of the project was to improve footwear for people in the early stages of diabetes. Nevertheless, this study has provided valuable information with regards to prescribing rocker soled shoes for people without neuropathy. Future studies can use the knowledge gained to advance the understanding of rocker shoe designs in people who suffer with neuropathy.

There are a number of studies which could be developed using the results from Study 2. The rocker sole design has now been investigated extensively and a method of prescribing shoes has been proposed. It would be of interest to complete a randomised control trial using this prescription method. The problem with randomised control trials in the past (Bus et al., 2008a, Lavery et al., 2008, Reiber et al., 2002), was it was not certain whether the most effective shoe was chosen for the study. This project has shown it is possible to significantly reduce plantar pressure using a rocker soled shoe. The next stage to evaluate is whether a configuration chosen using in-shoe pressure as an outcome measure results in a reduced rate of ulceration.

There is still a need to explore other methods of prescribing a rocker sole. As stated in the conclusion, despite the proposed method in this study being effective, it is not efficient enough to work in a clinic. Currently, this method requires all participants to try on one rocker condition and one third to try on at least three conditions. An ideal method would be to identify an optimal outsole design using a single condition. One method would have all the participants walk in a control whilst measuring in-shoe pressure and using CoP variables to predict an optimal outsole. However, the CoP analysis in Study 1 showed weak correlations between CoP variables and peak pressure. Unfortunately, it is unlikely that in-shoe CoP variables would be powerful enough to predict an optimal outsole.

4.8.8 Conclusions

This study has provided a comprehensive understanding of the rocker sole design. The key finding from this study was that sufficient offloading can be achieved using a 15° rocker angle. Rocker angle is a design feature which is heavily influenced by patient perception. If a more discrete rocker can be prescribed it will increase the acceptability of rocker soled shoes to people with diabetes. Apex position is still a design feature which has a degree of inter-subject variability between optimal configurations. For instance, despite the a large proportion showing the 52% position was optimal, there was still a considerable number of people who were distributed between the 57 and 62% positions. The people who showed these positions to be optimal, also showed there was a large increase in pressure when they walked in the shoe with a 52% position (mean optimal position). However, this study was able to define a mean optimal apex position which sufficiently reduced the risk of ulceration for over 60% of the participants.

Based on the experimental findings of the study, a new approach to prescribing rocker footwear has been suggested (Figure 4. 21). The method requires all participants to have in-shoe pressure measured in a baseline shoe, and the participants who need a different design would be identified using a threshold of 200 kPa (Owings et al 2009). This could be considered an effective method for prescribing a shoe because it would clearly achieve health benefits. However, an evaluation of more efficient methods is needed because one third of the participants in this study still need to try on a minimum of three shoes. The time required to complete this prescription does not reflect the time available provided by a normal clinical service.

Chapter 5: (Study 3) Developing an algorithm to predict optimal rocker shoe design from an input of gait data.

5.1 Introduction

The results presented in the previous two studies demonstrate that a one-design-fits-all approach for prescribing rocker footwear may not be effective. This is because optimal rocker designs (resulting in minimum peak pressures) can vary between individuals. For example, Studies 1 and 2 in this thesis, and the study by van Schie et al (2000), have shown that apex position may need to be adjusted on an individual-by-individual basis. Although there are a number of people who experienced sufficient offloading with a mean optimal shoe, others required different design. A procedure was presented in Study 2 for selecting the optimal design by measuring in-shoe pressures in a number of rocker shoes. This method would require almost one third of patients to have in-shoe pressure compared between at least three pairs different of shoes. This approach is time consuming and may not be practical in a clinic or shop setting. Therefore, in this study, three methods were investigated which could be more efficient in a shop or clinical setting (Figure 5. 1).

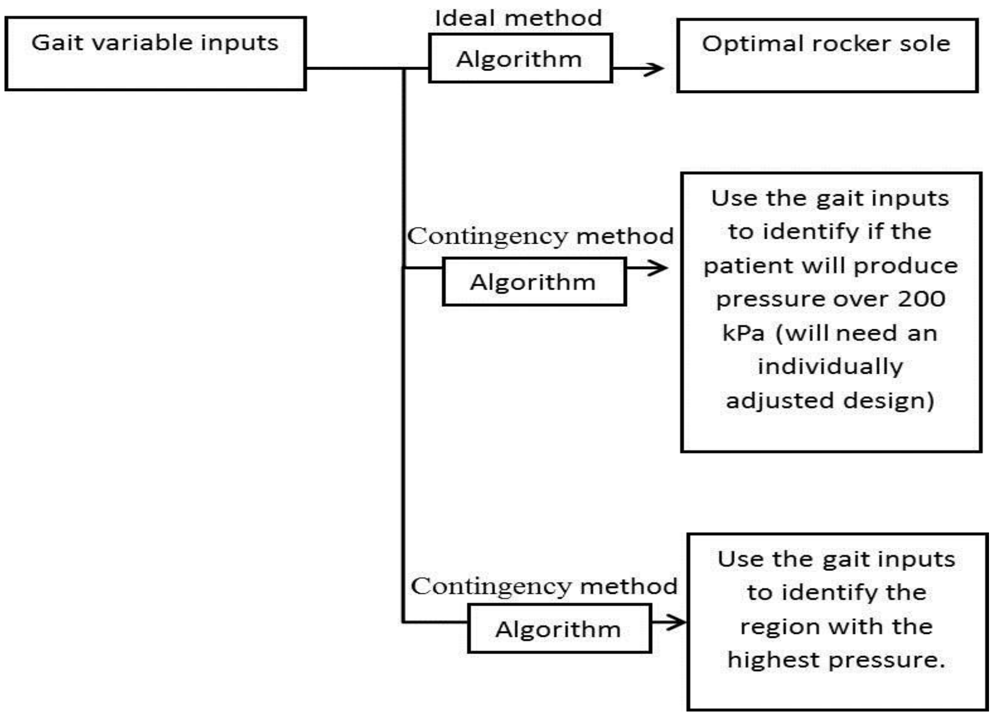

Figure 5. 1: Flow diagram of the different methods which were investigated in Study 3

The first aim of this study was to establish if it would be possible to develop a predictive system that could specify the optimal rocker shoe design from an input of variables (ideal method) (Figure 5. 1). This method could potentially be used in a shop or clinic because the data could be collected quickly and the shoe prescription would be automated. This PhD formed part of the European project SSHOES (FP7/2007-2013), in which another project partner was tasked with developing a miniaturised gait laboratory for collecting foot and ankle biomechanics data. I therefore chose to investigate whether optimal rocker shoe design could be predicted from an input of foot and ankle gait data, collected during barefoot walking. Given the results of previous research which have demonstrated factors such as joint range of motion and hallux length, to be correlated to plantar pressure values (Morag and Cavanagh, 1999), this study investigated a range of different structural, physical, and functional factors and analysed whether they could be used to predict in-shoe pressure.

A two-phased approach was used to develop the prediction system for in-shoe pressures in rocker footwear. Firstly, a stepwise-regression model was developed for each shoe to identify the factors which were related to peak plantar pressure. Once these factors had been identified, a neural network was developed for each shoe which was able to predict peak pressure from an input of gait variables. The outputs from different networks (one for each shoe) were then used to rank the different rocker shoe designs tested in the previous chapter and therefore to predict the optimal design.

A second aim of the study was to develop an additional neural network-based screening tool which could identify individuals who may exhibit high plantar pressures in the baseline shoe (defined in Study 2, 52% apex position and 15° rocker angle). This aim was included as it was felt that, if shown to be effective, it could be used as an additional screening tool in a shop/clinic to identify individuals who may need more specialist attention as they may be at increased risk of ulceration. To address this problem, a classification neural-network was chosen. This technique has been used successfully in other areas of biomechanics. For example, it was used by Barton and Lees (1997) to identify specific gait patterns from an input of kinematic variables, such as hip and knee angles.

The final aim of this study was to predict the region with the highest pressures. Between participants the region of highest pressure will vary and therefore dictate how a rocker sole is designed. Studies have shown that the region of highest pressure is most likely to develop an ulcer (Waaijman et al., 2012). This method may is not as efficient as the ideal method (Figure 5. 1), however, it may increase the understanding between gait kinematics and outsole design. The pressure predictions from the first research aim were used to rank the regions using the pressure collected in optimal individual design.

5.2 Study 3 Research Question

Is it possible to predict the optimal outsole configuration for an individual using barefoot gait data?

5.3 Study 3 Aims and Objectives

Aims

1. Establish whether in-shoe pressure can be predicted using biomechanical gait variables.

2. Establish whether participants who display elevated plantar pressures (over 200 kPa) can be identified using a set of biomechanical gait variables.
3. Understand whether the region of highest pressure be identified using biomechanical gait variables

Objectives

1. a. Identify biomechanical variables which can predict in-shoe peak plantar pressures in a rocker shoes with varying rocker angle and apex position
   b. Use a neural network to develop an algorithm to predict in-shoe pressure
2. Use a classification network to identify patients with pressure >200 kPa using gait variables as inputs
3. Use the neural network predictions from objective 1.b to establish whether the region of highest pressure can be identified.

5.4 Gait variables which may influence peak plantar pressure

1st MTP

To date, the most in depth study which has investigated biomechanical factors which may predict plantar pressure was carried out by Morag and Cavanagh (1999). This study reported comprehensive models which predict peak pressure for the at risk forefoot regions (1st MTP, Hallux and 2nd-4th MTH). These models incorporated a range of biomechanical variables. For example, the 1st MTP, ankle and 1st MTP joint range of motion (ROM) were incorporated as these variables characterise joint mobility which in turn can have an effect on plantar pressure (Fernando et al., 1991, Rao et al., 2006, Rao et al., 2010). In our study, the radiographic measurements used by Morag and Cavanagh (1999) were deemed unsuitable due their relative expense and invasive nature. However, measurements, such as Morton's index and Halux valgus have been shown to be predictors of plantar pressure (Mueller et al., 2003). Therefore, the measurements of hallux length and 1st MTP distance were included as.

Hallux

An interesting finding from the study by Morag and Cavanagh (1999) was that different regression algorithms, incorporating different biomechanical factors, were required to predict peak plantar pressure in the different regions of the foot. This observation has clear implications for the modelling approached used in this current study and means that each separate region of the foot will need to be investigated separately and appropriate predictor variables identified. For example, in the hallux region, the gait variables related hallux motion may be included in the final regression models, although may not feature in a regression model designed to predict heel pressures. A number of studies have shown the 1st MTP ROM and velocity to be predictors of plantar pressure (Payne et al., 2001, Morag and Cavanagh, 1999). Differences in the ROM and joint velocity of the ankle joint in the sagittal and transverse planes, are most likely to have an effect on plantar pressure.

2nd - 4th MTH

There is little data available from previous pressure studies on the 2nd-4th MTH region. It is therefore more difficult to hypothesis about which gait variables may influence pressures in this region. Although soft tissue thickness has been linked to pressure under the 2nd-5th MTH (Menz and Morris, 2006, Mueller et al., 2003), measurement of this parameter was not deemed feasible given the need to implement the system in a shop/clinic. However, dynamic variables, such as calcaneus motion and motion of the 1st MTP play a role in determining loading patterns during walking (Morag and Cavanagh, 1999). Furthermore, the 1st MTP and calcaneus are considered to be representative of motion of the arch (Rao et al., 2007). It therefore possible that these factors may also influence peak plantar pressure in the forefoot regions.

5.5 Design

A multiple regression design was chosen for this current study because the aim was to predict both design features of rocker shoes and in-shoe pressures from a set of gait variables. The analysis was carried out in two phases, the first of which involved using regression analysis to identify appropriate input variables, and the second was to develop a neural network which could predict in-shoe pressure.

5.6 Participants

The same participants who completed the in-shoe pressure study in chapter 5 were also used for this study. However, it was only possible to collect 76 datasets from (from a total of 87) participants because of time constraints in the laboratory. The University of Salford collected 38 of the 76 participants and the remaining 38 participants were collected at the German Sport University (Cologne). The gait measurements were taken before the participants underwent the in-shoe pressure measurements (described in the previous chapter).

Table 5. 1: Participant demographics. Mean (Standard deviation)

Height	1.708 (0.097)
Weight	87.8 (17.8)
Age	56.3 (9.4)
Male	n=44
Female	n=32

5.7 Gait analysis methods

This section describes the gait analysis procedure which was carried out for the study in this chapter. These procedures were standardised between the University of Salford and the German Sports University on number of exchanged visits. All of the gait measurements at the University of Salford were undertaken by the PhD candidate and the measurements were collected in the Brian Blatchford building gait lab at the University of Salford. The measurements taken at the German Sports University were carried out by Dr Bjoern Braunstein.

5.7.1 3-D kinematic data capture

This study collected three-dimensional kinematic data of the lower limb and foot to quantify the movement of walking. Vicon ^{TM} (Oxford, UK) infra-red cameras and passive reflective markers were used to capture these data. A connection to the cameras was enabled by Vicon's exclusive software, "Workstation" which was also used to complete the calibration procedure. Once the cameras had been calibrated, data collection could commence and following this, the reconstruction of the 3-D retro-reflective markers.

5.7.2 Camera setup

Prior to the calibration procedure of the cameras, careful consideration needs to be made to the positioning and orientation of the cameras. A total of nine cameras were positioned in order to create a capture volume of approximately, (x) 2.5 m, (y) 1 m and, (z) 1.6 m which would allow data for two steps to be collected. The volume was measured using the retro-reflective markers and the cameras were positioned at an even distance around the force plates. Pilot gait data collected at the front, middle and, end of each force plate, was used to ensure the cameras were positioned so they could see all of the markers in the capture volume and to ensure the markers did not merge during the gait cycle. All of the cameras were adjusted to a height of approximately 1.9 m and the angle was adjusted to prevent the cameras detecting another cameras infra-red light.

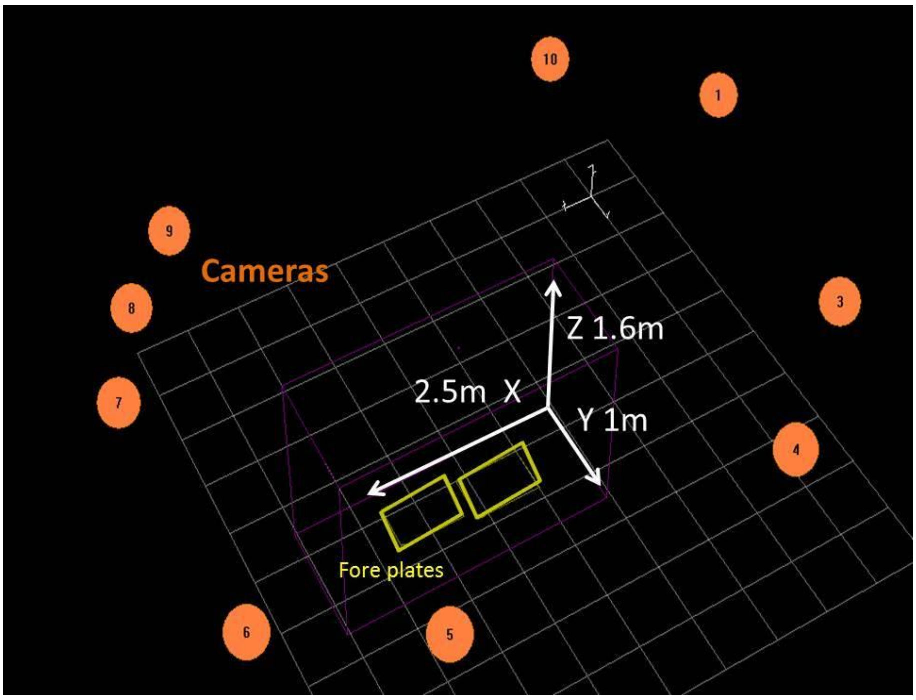

Figure 5. 2: Camera capture volume

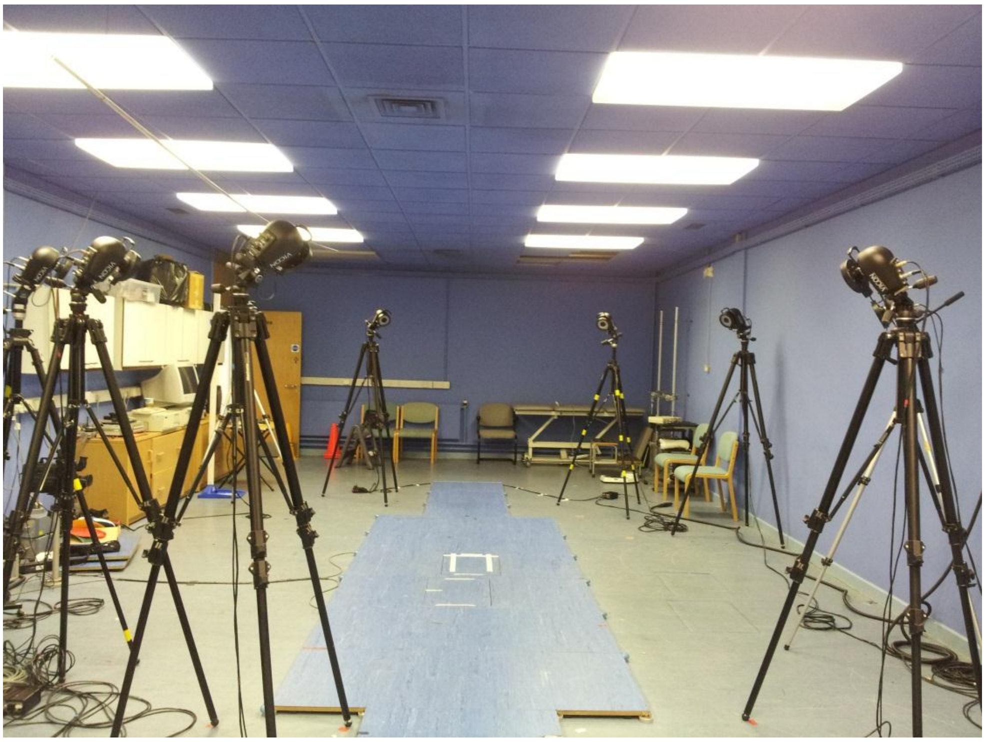

Figure 5. 3: Final camera setup

5.7.3 Calibrating the capture space

The calibration process is required for the three-dimensional coordinates to be calculated. In order to extrapolate three-dimensional coordinates from the individual two-dimensional coordinates provided by each camera, a global or lab reference system must be created. Firstly, in order to create a global coordinate system, the position and orientation of the cameras must be calibrated with a known frame of reference. This is known as the static calibration. In this study an "L" shaped group of four of retro-reflective markers which were attached to a frame which was placed on the floor, the frame had a lip so it attached to the edges of the force plate. The frame was positioned as shown in Figure 5. 2, where the X direction coincides with the direction the participants walked in. Placing the L frame over the bottom of the force plate ensured the first marker was over the bottom corner of force plate 1. This defines the origin of the global coordinate system (Figure 5. 2). However, because the first marker is placed higher than the floor, an offset was applied to the calibration process for the Z component. Therefore, the origin of the global coordinate system was 0, 0, 0, for the X, Y and, Z axis respectively.

In addition to defining the origin, a "wand" with retro-reflective markers attached was moved dynamically through the capture volume. In this current study, a 240 mm wand was used for the dynamic calibration. The dynamic calibration procedure, creates a large number of two dimensional coordinates and by applying a procedure called bundle adjustment (Richards, 2008), the position and orientation of the cameras and three-dimensional coordinates of the wand can then be calculated.

The determination of the coordinates for each marker is an estimation with errors. Errors in each marker are reported as a residual error, which is a summation of the errors present. A successful calibration will produce the results shown in Figure 5. 4. If the mean residual error is <= 1.00 mm, the calibration was unsuccessful. The aim of the calibration is to cover as much of the capture volume as possible and to have to mean residual error as low as possible. In this example, the mean residual was < 0.6 mm ± 0.05 with a maximum residual of 0.7 and a minimum of 0.54. These results were maintained throughout the course of the study.

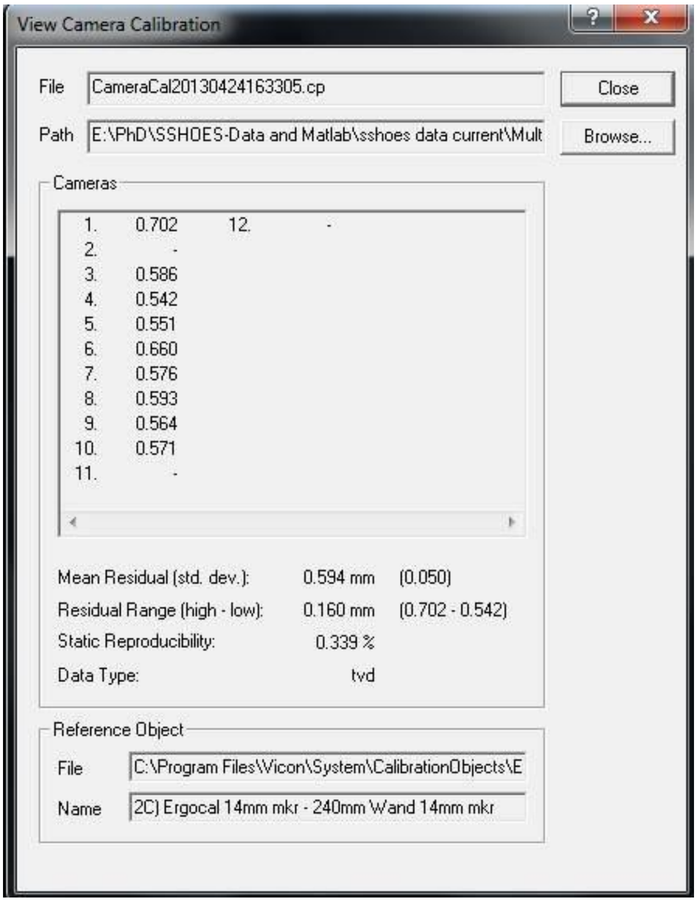

Figure 5. 4: Calibration results.

5.7.4 Global coordinate system

The calibration frame was used to define the global coordinate system as a Cartesian coordinate system. A position in the global coordinate system is defined in relation the origin, either by the 2-D (X, Y) or 3-D (X, Y, Z) coordinates (Robertson, 2004). In this study, the origin was placed on the corner of the first force platform (Figure 5. 5). A slight variation of the axis was used in this study compared to what was recommended by Wu and Cavanagh (1995) (Wu and Cavanagh, 1995). The X- axis still pointed in the anterior-posterior direction, however, the Y- axis pointed in the medial lateral direction, and the Z axis pointed vertically. Once the global coordinate system is defined, the location of the markers attached to the subject can be located.

The infrared cameras each provide a set of 2-D coordinates which are converted into 3-D coordinates. In order to create a set of 3-D coordinates, a minimum of two cameras must each provide a set of 2-D coordinates for a single marker. For each time frame this process is completed which forms a number of points defining the trajectory of the marker (Robertson, 2004). The coordinates for each of the markers can then be exported in a c3d format ready for the calculation of the kinematic variables.

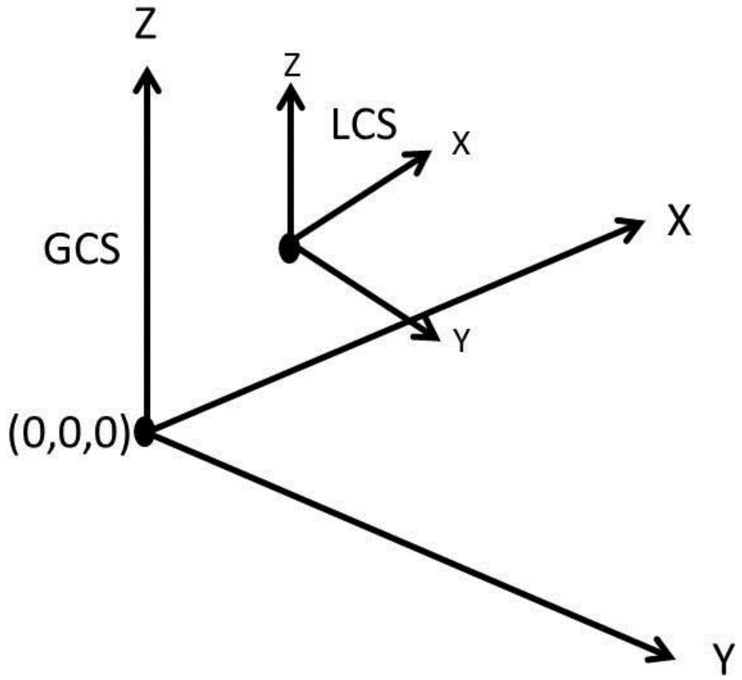

Figure 5. 5: Local coordinate system attached to a moving segment (LCS) within the global coordinate system (GCS).

5.7.5 Kinetic data

In addition to motion data, ground reaction force data was collected using two portable Kistler 9268 force plates. Force measurements are considered as a basic but an extremely important tool for gait analysis (Richards, 2008). The force plates were mounted in a raised walkway and were aligned so the stride collected was always the left foot followed by the right foot (Figure 5. 6). During testing, participants were not instructed to make contact with the force plates but to maintain a constant walking speed of 1m-s. To achieve a constant walking speed, participants walked for a few strides prior to making contact with force plates (Figure 5. 6). The researcher simply moved their starting position in order for them to make contact in the middle of the force plate. A trial was deemed successful if participant positioned their foot within the first force plate and their right foot within the second.

Force data was collected through a 64 channel Measurement Computing analogue-to-digital board. Kistler force plates are piezoelectric, which are more sensitive and allow for a larger range of force measurements (Richards, 2008). However, piezoelectric force plates have the disadvantage of signal drift. Therefore, prior to each set of trials, the force plates were reset which restores all signals to zero and therefore eliminates the effect of drift.

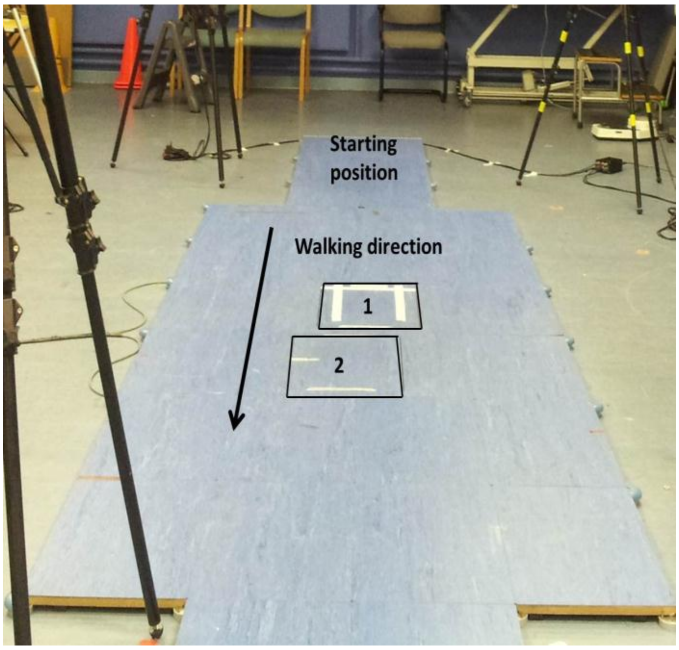

Figure 5. 6: Force plate and walkway arrangement.

Piezoelectric force plates work by using piezoelectric crystals or quarts. A group of these quarts are contained at each corner of the force plate. When a person walks over the force plate, they cause a deformation of the crystals which then generate an electric current. The electric current responds to the force applied over the force plate. Eight analogue channels produce the following voltage data which is used to quantify the force in Newton's:

Chanel 1: fx – force measured in the x direction by transducers 1 and 2.
Chanel 2: fx – force measured in the x direction by transducers 3 and 4.
Chanel 3: fy – force measured in the y direction by transducers 1 and 2.
Chanel 4: fy – force measured in the y direction by transducers 3 and 4.
Channel 5 – 8: fz - force measured in the z direction by transducers 1 – 4.

The force data is calculated in each direction by simply summing the channels for the X, Y, and Z components together.

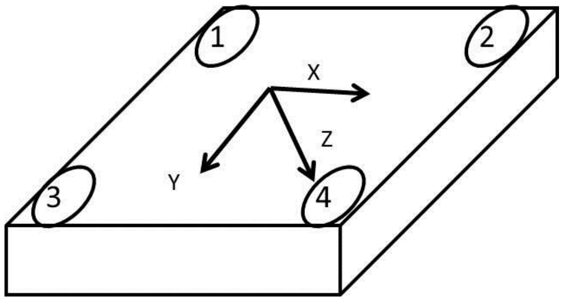

Figure 5. 7: Piezoelectric force plate schematic.

5.7.6 Kinematic marker placement

The most important assumption in 3-D analysis is to assume all the segments are rigid (Cappozzo et al., 1996). Although, in reality the human skeletal structure is not a rigid structure. However, by making this assumption it reduces the mathematical error. In order to track a segment in a 3-D space, three noncollinear markers are needed for each individual segment (Robertson, 2004). There are various methods of attaching these markers to a segment, markers mounted on bone pins, skin-mounted markers on anatomical landmarks, arrays of markers on a rigid plate attached to the skin, and a combination of skin-mounted and rigid plate.

In this study, because the marker set up needed to be kept as simple as possible, skin mounted markers attached to bony landmarks were chosen. Even though markers mounted on bone pins are considered the gold standard, they are clearly not applicable in a clinic setting and markers on arrays will increase the complexity of the protocol. In this protocol, the same markers which were used for the static calibration were also used for the dynamic trials.

Three segments (shank, calcaneus, and forefoot) were defined and tracked using reflective markers. Dynamic variables such as calcaneus motion and motion of the 1st MTP may be related to loading patterns during walking (Morag and Cavanagh, 1999). Furthermore, the 1st MTP and calcaneus are considered to be representative of motion of the arch (Rao et al., 2007). The marker set-up employed was similar to the marker set up used in the studies by Braunstein et al (2010) and Goldmann et al (2012) and was chosen because of its simplicity and therefore viability in a clinical setting.

Vicon reflective markers with a diameter of 9 mm were attached via double sided adhesive tape to the skin (Figure 5. 8).

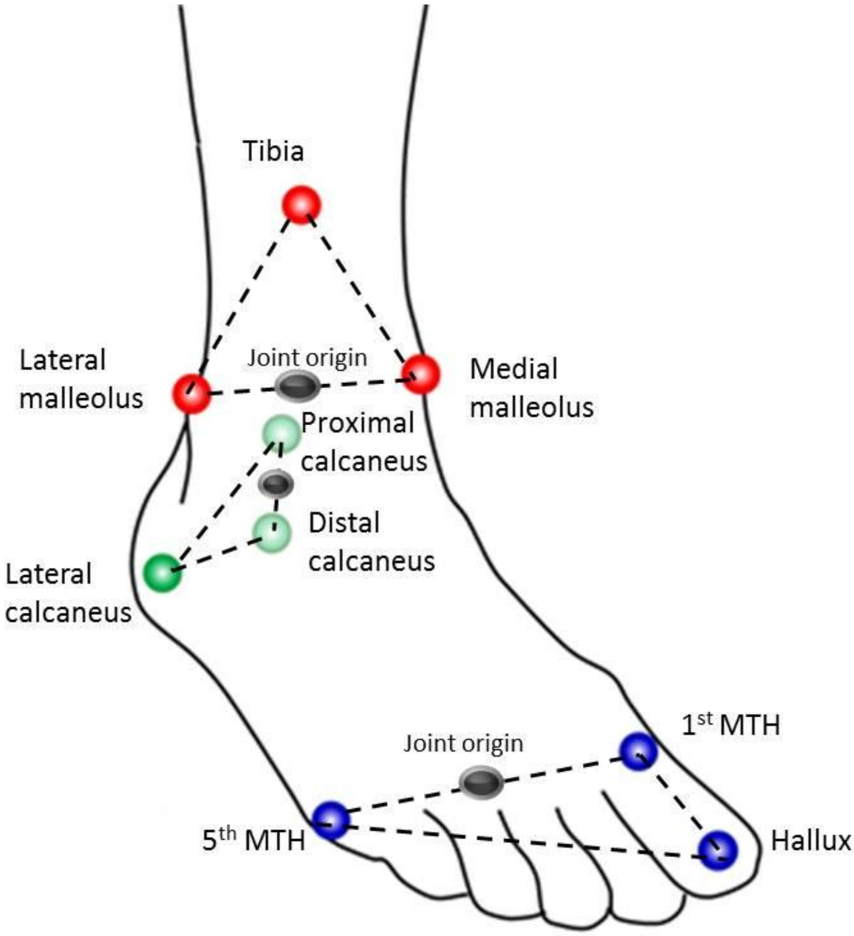

Figure 5. 8: Marker positions and corresponding model.

Markers for the ankle joint centre

The accurate location of the ankle joint centre is paramount because it does not move in a single plane. In addition to movement in the sagittal plane, the ankle joint also moves in the coronal and transverse planes. The most accurate method to locate the centre is to use markers on the medial and lateral malleolus. Nair et al (2010) showed that using markers on the malleolus was significantly more accurate than the Plug-in-gait method (Nair et al., 2010). This study also found reliability and repeatability coefficients greater than 0.9, demonstrating that using markers on the malleolus will minimise measurement errors between subjects. Finally, given the ease with which the medial and lateral malleolus can be palpated, this approach is easy to use in a clinic setting. Therefore, in this study, markers were attached to the medial and lateral malleolus to locate the ankle joint centre.

Shank segment: A marker was placed on the anterior side of the tibia, medial malleolus, and lateral malleolus (Figure 5. ***8***). These markers were then used to define this segment (see section 5.7.10 below) and to track its motion (Braunstein et al., 2010).

Calcaneus segment: Two markers, vertically aligned, on the most posterior position of the calcaneus. The most proximal of the two markers was placed at the most proximal location of the calcaneus and distal of the two markers was positioned just above the fat pad of the heel (Figure 5. 8). Finally, a marker was placed on the lateral side of the calcaneus, just above the heel fat pad and in line with the lateral malleolus (Figure 5. 8). These markers were then used to define (see section 5.7.10) and also to track the movement of the calcaneus segment.

1st MTP segment: The 1st MTP segment was defined with markers on the 1st MTH, 5th MTH, and hallux (Figure 5. 8). The combination of the 1st and 5th MTH markers represents the MPJ axis, which is the same method described by Goldmann et al (2012). In this method, the five metatarsal phalangeal joints are considered as a single joint rotating around the transverse axis (Goldmann et al., 2013) (Figure 5. 8).

5.7.7 Gait analysis protocol

Following informed consent, participants were asked to remove their socks and change into a pair of provided nylon shorts. The relevant anatomical landmarks were then located using palpation and marked with a dry marker pen. Once all of the landmarks were located, the 9 mm reflective markers (Vicon) were applied using double sided tape. Data was collected on both the left and right feet, using two force plates mounted in a 10 m walkway.

A static calibration trial was then collected by placing the participant in subtalar neutral position during standing, on the first force plate. This position was used because, with the modelling approach used in this study, (5.7.9), the static orientation of the foot can influence the final joint angle. A line parallel to the Y global coordinate was made on the force plate as well as two lines parallel to the X global coordinate 40cm apart (Figure 5. 9 A). The middle of the heel was positioned where the X axis line crossed the Y axis line (see Figure 5.8 B). The distance between the 1st and 5th MTH's was measured using a calliper and the median position was marked (Figure 5. 9 C). Rotating the foot, whilst the heel remained in the same position, the median point was positioned in line with the X axis. Once the foot was in this position the proximal and distal calcaneus markers were attached.

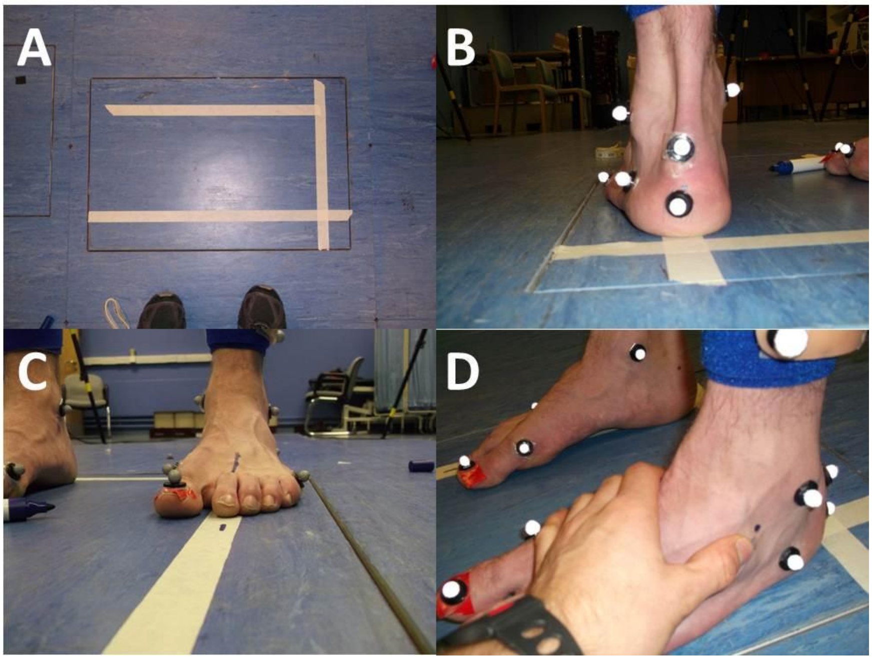

Figure 5. 9: Position of the foot for the static calibration and positioning for subtalar neutral position.

In a subtalar neutral position the subtalar joint is neither pronated or supinated. This position was obtained using the following procedure: First the participant was asked to pronate their foot and the depression anterior and distal to the lateral malleolus was identified and marked with a pen. Following this, participant was asked to supinate their foot and the depression on the medial side identified. This depression is just above the talar head. Placing the thumb and forefinger on the two marks, the researcher then palpated the prominent bone structure on either side of the foot and manipulated the foot until subtalar neutral position was achieved (Figure 5. 9 D). Once this positioned was achieved the participants were asked to stand as still as possible and the static calibration trial was collected. Participants then underwent a walking familiarisation period, 3-5 minutes, before the dynamic data collection begun.

The same walking speed as the in-shoe pressure measurement protocol (1m-s ±10%) was chosen for the barefoot gait data collection. As stated in section 3.6.2, this is a common walking velocity for people with diabetes. Seven dynamic gait trials were collected for which the subject made appropriate contact with the force plates.

In-shoe plantar pressure collection procedure

Plantar pressure data was collected on all 76 participants using the same method described in Study 2. The plantar pressure was collected immediately after the gait analysis protocol. The participants walked in the same outsole configurations described in 4.6.1, however, only six of the rocker shoes were used in the analysis because the apex position of 67% always caused an increase in pressure and therefore was excluded (see Section 4.7.2). Only three regions of interest were selected for the analysis (1st MTP, hallux, and 2nd-4th MTH) because these are the most common sites of ulceration (Cavanagh et al., 2000, Kosiak, 1961, Veves et al., 1992).

5.7.8 Signal processing

Firstly, an interpolation, or gap-filling, algorithm was applied to the raw marker data which had missing data for a maximum of ten frames. Following the interpolation, a smoothing or filtering operation was performed on the coordinates of each of the markers. A 4th order low pass Butterworth filter (Robertson and Dowling, 2003), with a cut off frequency at 12 Hz was applied. Low pass filters allow the low-frequency through, but eliminates the high frequency data. The advantage of this is that the small random digitizing errors and soft tissue errors are removed, however, careful consideration needs to be taken so that the filtering does not change the movement data itself (Richards, 2008). Finally, the ground reaction force, centre of pressure, and free moment signals were also filtered using a low pass Butterworth filter (Robertson and Dowling, 2003) at 25 Hz. To define the stance phase, a threshold of 20N was chosen the define the onset of the foot and toe-off. The events of the stance phase were then used to time-normalise the gait data.

5.7.9 Kinematic model

The modelling approach used in this study created a local coordinate system for which the orientation was defined by the static measurement. With this approach it is necessary to position each subject in the same pose during the static trial to avoid unwanted offsets in kinematic data between different subjects. To achieve this each subject was placed in subtalar neutral position and the foot was aligned with the lab coordinate system for the static measurement. A cardan sequence of X-Y-Z was chosen because the coordinates of the segments were as follows, z- up, y – anterior , x – lateral (Richards, 2008). Therefore, the resultant first, second and third angular displacements resulted in, flexion-extension (X component), abduction-adduction (Y component), and internal-external (Z component). Angular displacement was then used to calculate the ROM). Following this, the joint angular velocity was then calculated. Joint angular velocity is the rate of change in the angular displacement. Finally, the joint moment for the ankle joint was calculated ().

5.7.10 Calculating variables

The software Visual 3D (c-motion) was used to calculate the kinematic trajectories. The model described above was implemented. See Table 5. 2 and Figure 5. 10 for the calculation of the biomechanical variables.

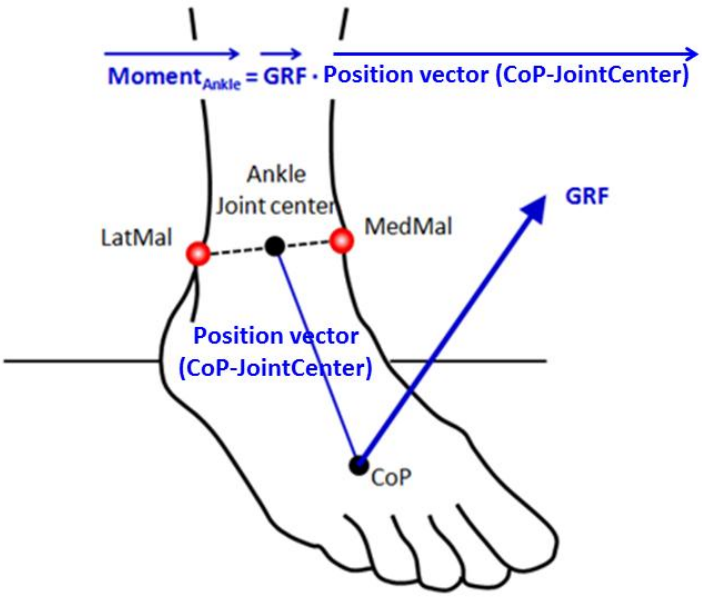

Figure 5. 10: Joint moment definition for the ankle joint.

5.7.11 Gait variables

In order to characterise the kinematic and kinetic data , a number of specific gait parameters were derived from the kinematic/kinetic trajectories. These were based around the hypotheses stated in section 5.4 and are detailed in Table 5. 2. Note that to avoid confusion with the static variables these measurements will be referred to as dynamic measurements for the remainder of this chapter.

Table 5. 2: Dynamic variables included in the stepwise multiple regression.

Ankle joint maximum moment (x, y, z)	The maximum moment value during stance.
MTP joint ROM (x, y, z)	The difference between the minima and maximum MTP joint angle during stance.
Ankle joint ROM (x, y, z)	The difference between the minima and maximum ankle joint angle during stance.
MTP joint maximum angular velocity time (x, y, z)	The maximum angular velocity during stance for the 1st MTP joint.
Ankle joint maximum angular velocity time (x, y, z)	The percentage of stance where the maximum velocity occurred.
MTP joint maximum angular velocity (x, y, z)	The maximum angular velocity during stance for the 1st MTP joint.
Ankle joint maximum angular velocity	The maximum angular velocity during

(x, y, z)	stance for the ankle joint.
COP displacement (x, y)	The difference between the minima and maximum COP value during stance.

5.7.12 Physical characteristics and foot structure inputs

In addition to the gait variables, a number of physical characteristics and foot structure variables were also derived. Most of the foot structure inputs were obtained from the static gait trial, with the exception of, foot length which was measured using the 3D foot scan data. Each of these variable is listed in Table 5. 3. To avoid confusion, these measurements will be referred to as static measurements for the remainder of the study.

Table 5. 3: Static measurements included in the stepwise multiple regression.

Foot length	Distance between the most distal point of the heel and the most proximal point of the hallux
1^{st} MTP length	Distance between the most distal point of the heel and the middle of the 1^{st} MTP
5^{th} MTH length	Distance between the most distal point of the heel and the middle of the 5^{th} MTH
Hallux length	Distance between the most proximal point of the hallux and the middle of the 1^{st} MTP
Body weight	Weight of the person measured in Kg
MTH break angle	The angle between the 1^{st} MTP and 5^{th} MTH

5.7.13 Statistical analysis

A statistical analysis plan was developed to address each of the three questions stated at the end of the introduction. The first aim was to identify variables which can predict in-shoe plantar pressure whilst walking in rocker soled shoes. To answer this question a two-phased approach was used (objectives 1a/b). Firstly, a multiple linear stepwise regression algorithm was employed to build a model of predictive variables. The stepwise method begins with no terms in the model and uses a p-value tolerance of 0.05 to build a model by adding and removing variables based on the p-value tolerance. This process is continued until there is no further improvement in the model. In this study, there were 76 rows of data (participants) and 24 columns of variables, giving a ratio of 3:1. Separate stepwise regressions were conducted for each region and each shoe, producing a total of 18 models (three regions six shoes). Finally, the r-square and r square adjusted were calculated. The r-square adjusted value is the r-square adjusted for the number of variables in the model. If the r-square adjusted value is much lower than the r-square value, it would suggest that the regression has been over-fitted making conclusions limited.

The variables included in the final model of the stepwise regression were then used to conduct a multiple linear regression analysis. This was again conducted for each region and shoe using the variables identified for that region/shoe in the stepwise regression analysis explained above. Prior to running the regression, all of the inputs were normalised using the mean and standard deviations. Specifically, the mean was subtracted from every value to obtain a difference and this difference was then divided by the standard deviation. This approach ensures that the values of each input lies within the range -3 to 3 and therefore balances the effect of each input variable making it easier to understand the relative contribution of each input in the final model.

The first aim sought to establish whether the optimal shoe design can be predicted from a set of gait variable for a specific individual. To answer this question, a fitting neural network was chosen. A fitting network is a type of regression analysis which adjusts its formula by learning from a set of training data (Figure 5. 11). Similar to a biological neuron where information goes in, the neuron processes it and results are created. In terms of a neural network the process is mathematical where a number of layers of artificial neurons are connected creating a multi-dimensional polynomial. Separate networks were conducted for each of the shoes and regions. A customised feedforward fitting network, with 10 hidden layers, was used to fit an input-output relationship. In this case, the variables from the stepwise regression model were used as inputs and the output was the peak in-shoe pressure in that particular region. To train the network, the Levenberg-Marquardt algorithm was used (Ngia and Sjoberg, 2000) and a leave-one-out cross validation was chosen to evaluate the performance of the network in predicting peak pressure. Leave-one-out cross validation involves using a single subject from the original sample as the test data, and the remaining subjects as the training data. This is repeated such that the data from each subject is used once as test data. The advantage of using this is that all the data can be used for training and it avoids any possible bias introduced by relying on a particular division in the data.

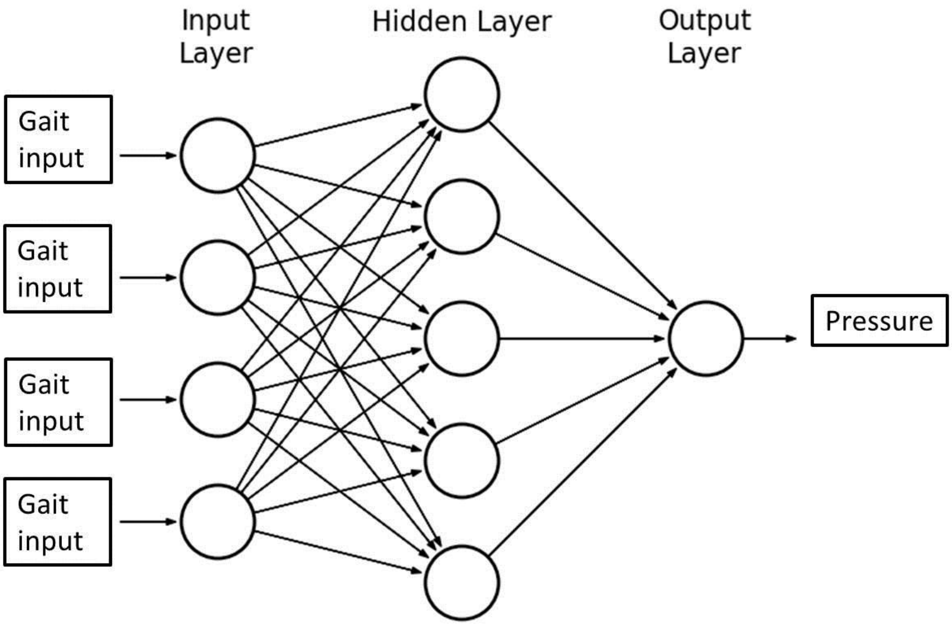

Figure 5. 11: An example of a neural network with one hidden layer (artificial neurons) Many neural networks use a number of hidden layers to increase the accuracy.

For each participant a predicted pressure value for each shoe was obtained (from a network which had not been trained with data on that individual). These pressure predictions were compared to the actual pressures and a root mean square difference (RMS) between obtained. This RMS error was calculated for each individual and then averaged across all individuals to give an overall level of accuracy. This process was carried out separately for each region of the foot.

The predicted pressures were then used to rank the six rocker shoe designs for each individual . From this predicted ranking of the shoes, a mean optimal was identified and this process was repeated for all subject. In order to evaluate the accuracy of this ranking, a Cohens-Kappa was used. This was deemed appropriate as it adjusts categorical comparisons for chance agreement to give a more appropriate measure of accuracy than a simple percentage agreement. For example, a 50% agreement between two binary categorical variables would be expected by chance alone and this would have a Kappa score of 0. The Kappa coefficient reported in the results section was obtained from a comparison of all the relative rankings of the footwear for each subject in a given region of the foot. This whole processes was repeated separately for each foot region.

The second aim sought to identify the participants who exhibited plantar pressures over the 200 kPa threshold when wearing the baseline shoe (15° rocker angle and 52% apex position), from an input of gait variables. To address this research question, a pattern recognition network was chosen. This is a logistic regression method, which instead of predicting a pressure value (continuous data), is trained to predict a classification, in this problem, either above or below the threshold. A two layered feed-forward pattern recognition network, with 15 hidden layers, was trained using a leave-one-out cross validation. This networks was developed with the full 24 variables (Tables 5.2 and 5.3) as the input data and trained to predict whether a given individual would exhibit plantar pressures above the 200 KPa threshold. A scaled conjugate gradient algorithm chosen for the training of the network (Møller, 1993). A separate network was created for each of the high risk regions (1st MTP, hallux and 2nd-4th MTH) and again Cohens-Kappa was chosen to evaluate the agreement between the actual class of participant and the predicted class of participant.

5.8 Results

The following results are presented in order of foot region for the regression models and footwear predication algorithms. Following this, the pattern recognition network results are presented.

5.8.1 1st MTP Region: stepwise/regression and fitting network predictions

Regression results

The variables included in the stepwise regression model also varied between the different shoe designs. Table 5. 4 displays the variables included for each of the shoe conditions. For the shoe with the highest r-square value (R1 A2), there were five variables included, however, the shoe with the lowest r-square value only had three variables included (Table 5. 5). Of the included variables across all of the shoes, there was only two static variables included which were body weight and foot length. Furthermore, these were only included in two of the shoe conditions. Functional variables such as, maximum moment at the ankle joint in the sagittal plane and the time of the MTP maximum angular velocity in the transverse plane had the largest contribution of the variables included from the stepwise regression. The time of the maximum angular velocity in the transverse plane, was included in four out of the six shoes. Other angular velocity variables such as the time of the maximum angular velocity at the MTP joint were included four times.

Table 5. 4: Summary table of the variables included in the stepwise model in the 1st MTP region. AJ = ankle joint. MJ = MTP joint.

Shoe	Variables included from the stepwise regression model				
R1 A1	MTP ROM x	COP disp y	BW		
R1 A2	AJ max torque x	COP disp x	AJ max vel ind z	MJ max vel ind z	Foot length
R1 A3	MJ ROM x	AJ max vel z	MJ max vel ind z		
R2 A1	AJ max torque x	COP disp y	AJ max vel ind z	MJ max vel ind z	
R2 A2	AJ max torque x	COP disp y	AJ max vel x	AJ max vel ind z	MJ max vel ind z
R2 A3	AJ max torque x	COP disp y	AJ max vel ind z	MJ max vel x	

For the 1st MTP region, the r-square value varied between the different outsole designs (Table 5. 5). Table 5.5 displays the r-square values for all the shoe conditions. The highest r-square value was 0.45 and with an adjusted value of 0.42, for the shoe with a 15° rocker angle and 57% apex position. An r-square value of 0.27 was the lowest out of the six designs for the 1st MTP region. Finally, the remaining four shoes had r-square values ranging from 0.30 -0.39 and adjusted values ranging from 0.27-0.36.

Table 5. 5: 1st MTP: Variables identified from stepwise regression with the coefficient estimates from the multilinear regression. These values represent the relative weighting of the variable within the model. R square and R adjusted values from the stepwise regression are in bold.

	R1 A1	R1 A2	R1 A3	R2 A1	R2 A2	R2 A3
AJ max moment x		44.63		41.88	40.59	40.30
AJ max moment z						
AJ ROM x						
AJ ROM y						
MJ ROM x	22.77		26.55			
MJ ROM y						
COP disp x		-19.32				
COP disp y	-21.61			-32.33	-30.53	-32.07
AJ max vel x					17.68	
AJ max vel z			21.08			
AJ max vel ind x						
AJ max vel ind z		-13.35		-17.93	-14.28	-16.36
MJ max vel x						16.27
MJ max vel y						
MJ max vel z						
MJ max vel ind x						
MJ max vel ind y						
MJ max vel ind z		22.03	15.43	17.44	20.46	
foot length		-40.15				
BW	38.63					
1st MTP distance						
5th MTH distance						
hallux length						
MTH break angle						
R square (%)	**27.34**	**44.51**	**29.83**	**35.76**	**37.37**	**38.55**
R square adjust	**0.24**	**0.42**	**0.27**	**0.33**	**0.35**	**0.36**

Fitting network results

To evaluate the performance of an algorithm a confusion matrix is used. These are also known as an error matrix. Table 5. 6 shows the confusion matrix of the fitting network for the 1st MTP region showing the performance of the algorithm. In this matrix, each row represents the number of predicted classes and each column represents the actual class. The diagonal shaded area shows the correctly identified classes. Under this region there was an optimal shoe identification accuracy of 24% and a Cohen's-Kappa of 0.04.

Table 5. 6: 1st MTP: Confusion matrix, the number of participants for the actual and predicted optimal shoe, produced using the fitting network (total participants = 76). The accuracy and Kappa are in bold.

Outputs	**R1 A1**	0	0	0	1	0	1		
	R1 A2	0	1	1	9	5	4		
	R1 A3	1	0	1	3	1	2		
	R2 A1	2	2	1	11	4	3		
	R2 A2	3	2	1	5	3	4		
	R2 A3	0	0	1	2	0	2	**Accuracy**	
		R2 A3	**R2 A2**	**R2 A1**	**R1 A2**	**R1 A2**	**R1 A1**	**24%**	**Kappa**
		Targets							**0.04**

5.8.2 Hallux Region: stepwise/regression and fitting network predictions

Regression results

The variables included from the stepwise included more static variables compared to the other regions (Table 5. 8). At least one of; hallux length, 1st and 5th MTH distance, and the MTH break were included in four out of the six shoes. Furthermore, the shoe with the highest r-square value included three static variables (Table 5. 8). For the dynamic variables, the majority of the regressions included a maximum moment variable or a maximum angular velocity time. Maximum moment at the ankle joint was included in five out of the six shoes, additionally, the maximum angular velocity time for the MTP joint was also included in five out of the six shoes.

Table 5. 7: Summary table of the variables included in the stepwise model in the Hallux region.

AJ = ankle joint. MJ = MTP joint ind = index (the index of the variable during the stance phase).

Shoe	Variables					
R1 A1	AJ max torque z	MJ max vel ind x	MJ max vel ind y	l hallux		
R1 A2	AJ max torque z	AJ max vel ind z	MJ max vel ind x	5th MTH		
R1 A3	AJ max torque z	MJ ROM x	MJ max vel ind x			
R2 A1	MJ ROM x	MJ max vel ind x				
R2 A2	MJ max vel ind x	5th MTH				
R2 A3	AJ max torque x	COP disp x	MJ max vel ind x	1st MTP	5th MTH	MTH break

The stepwise regression for the hallux region produced the highest r-square value out of all of the regions (Table 5. 8). The highest values were 0.47 for the r-square and an adjusted value of 0.45 for the shoe with a 62% apex position and 20° rocker angle. The three shoes with a rocker angle of 15° all had r-square values which were adjusted to 0.33-0.35. Finally, the remaining two shoes had r-square values of 0.28 and 0.25 which were adjusted to 0.25 and 0.21 respectively.

Table 5. 8: Hallux: Variables identified from stepwise regression with the coefficient estimates from the multilinear regression. These values represent the relative weighting of the variable within the model. R square and R adjusted values from the stepwise regression are in bold

	R1 A1	R1 A2	R1 A3	R2 A1	R2 A2	R2 A3
AJ max moment x						23.21
AJ max moment z	-19.74	-20.33	-26.14			
AJ ROM x						
AJ ROM y						
MJ ROM x			22.85	24.15		
MJ ROM y						
COP disp x						30.26
COP disp y						
AJ max vel x						
AJ max vel z						
AJ max vel ind x						
AJ max vel ind z		-20.00				
MJ max vel x						
MJ max vel y						
MJ max vel z						
MJ max vel ind x	-34.64	-34.06	-47.44	-36.49	-29.09	-20.74
MJ max vel ind y	18.06					
MJ max vel ind z						
foot length						
BW						
1st MTP distance						-232.66
5th MTH distance		-21.06			-21.19	163.35
hallux length	-21.52					
MTH break angle						-150.16
R square (%)	**37.04**	**37.65**	**35.80**	**28.14**	**24.77**	**47.16**
R square adjust	**0.34**	**0.35**	**0.33**	**0.25**	**0.21**	**0.45**

Fitting network results

Table 5. 9 shows the confusion matrix of the fitting network for the Hallux region. Under this region there was an optimal shoe identification accuracy of 26% and a Cohen's-Kappa of 0.11.

Table 5. 9: Hallux: Confusion matrix, the number of participants for the actual and predicted optimal shoe, produced using the fitting network (total participants = 76). The accuracy and Kappa are in bold.

Outputs	**R1 A1**	1	0	1	2	3	1		
	R1 A2	0	4	1	8	6	4		
	R1 A3	0	1	0	4	0	3		
	R2 A1	0	0	0	10	3	1		
	R2 A2	2	1	3	3	2	3		
	R2 A3	1	2	1	1	1	3	**Accuracy**	
		R2 A3	**R2 A2**	**R2 A1**	**R1 A2**	**R1 A2**	**R1 A1**	**26%**	**Kappa**
		Targets							**0.11**

5.8.3 2nd-4th MTH Region: stepwise/regression and fitting network predictions

In contrast, to the 1st MTP region, the 2nd-4th MTH region had very few variables included by the stepwise regression (Table 5. 10). All of the stepwise regressions included the maximum toque in the sagittal plane at the ankle joint, however, this was the only functional variable included. For the static variables, five of the six shoe regressions had foot length included and the remaining shoe regression had 1st MTP length included.

Table 5. 10: Summary table of the variables included in the stepwise model in the Hallux region.

Shoe	Variables	
R1 A1	AJ max torque x	Foot length
R1 A2	AJ max torque x	Foot length
R1 A3	AJ max torque x	Foot length
R2 A1	AJ max torque x	1st MTP distance
R2 A2	AJ max torque x	Foot length
R2 A3	AJ max torque x	Foot length

Table 5. 11 shows the r square, r square adjusted values and variable weightings for the 2nd-4th MTH region. Overall, the r-square values for the 2nd-4th MTH region were lower compared to the 1st MTP. The highest r-square value of 0.33 was for the shoe with a 52% apex position and a 20° rocker angle and an adjusted r square value of 0.3 (Table 5. 11). Furthermore, the five remaining shoes had r-square values which ranged from 0.21-0.27 and adjusted r square values between 0.18-0.24.

Table 5. 11: 2nd-4th MTH: Variables identified from stepwise regression with the coefficient estimates from the multilinear regression. These values represent the relative weighting of the variable within the model. R square and R adjusted values from the stepwise regression are in bold.

	R1 A1	R1 A2	R1 A3	R2 A1	R2 A2	R2 A3
AJ max moment x	36.65	40.42	46.68	34.59	34.17	38.46
AJ max moment z						
AJ ROM x						
AJ ROM y						
MJ ROM x						
MJ ROM y						
COP disp x						
COP disp y						
AJ max vel x						
AJ max vel z						
AJ max vel ind x						
AJ max vel ind z						
MJ max vel x						
MJ max vel y						
MJ max vel z						
MJ max vel ind x						
MJ max vel ind y						
MJ max vel ind z						
foot length	-20.70	-21.20	-27.57		-20.96	-22.10
BW						
1st MTP distance				-16.62		
5th MTH distance						
hallux length						
MTH break angle						
R square (%)	**24.18**	**27.37**	**22.37**	**32.88**	**22.48**	**21.43**
R square adjust	**0.21**	**0.24**	**0.19**	**0.30**	**0.19**	**0.18**

Fitting network results

Table 5. 12 shows the confusion matrix of the fitting network for the 2nd-4th MTH region. Under this region there was an optimal shoe identification accuracy of 49% and a Cohen's-Kappa of 0.06.

Table 5. 12: 2nd-4th MTH: Confusion matrix, the number of participants for the actual and predicted optimal shoe, produced using the fitting network (total participants = 76). The accuracy and Kappa are in bold.

Outputs	**R1 A1**	0	0	0	6	2	0		
	R1 A2	0	0	1	13	1	0		
	R1 A3	0	0	0	3	0	0		
	R2 A1	3	1	0	35	3	0		
	R2 A2	1	0	0	0	2	0		
	R2 A3	0	0	0	4	1	0	**Accuracy**	
		R2 A3	**R2 A2**	**R2 A1**	**R1 A2**	**R1 A2**	**R1 A1**	**49%**	**Kappa**
		Targets							**0.06**

5.8.4 Identification of individuals over the 200 kPa threshold

The second aim of the study was to develop an algorithm which could identify participants who exhibited plantar pressures above 200 KPa from a set of gait variables. Table 5. 13 (a-c) shows the confusion matrices of the pattern recognition network. Under the 1st MTP there was a class identification accuracy of 74%, however, a Cohen's-Kappa of 0. For the Hallux regions there was an accuracy of 74% and a similarly low Cohen's-Kappa of 0.33. Finally, under the 2nd-4th MTH region there was a class identification accuracy of 78% and a Cohen's-Kappa value of 0.37.

Table 5. 13: Confusion matrices (a) 1st MTP, (b) Hallux, (c) 2nd -4th MTH the number of participants for the actual and predicted class of participant, produced using the pattern recognition network (total participants = 76). The accuracy and Kappa are in bold. High = participants who are at higher risk of ulceration (peak pressure > 200 kPa) when wearing the baseline shoe (52% apex position 15°). Low = participants who receive sufficient offloading when wearing the baseline shoe (peak pressure <200 kPa).

1st MTP (a)

Outputs	Low	56	20		
	High	0	0	**Accuracy**	
		High	Low	74%	**Kappa**
		Targets			0

Hallux (b)

Outputs	Low	46	13		
	High	7	10	**Accuracy**	
		High	Low	74%	**Kappa**
		Targets			0.33

2nd-4th MTH (c)

Outputs	Low	50	10		
	High	7	9	**Accuracy**	
		High	Low	78%	**Kappa**
		Targets			0.37

5.8.5 Identifying the region with the highest pressure

Table 5. 14 shows the confusion matrix of the fitting network for the ranking of the three regions (1st MTP, Hallux, and 2nd-4th MTH). To calculate these results, the pressure value for the optimal shoe under each of the three regions was used to rank the three regions. This would show which region the outsole of the rocker shoe would need to be designed for. There was an region identification accuracy of 58% and a Cohen's-Kappa of 0.36.

Table 5. 15 shoes the root mean error (RMS) for each of the shoes and forefoot regions. The 2nd-4th MTH region showed the smallest RMS values between the regions with all of the values being <89 kPa. The hallux region showed the highest RMS values with four out of the six values over 100 kPa.

Table 5. 14: Confusion matrix for the ranking the different regions, 1st MTP, Hallux, and 2nd-4th MTH. The value in the analysis was the pressure value for the individual optimal shoe for each region. (total participants = 76). The accuracy and Kappa are in bold.

Outputs	**MTP1**	9	3	2		
	Hallux	3	14	3		
	MT24	12	9	21	**Accuracy**	
		MT24	**Hallux**	**MTP1**	58%	**Kappa**
		Targets				0.36

Table 5. 15: The fitting network root mean error for each of the shoes and regions (kPa).

	R1 A1	R1 A2	R1 A3	R2 A1	R2 A2	R2 A3
1st MTP	89.15	83.31	81.64	92.21	100.51	111.28
Hallux	105.98	181.41	184.20	103.01	85.46	89.46
2nd-4th MTH	66.86	65.65	88.94	77.18	66.25	71.83

5.9 Discussion

The overall aim of this study was to explore prediction methods which could be incorporated into a clinical setting. Three methods, which relate to rocker sole design, were evaluated. Each of these methods was explored using a specific a research aim and objective(s). The first aim of this study was to understand whether it would be possible to develop an algorithm which could predict optimal rocker shoe design using gait data variables as inputs. In order to accomplish this aim, two objectives were defined. The first objective sought to establish biomechanical variables which account for the most variance between the different optimal outsole designs. Previous studies have shown that different factors can be combined to account for a large amount of variance between plantar pressure during values during barefoot walking (Morag and Cavanagh, 1999, Mueller et al., 2003). The factors which could predict in-shoe plantar pressure in different rocker shoe designs have never been investigated. To address this gap in the research, this study used regression methods to establish the biomechanical variables which account for the most variance for in-shoe plantar pressure in different rocker shoe designs.

The second objective of this aim was to establish if an individual optimal shoe design could be predicted from the set biomechanical variables defined from the regression analysis. Using the variables included in the stepwise model, a fitting network was chosen to predict the peak plantar pressure in six pairs of rocker soles. The shoes were then ranked and the optimal shoe defined for each region.

The second aim of this study was to use biomechanical variables to identify the participants who may be at high risk of ulceration in the baseline shoe. A different approach was used to address this aim. Specifically, a pattern recognition network was chosen to classify biomechanical variables according to target classes, and thus identify the individuals who would need a different rocker design compared to the baseline shoe.

The final aim of this study was to establish whether the region of the highest pressures could be identified using biomechanical variables. The pressure predictions from the neural network used in research aim 1 were used to rank each of the region in the individual optimal rocker sole. The following discussion of results will first explain the findings from the regression analysis and the performance of the fitting network for each of the three regions. Following this, the findings and implications for the performance of the pattern recognition network will be discussed and related to other studies which have used this type of analysis in clinical biomechanics. Finally, methods for improving the accuracy to identify the region of highest pressure will be discussed.

5.9.1. Findings from the regression analysis

1st MTP

The first aim of this study was to identify gait variables which could potentially predict in-shoe plantar pressure. Results from the stepwise multiple regression showed that the variables included in the final model differed considerably between the regions. Furthermore, the final models for each of the shoes included slightly different variables. For the 1st MTP region, there were a number of variables which were shown to be associated with peak pressure. Maximum ankle joint moment (sagittal), COP displacement (anterior-posterior), maximum ankle joint velocity (transverse), and maximum MTP joint velocity (transverse) were included in four out of the six models. Furthermore, the coefficient estimates for these variables were higher than other dynamic variables which were only included in one or two models.

It was hypothesised that ankle and 1st MTP joint ROM would be the variable most closely correlated with peak plantar pressure. This was based on previous literature which has shown that changes in joint mobility can have an effect on plantar pressure (Fernando et al., 1991, Rao et al., 2006, Rao et al., 2010). However, the results showed that ankle ROM was not included at all and 1st MTP ROM was only selected in two of the regression analyses. These variables may not have been included because, although these variables can influence barefoot pressure, there is minimal motion of the 1st MTP joint in a stiff rocker shoe and this may limit the influence of distal joint motion on plantar pressure in this type of footwear. The regression analyses identified ankle and 1st MTP maximum velocity in the transverse plane to be important variables and this agrees with previously published research. Mueller et al (1994) showed that if participants decreased their plantar flexion joint velocity, there was also a reduction in peak pressure under the forefoot. This suggests that angular velocity (rate of change of displacement) of the ankle joint has more of an effect on peak pressure compared to displacement.

For the 1st MTP region there were only a total of two static measurements identified by the regression analysis. Body weight and foot length were included once each in two different analyses, however, the coefficient estimates for these two variables were similar to the highest from the dynamic variables. This suggests that static measurements also have a significant influence on peak plantar pressure. The inclusion of these two variables was unexpected because it was hypothesised that length of the hallux or distance from the heel to the 1^{st} MTP would be included in the final model.

There have been a number of studies proposing variables which may account for variance between plantar pressure results during walking. However, the link between barefoot walking and in-shoe pressure has not been explored, therefore, the comparison of literature (given below) has been completed using studies which have used barefoot pressure data. One of the most comprehensive studies which aimed to identify biomechanical variables related to peak pressure was carried out by Morag and Cavanagh (1999). Morag and Cavanagh suggested that both dynamic and static variables need to be combined to predict plantar pressure. The model of Morag and Cavanagh consisted of a number a structural measurements, including sesamoid height (obtained from x-ray data), and one EMG variable. It is possible that the inclusion of these structural and EMG variables may have increased the accuracy neural network in this study. However, the aim of this current study was to develop an efficient method which could be incorporated into a clinical setting, therefore, these types of structural and EMG variables were not measured.

A number of other studies have also suggested variables which may predict plantar pressure (Abouaesha et al., 2001, Cavanagh et al., 1997, Chao et al., 2011, Martinez-Nova et al., 2008, Menz and Morris, 2006). Structural measurements of the foot have also been shown to predictors of plantar pressure. A study by Cavanagh (Cavanagh et al., 1997) reported similar r-square values to this study when using only structural measurements of the foot. As well as soft tissue thickness, sesamoid measurements were shown to be the strongest predictors of plantar pressure under the 1^{st} MTP. Two further studies (Abouaesha et al., 2001, Chao et al., 2011) both suggested that plantar tissue thickness is related to pressure under the foot. Therefore, differences of tissue thickness between people may account for a large proportion of variance between peak pressure. However, the variables suggested in these studies were measured using radiographic techniques, therefore were not deemed appropriate for the current study.

Hallux

The regression analysis for the hallux region contained a different set of variables from the 1st MTP. For this region, there was less difference in the variables included in comparison with the 1st MTP region. The maximum velocity time for the 1st MTP joint was included in all of final models for the different shoe conditions suggesting that it has a strong association with peak pressure under the hallux. Furthermore, the coefficient estimates for this variable were generally higher than the other dynamic variables in the model. In this region there was also the highest amount of variance explained (47%). The corresponding model contained six variables consisting of three dynamic (maximum ankle joint moment (x), COP displacement (x), and 1st MTP maximum velocity time (x) and three static measurements (1st MTP distance, 5th MTH distance, and MTH break angle). The variance explained for this regression model was considerably greater than the other models which only contained two to three variables. Therefore, it is possible that, to predict in-shoe pressure accurately, there may need to be a minimum of six biomechanical variables all of which relate to plantar pressure.

It was hypothesised that a number of 1st MTP dynamic variables would be included in the final models. Apart from the 1st MTP maximum velocity time (x) being included in all six models, 1st MTP ROM and maximum velocity time (y) were only included twice and once respectively. It was hypothesised that 1st MTP ROM and velocity would be the predominant dynamic variable in the final models following the results of Morag and Cavanagh (1999) who included this parameter in their final regression model (Payne et al., 2001). However, in this current study, the time of the maximum velocity was shown to be a stronger predictor of peak pressure than the actual maximum velocity. This may be because differences in timing of joint motions may influence when load passes through different anatomical structures and therefore both the timing and the magnitude of peak pressures.

There were a number of similar findings for the hallux models compared to the model reported by Morag and Cavanagh (1999). Interestingly, the proportion of the variance explained by the dynamic and static variables was similar in both studies, 47% in our study and 49% in the study by Morag and Cavanagh (1999). Furthermore, both models consisted of three static variables. However, the variables included in our model differed slightly because 1st MTP ROM did not feature. This finding also differs from the results reported by (Payne et al., 2001), who found that 28% of variance was explained by 1st MTP ROM. The difference in these findings suggests that the variables that are associated with peak pressure during barefoot walking differ from the variables which are associated with in-shoe pressure in a rigid rocker shoe. As explained above, this could be because the rocker shoe design reduces the motion of the 1^{st} MTP joint during walking.

Other studies have suggested other variables to influence pressure under the hallux. Arch index, navicular drop and drift were reported by Jonely et al (2011) to be significantly related to peak pressure under the medial forefoot. Furthermore, it was reported that as arch height decreases hallux pressure is increased (Jonely et al., 2011). Like the 1^{st} MTP region, other studies also reported that tissue thickness was a predictor of plantar pressure (Chao et al., 2011, Menz and Morris, 2006). However, whether these structural variables have an influence in-shoe pressure is unknown because these types of variables were not measured in this current study.

2^{nd}-4^{th} MTH

The final models for the 2^{nd}-4^{th} MTH contained only two variables. Given this low number of predictor variables, only a small proportion in the peak pressure could be explained by the regression model. In contrast regression models created for other regions with higher r-square values tended to include five to six predictor variables. The maximum joint moment for the ankle joint was included in all six final models and was the only dynamic variable included. Foot length was included five times and 1^{st} MTP distance was included in one model.

The reason for the low r-square values and models with few variables may be associated with the lack of variability for this region. The previous study reported that 84% of the population exhibited maximal pressure reduction in the shoe with a 52% apex position and 20° rocker angle. Therefore, because of this very consistent effect across individuals, a regression model to predict variably will have little success.

There have been few studies which have presented regression models for the 2^{nd}-4^{th} MTH region. For example, Mueller et al (2003) presented factors for each of the MTH during barefoot walking and their contribution to the final regression model. Soft tissue thickness was again found to be a significant predictor of peak plantar pressure under the medial MTH. Furthermore, another study have proposed variables such as walking speed and body weight as predictor variables (Menz and Morris, 2006). However, these studies used a different mask for the medial MTH making a comparison with this study limited. Also, the walking speed was controlled in this study.

5.9.2. Fitting network predictions

In this study, the fitting network could not accurately predict the optimal shoe for any of the regions. Low accuracy results of the fitting network regression were an expected consequence of the low r-square values from the regression analysis. The prediction of an optimal shoe under the 2^{nd}-4^{th} MTH is not possible because of the lack of inter-subject variability. The results in Study 2 showed that a single rocker design was optimal for over 80% of the population. The resulting RMS values from the fitting network also suggest that the input variables did not account for enough variance to make an accurate prediction. Therefore, it is not currently possible to implement this method into a clinical setting.

In order to implement such a system into a clinical setting a much higher accuracy much be achieved. The results in Study 2 showed that if an incorrect design is prescribed, pressures can be increased significantly. Therefore, accuracy close to 100% needs to be achieved. The findings of this study suggest that additional factors, over and above simple gait variables and anthropometric variables, may be needed to accuracy predict plantar pressure. Including such factors may require an infeasible and expensive method which may not be suitable in a shop or clinic.

There are other factors which may have accounted for the poor performance of the network. Over-fitting of the data is a common problem in a variety of neural networks and can lead to predictions that are beyond the range of the training inputs (Schöllhorn, 2004). However, this study contained approximately ten-fifteen times as many training sets to the inputs, and only five times the inputs is recommended to avoid over-fitting (Haykin, 1999). The effect of the prediction being caused by under-fitting is far more likely. Under-fitting occurs when the model is too simple to make an accurate prediction. Not training the network for long enough and having too few hidden layers can cause this problem. However, in this current study the network was trained using all the data sets with the leave-one-out-cross-validation and different numbers of hidden layers were tested. Therefore, the low accuracy of the network is more likely to be associated with the inputs not accounting for enough of the variance.

There is one known study which have used a fitting-network to predict in-shoe pressure (Rupérez et al., 2012). A study by Ruperez et al (2012), used a feed-forward fitting network to predict dorsal pressures exerted by the shoe upper. The study demonstrated that it may be possible to use a neural network to select shoe upper material. Material properties, such as young's modulus, and the position of the pressure sensors were used as the inputs for the neural network. Predictions from this study were shown to be accurate and thus suggest that material properties and sensor position are highly correlated to dorsal pressures. This study had a much simpler design compared to Study 3. Neural networks may only be capable of identify simple relationships, as shown in the study by Ruperez (2012). Their ability to predict outsole geometry based on gait variables certainly needs further investigation.

5.9.3. Discussion of classification algorithm designed to identify individual with elevated pressures.

Study 3 explored a single method to classify people who would be at risk of ulceration. The results from Study 3 show that the method of classification needs improving. For the 1st MTP region, the network failed to identify any of the participants over the 200 kPa threshold. The network simply classed all of the participants as low risk. Therefore, the results suggest that the variable selection for this network was not able to train the network to accurately define the two classes of participant.

There was a large improvement in the accuracy of the network to predict participants with pressures over 200 kPa for the hallux region. The network was able to make a separation between participants and gave an overall accuracy of 74% but Kappa score was low, with a value of 0.33. Furthermore, the performance of the 2nd-4th MTH region was almost identical to the hallux with very similar accuracy and Kappa values. These results suggest that this approach is not yet ready to be implemented in a clinical setting. Despite the improvement compared to the 1st MTP performance, the low kappa scores suggest that the network was not trained with an appropriate set of input variables.

There are a number of studies which have shown a classification-network to have the potential to be a diagnostic tool (Gioftsos and Grieve, 1995). Classification-networks in biomechanics have traditionally been used to classify people’s movements using a number of variables. For instance, a classification-network could be used to the identify if a patient has healthy or a pathological gait pattern (Schöllhorn, 2004). This is a similar classification outcome to this study, however, whether there is a strong enough relationship between gait variables and in-shoe pressure remains to be seen.

There have been other studies which have reported success using classification-networks, compared to fitting networks, in clinical biomechanics. Sazonov et al (2005) attempted to identify abnormal gait patents which help in the detection of gait changes and the prevention of falls in the elderly. The results in this study showed good potential for using plantar pressure and heel acceleration patterns to identify age-related non-pathological and pathological changes in human motion. The network was trained using the same algorithm which was used in this study (Levenberg-Marquardt (Ngia and Sjoberg, 2000)). The results showed that pathological gait patterns, which are distinctly different from other patterns, were identified with high accuracy. However, identifying normal and elderly gait was less accurate. This may be caused by differences in the gait patterns being too subtle for the network to identify. The low accuracy when identifying the participants over the 200 kPa threshold may also be associated with the differences in the kinematics and kinetics not being sufficiently different for the network to identify them accurately.

Classification networks have also been used to identify people with foot pain using plantar pressure variables (Keijsers et al., 2013). The aim of one study was to discriminate people with and without forefoot pain using barefoot plantar pressures. A total of fourteen pressure variables were entered into network and trained using a different algorithm (backpropagation) and a different training method. Study 3 used the leave-one-out-cross-validation method to train the network in order to avoid bias in the data. The study reported by Keijsers et al (2013) used 80% of the data to train the network and tested it on 20%, so different results are possible depending on the random selection of the training data. However, the results showed that over 70% of people were accurately identified as having foot pain. A key finding from the study, which may have improved the results of Study 3, was that because the differences in peak pressures were small between people, forefoot pain is related more the distribution of pressure under the foot rather than the absolute values at a fixed location.

In Study 3, the use of a different network may improve the identification of the participants at risk of ulceration. Using a feedforward-network, instead of a classification network, may improve the identification accuracy if the outcome variable have a large enough difference between people. A ratio of pressure between regions as an outcome rather than the peak values may be more appropriate based on the findings of Keijsers et al (2013) who used distribution of pressure to identify foot pain. For instance, a person who has an absolute value over the 200 kPa threshold may also have a large ratio between the pressure in the forefoot and the heel because it has been shown that people who have higher forefoot pressures have a large ratio between the heel and forefoot (Caselli et al., 2002). However, a distribution or ratio of pressure which corresponds to the 200 kPa threshold would need to be established first.

Another variable which could be used as an outcome is pressure gradient. Pressure gradient may be a useful indicator of skin trauma because spatial changes in pressure may identify stress within the soft tissue. Pressure gradient has been shown to be significantly higher in the forefoot compared to the rearfoot. Mueller et al (2005) showed that peak pressure gradient was 143% higher in the forefoot whereas peak pressure was only 43% higher. Therefore, it may be possible to use a feedforward-network to predict pressure gradient in people with diabetes who are at risk of ulceration. Finally, a number of pressure outcomes may need to be combined in order to predict people at risk of developing an ulcer because using a classification network alone was not sensitive enough to identify these individuals despite it being successfully used in previous clinical biomechanics studies (DeLiang, 1993, Gioftsos and Grieve, 1995, Goulermas et al., 2005, Sazonov et al., 2005). The successful use of a feed-forward network would also require more detailed biomechanical inputs to increase the accuracy (Morag and Cavanagh, 1999).

5.9.4. Identifying region of highest pressure

Study 3 also investigated a method to identify the region of highest pressure. The predictions from the feed-forward network were used to rank the regions when walking in the baseline shoe. The accuracy of the method was similar to the classification-network results, therefore the method needs improving before it can be used in a clinical setting. The variables which were included in each of the algorithms have already been discussed in section 5.9.1, This section will therefore discuss how the method can be improved by using more detailed inputs and a combination of different pressure variables as outputs.

Study 3 incorporated a number of kinematic and kinetic gait variables which were used as inputs for a fitting-network. The results showed that these inputs accounted for a proportion of variance between people, however, it is clear that extra variables are needed for the network to predict plantar pressures more accurately. Previous studies have shown that gastroc muscle activity has been linked to pressure under the 1st MTP (Morag and Cavanagh, 1999). Technology now exists which allows for the EMG data to be collected on foot muscles inside a shoe whilst walking (Delsys Trigno™ Mini Sensor). EMG sensors incorporate wireless technology and the attachment of a single sensor would not increase the measurement time significantly. Therefore, it would of interest to evaluate whether foot muscle activity is correlated to pressure under the foot.

A combination of pressure outcomes could also be applied to this method. As stated above, differences in absolute peak pressures between people can be very small, it therefore may be of interest to evaluate different outcomes such as gradient or a distribution between the three regions. A combination of networks could be used in order to predict the gradient, ratio and peak values. For instance, if a person shows a difference between two out of the three variables then the prediction system would be confident that the region in question would be highest. It may also be of interest to add in a threshold between the regions because if the differences between the absolute values is less than 10 kPa then there is not a large enough difference in order to prescribe a shoe specifically for one region. It is clear that other variables of pressure may need to be used as well as the absolute values in order to identify the region at most risk.

5.9.5. Limitations

There are three main limitations of this current study. The first limitation is that the biomechanical variables selected did not have a strong enough relationship with in-shoe peak pressure. Neither of the neural network designs were able to detect the target outputs with sufficient accurately to justify use in a clinical setting. Including tissue and structural measurements may have improved the performance of the networks. However, these measurements were deemed inappropriate in this study because they require the use of radiographic imaging which would not be possible in a clinical setting.

The second limitation of this study was the population only included low risk patients with diabetes who did not have foot deformity or serious neuropathy. This group was selected because the focus of the project is to improve footwear for people in the early stages of diabetes. However, the incorporation of patients with neuropathy would have been clinically relevant also.

Finally, the lower-limb model selected for this study was a simple model which could be incorporated into a clinical setting easily. However, more detailed segmental foot models exist which have shown differences in dynamic foot function between groups. It is known that diabetes effects the function of the foot (Rao et al., 2010). In this current study, the foot model consisted of only two segments, other segmental foot models consist of four to five segments (Nester et al., 2007, Rao et al., 2010, Nester et al., 2010). It has been reported that reductions in segmental foot mobility were associated by increases in plantar loading in people with diabetes (Rao et al., 2010). Therefore, a more detailed foot model may explain a greater amount of variance.

5.9.6. Conclusions

The results demonstrated clear correlations between groups of dynamic and static variables and in-shoe pressure, the predictive power of the algorithm was not high enough for this method to be implemented in clinical practice. This may be because additional input variables, such as bony geometry are required to improve algorithm accuracy (Morag and Cavanagh, 1999). Furthermore, the simple foot model may not have provided enough variables to predict in-shoe pressure. The evaluation of a more detailed segmental foot model, in combination with EMG data, is needed, however, such a model may be too complex to implement into clinical practice.

The combination of outcome variables may also increase the accuracy of the networks when classifying the participants. A combination of networks which predict variables such as pressure gradient and a ratio between the regions as well as the absolute values of pressure may be of benefit when classifying the participants as high risk or identifying the region of highest pressure. Other studies have shown success using both fitting and classification networks in clinical biomechanics (Barton and Lees, 1996, Barton and Lees, 1997, Rupérez et al., 2012), therefore it is justifiable to investigate prediction methods further. This study was the first attempt to develop an outsole prescription system using gait variables and it has provided some valuable information in order to design future studies.

Chapter 6: Summary of findings

The main aim of this PhD project was to improve the design of the curved rocker sole. This has been achieved with the, three studies. The first two studies evaluated the effect of rocker sole design on plantar pressure and the third study looked at prediction methods using biomechanical variables. As it was not possible to evaluate every combination of design feature (which would require testing in excess of 100 shoes), a two phased approach was adopted (Studies 1 and 2) to understanding the effects of the three main design features (apex angle, apex position and rocker angle).

Study 1

The first study sought to quantify the effect of independently varying the three principle design features. This first phase was designed to identify a subset of possible design features which needed to be investigated in more depth. As well quantifying the mean effect, the study sought to quantify the inter-subject variability between the optimal designs. Finally, by using centre of pressure measurements, the study investigated how loading changes under the foot with the three different design features.

The results of this first study suggested that fixing apex angle at 95° would be a suitable compromise to offload the high risk areas (medial forefoot). However, it also showed that apex position and rocker angle needed further investigation. Apex position showed the largest amount of inter-subject variability between the optimal designs, therefore it was suggested as a design feature which may need to be selected individually for each person. Rocker angle is the only design feature influenced by patient perception. Increasing the height of the rocker angle requires the heel height to be increased, however, some patients; especially those at low risk, may not accept a shoe with a large heel (Nawoczenski et al., 1988). Study 1 demonstrated an apparent threshold between 15° and 20° in which there was a significant reduction in plantar pressure when rocker angle was increased from 15° to 20°. Further increases in rocker angle provided little improvement. Given this effect, and the need to maintain a low rocker angle, subsequent investigation focused on shoes with 15° and 20° rocker angles, each with a range of four apex positions.

Study 1 also showed that there were changes in the CoP displacement and velocity when the outsole was adjusted. This provided insight into how the outsole influenced the way the plantar foot loads were transferred to the ground during walking. Results showed that there were significant differences for both the CoP displacement and velocity when the outsole was adjusted. However, the correlations between the CoP variables and the peak pressures were only weak to moderate, suggesting that a range of other factors may also influence peak pressure.

Study 2

Study 1 was not designed to generate insight into the interactions between different design features. Therefore, a subsequent study was needed to evaluate the combined effect of two rocker angles (15 and 20°) and four different apex positions (52%, 57%, 62% and 67%). This study also considered the clinical implications of having to prescribe a shoe from a range of eight designs. Previous studies have reported that people who exhibit plantar pressures below a specific threshold (200 KPa) are less likely to develop an ulcer (Owings et al., 2009). This threshold was used to establish whether each individual experienced sufficient offloading with each of the eight rocker designs.

The results suggested there was still a degree of inter-subject variability between the outsole designs. However, a mean optimal apex position of 52% for the 2nd-4th MTH region was reported. Additionally, the apex position of 67% caused a significant increase in pressure. The results showed that two thirds of the participants experienced acceptable offloading with the mean optimal design (52% apex position and 20° rocker angle). Furthermore, a similar number of participants received sufficient offloading when walking in a shoe with a 15° rocker angle. As a result of these findings, a rocker sole recommendation process was developed. Using this procedure, patients would initially walk in a shoe with a 15° rocker angle and 52% apex position whilst in-shoe pressure was measured. Over 60% of the population received sufficient offloading (<200 KPa) using this set of design features. Those who did not would be required to try further designs, with the exact choice of rocker angle and outsole thickness being driven by a patient's perception of the footwear. The proposed approach to prescribing footwear would be effective in a shop/clinic. However, this method could be quite time-consuming. Therefore, an alternative approach was explored in Study 3 in which optimal rocker shoe design could be predicted following a simple gait assessment.

Study 3

The main aim of the final study was to establish whether a rocker soled shoe could be prescribed using an algorithm which required an input of gait variables. As explained above, these inputs were obtained from a simple barefoot gait assessment Study 3 also investigated other methods which could be used as screening tools to identify people at risk of ulceration. Previous literature suggested that biomechanical gait variables, such as joint range of motion and structural measurements, have an effect on peak plantar pressures (Morag and Cavanagh, 1999). Therefore, in this final study, a range of biomechanical barefoot gait variables were first investigated in a regression model to identify the variables which were correlated with peak pressure. Subsequently, appropriate variables were used as inputs to train a neural network which predicted the in-shoe pressure for each different rocker shoe design. The outputs from this neural network were then used to rank the designs and so to identify the optimal design.

The results of the regression models showed it was possible to explain a similar amount of variance in peak pressure to the regression models developed by Morag and Cavanagh, 1999. Despite regression models explaining nearly 50% of the variance, the predictive power of the fitting network was not found to be high enough for incorporation into clinical practice. It is likely that the low levels of prediction accuracy may have been due to an insufficient number and type of biomechanical variables. Although, other variables could have been included, the system was envisaged to work in a shop/clinic and so more complex measurements were deemed unfeasible.

Chapter 7: Final conclusions

This project has provided valuable information relating to rocker sole design. Traditionally and to date, the rocker sole has been prescribed based on theoretical considerations with little scientific evidence (Hutchins et al., 2009). Therefore the contribution of the studies in this thesis is that that the results indicate that current practice is not providing the optimum intervention and hence the risk of foot ulceration remains. A current rocker sole is designed with a 80° degree apex angle, approximately 60% apex position and 10-15° rocker angle (Hutchins et al., 2009). In contrast this study showed that an 80° apex angle will increase pressure in the high-risk forefoot regions. Therefore an apex angle greater than 90° would be more appropriate. Secondly, this project showed that apex position was still a design feature with a degree of inter-subject variability despite a large proportion of the participants (>60%) receiving sufficient offloading in Study 2 when a mean optimal shoe was defined. This was the first study to show a mean optimal for one of the forefoot regions (2^{nd}-4^{th} MTH), however, it is still a design feature which still needs careful consideration when prescribing a rocker sole. Finally, the project showed that sufficient offloading can be achieved using a smaller, more aesthetically acceptable, rocker angle of 15°. However, this appears only to be possible when combined with an apex angle of 95°.

Recommendations with regards to rocker sole design

Clinicians

This PhD project has improved the scientific understanding of how rocker soled shoes should be designed. This understanding will not only influence the shoe design sector but also the clinical sector. To date, rocker soles have been prescribed with minimal scientific evidence. However, this project has provided clear evidence of the effects of the three principle design on plantar pressure in a rocker shoes. Clinicians will now be able to use these findings to inform their clinical prescriptions of rocker outsoles and this will allow them to be more confident that the shoes they give to patients will reduce plantar pressure. A primary finding of this study was the need to increase apex angle from the current value of 80° to 95°. This was a recommendation from Study 1 and was supported by the improvement in overall offloading achieved by the rocker soles in Study 2. Clinicians will now need to reconsider the apex angles this used in prescription shoes. Previous studies have shown a large amount of inter-subject variability between the apex positions (van Schie et al., 2000). The results from Study 2 showed less inter-subject variability and a large proportion of participants received sufficient offloading using a pre-defined shoe (>60%). The most successful method for prescribing an effective rocker sole would be to test in-shoe- pressure in 3-6 pairs of shoes and select the minima, simply prescribing a pre-defined rocker sole will increase pressure in approximately one third of people with low risk diabetes.

Designers

The findings from this project also benefit the design sector. This project has shown it is possible to achieve sufficient offloading, in order to reduce the risk of ulceration, without using a large rocker angle. Providing the apex angle and apex position are chosen appropriately, sufficient offloading can be achieved using a 15° instead of a 20° rocker angle in a large proportion of people. This will help to maintain the aesthetic appeal of rocker soled shoes. This is beneficial to shoe designers because an effective shoe can be designed without impacting on the aesthetic appeal. However, there is a need for individual testing in order for a 15° rocker sole to be prescribed because the apex position needs to be optimised to increase pressure reduction. This is why automated testing procedures would benefit the design sector because it would allow for an individual optimal design to be selected without the need for in-shoe pressure to be evaluated between a number of pairs of shoes.

If the design sector chooses to manufacture a pre-defined shoe, there are a number of recommendations which can be made from this project. Orthopaedic shoe companies have already taken the results from this project into consideration when design their rocker soles. Duna®, are incorporating a 95° apex angle into their rocker sole design. However, the results from this project can also make some recommendations with regards to apex position and rocker angle. This project strongly suggest that an apex position of 52% should be incorporated into a pre-defined outsole design because the results in Study 2 showed that this would reduce the risk of ulceration in over 60% of participants. Finally, designers can also use a rocker sole with a 15° rocker angle in order to maintain the aesthetic appeal of the shoe because the results in Study again showed that this would reduce the risk of ulceration in over 60% of the participants.

Automating rocker shoe prescription

Study 3 investigated a new method of prescribing a rocker soled shoe. Despite the decrease in inter-subject variability, there is a proportion of participants who require a different apex position. Comparing in-shoe pressure results between shoes is an effective method but not may not be feasible in a shop/clinic because measuring and analysing in-shoe pressure of 3-6 pairs of shoes can take up to 45 minutes. Study 3 therefore explored prediction methods using barefoot biomechanical variables. The final study found that the prediction power would not be high enough with simple gait variables and would most likely require a more complex set of measurements. The implications of this finding are a more comprehensive set of variables are needed for an automated prescription system to be developed, such as EMG and multi-segmental foot model. This may increase the time an automated procedure would take during a clinic, however, it would still be more efficient than comparing in-shoe pressures of 3-6 pairs of rocker sole designs.

Future research

Overall, these studies have provided valuable information relating to rocker sole design. However, it is possible that the design could be improved further with future research. In this project involved people with diabetes who were classed as low risk (therefore this study needs to be replicated with people who have neuropathy. Despite Study 1 showing increasing the apex angle was associated with a significant reduction in pressure, this project was not able to evaluate the effect of varying apex angle in combination with apex position. A future study is needed which varies apex angle and position using a single rocker angle because it is not known if an optimal combination of these design features exists.

There are a number of studies which could be developed using the results from this project. The rocker sole design has now been investigated extensively and a method of prescribing shoes using in-shoe pressure has been proposed. A randomised controlled trial using this prescription method or the baseline shoe (both presented in Study 2) is needed to evaluate the effectiveness of these interventions at reducing the risk of ulceration. The problem with previous randomised controlled trials (Bus et al., 2008a, Lavery et al., 2008, Reiber et al., 2002), was the footwear used in the studies had limited scientific evidence supporting them. This project has shown it is possible to significantly reduce plantar pressure using a rocker soled shoe. The next stage to evaluate is whether a design configuration chosen using in-shoe pressure as an outcome measure results in a reduced rate of ulceration.

Finally, this study investigated methods for prescribing a rocker soled shoe using gait variables. This was the first attempt to develop a method to prescribe a rocker sole using artificial neural networks and a range of biomechanical variables as inputs. Previous studies have shown success using artificial networks in clinical biomechanics (Barton, 1999, Gioftsos and Grieve, 1995, Schöllhorn, 2004, Yavuz et al., 2009). The prescription method of a rocker soled shoe using this method needs further evaluation Firstly, a study is needed to evaluate a more detailed in respect of foot modelling and to identify which joint movements in the foot are related to in-shoe pressure. Also, variables, such as EMG, need to be evaluated as potential inputs into an algorithm because previous studies have shown EMG to be a predictor of plantar pressure (Morag and Cavanagh, 1999). It was not possible to investigate these additional variables in this current project because of the boundaries set by the SSHOES project.

Appendices

Appendix 1: Consent form

SSHOES – Diabetic footwear
Consent form Version 1 (12-03-10)

Center Number:
Study Number:
Patient Identification Number for this trial:

CONSENT FORM

Title of Project:
SSHOES – Diabetic footwear

Name of Researcher:

Stephen Preece, PhD, Research Fellow, Center for Rehabilitation and Human Performance, University of Salford, Salford, M6 6PU.

1. I confirm that I have read and understood the **Patient Information Sheet** for the above study and have had the opportunity to ask questions.
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.
3. I understand that the data collected during the study, may be looked at by individuals from the University of Salford. I give permission for these individuals to have access to my records.
4. I agree to take part in the above study.

--------------------------------	----------	----------------------------------
Name of Patient	Date	Signature
--------------------------------	----------	----------------------------------
Name of Person Taking Consent (if different from Researcher)	Date	Signature
--------------------------------	----------	----------------------------------
Name of Researcher	Date	Signature

When completed, 1 patient, 1 researcher site file, 1 (original) to be kept in medical notes

Appendix 2: Participant information sheet

School of Health, Sports and Rehabilitation Sciences
Participant Information Sheet
SSHOES – Diabetic footwear

INFORMATION ABOUT THIS DOCUMENT

You are being invited to take part in a research study to help us develop a new way to prescribe shoes for people with diabetes. Before you decide, it is important for you to understand why the research is being done and what it will involve. This document gives you important information about the purpose, risks, and benefits of participating in the study. Please take time to read the following information carefully. If you have any questions then feel free to contact the researcher whose details are given at the end of the document. Take time to decide whether or not you wish to take part.

BACKGROUND TO THE STUDY

People with diabetes are at risk of developing foot ulcers. To reduce this risk, special shoes are often prescribed to reduce pressure under the foot. These shoes are designed so the heel is raised and the sole is stiff and curved upwards at the front. Although these shoes are used widely by diabetic patients, we do not know the best design for each individual patient. This research project will test how different design features change the pressure under the foot and develop a quick and simple way to choose the best shoe design for each person.

The study will involve 50 participants with diabetes and 50 participants who do not suffer with diabetes. Participating in this study is completely voluntary and you may withdraw at any time. You will not be penalized if you decline to participate or leave the study early. A decision to withdraw at any time, or a decision not to take part, will not affect the care you receive.

WHAT WILL HAPPEN TO ME IF I PARTICIPATE IN THIS STUDY?

How long will it take?

If you agree to take part in the study, you will be required to visit the movement science laboratory at Salford University on one occasion. The total time for the visit is 1.5-2 hours. The visit will involve:
Taking consent and sensory examination (15-20 minutes)
Footscan of the shape of your foot (5 minutes)
A biomechanical assessment of the way you walk (45minutes)
Walking in up to 12 different pairs of shoes (45-60 minutes)

What will you do?

Consent and medical screening: We will first test your feet and legs for diabetic neuropathy. This will involve touching different parts of your foot with a vibrating tuning fork and then a thin wire and asking you if you can feel anything. The reflexes in your calf muscles will also be tested.
(Please note that if you are a healthy volunteer and we find any signs of neuropathy we are obliged to communicate our findings to your GP)

Footscan: this will involve placing your foot in a box containing a number of special scanners which record data for approximately 5 seconds and then generate a 3D picture of your foot.

Biomechanical assessment: We will place a number of reflective markers at different points on your legs, as shown in the photo below so we can measure your joint motions. You will then walk up and down the clinic while motion sensors track the movements of the markers and therefore your legs and feet. For these measurements you will need to wear a pair of shorts. You can either bring your own shorts, or we can provide a pair.

Walking in different pairs of shoes: We want to assess how different footwear designs change the pressure under your foot as you walk. You will be asked to walk in each pair of shoes for 3-5 minutes each whilst we record in-shoe pressures with the system described above.

Expenses
The researcher team will arrange and pay for a taxi to pick you up and to take you back home at the end of the visit. If you prefer to make your own transport arrangements, we will refund any reasonable travel expenses. We will also refund any loss of earnings that you incur as a result of participating in this experiment.

RISKS & POTENTIAL BENEFITS OF THE STUDY

What risks are involved in participating in the study?
This is a very simple, straight forward study with negligible risks. The foot pressure measurements and biomechanical assessment be operated by an experienced researcher and involves well-designed technical equipment that has been used for many years both in movement science laboratories and in routine patient care in hospitals around the world.
If I participate in this study, can I also participate in other studies?
As the testing for the SSHOES project only one visit and there is no on-going treatment or assessment taking part it should not affect any other studies that you are involved in. However, if you are already taking part in other research, or would like to do so, please discuss this with the researcher (Dr Preece).

What benefits are involved in participating in the study?
You will not benefit directly from taking part in the study. However, the results will improve our understanding of how to produce shoes for individuals with diabetes which reduce their chance of developing an ulcer. In the future this will enable us to quickly design and produce shoes which minimize pressure problems for people with diabetes; this will ultimately reduce the number of ulcers and complications, such as foot amputation.

What if something goes wrong?
The university has insurance to cover against any harm to you which may occur whilst you are taking part in these tests. However, if you decide to take legal action, you may have to pay for this. If you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, you can approach the University of Salford and if you are not happy you may then go through the standard NHS complaints procedure.

ENDING THE STUDY
What if I want to leave the study early?
You can withdraw from this study at any time without loss of any non-study related benefits to which you would have been entitled before participating in the study. There is no danger to you if you leave the study early. If you want to withdraw you may do so by notifying the study representative listed in the "Contact Information" section below.

FINANCIAL INFORMATION
Who is organizing and funding the research?
The European Union is funding this study which is part of the SSHOES project (www.sshoes.eu).

Will I be paid for participating?
Although we are not permitted to pay cash we will offer each participant a £20 voucher, which can be used to buy goods from Amazon (www.amazon.com), Tesco or Morrison's, each time you attend for testing at the University of Salford. This means you will receive a total of £40 in vouchers for the three testing sessions.

CONFIDENTIALITY OF SUBJECT RECORDS

Will my taking part in this study be kept confidential?
All information which is collected about you during the course of the research will be kept strictly confidential. Any information about you which leaves the University of Salford will have your name and address and any other identifying features removed so that you cannot be recognized from it.

What will happen to the results of the research study?
A summary of the research findings will be sent to everyone who participates in the experiments. Significant findings may be published in clinical and engineering journals.

CONTACT INFORMATION
If you require more information about the study, want to participate, or if you are already participating and want to withdraw, please contact

Mr Jonathan Chapman
Email: J.D.Chapman@edu.salford.ac.uk
Phone : 0161 295 2670 or 07788 940 472
Address : School of Health, Sport and Rehabilitation Sciences
Blatchford Building,
University of Salford,
Frederick Rd Campus,
Salford, M6 6PU.

RECORD OF INFORMATION PROVIDED
Your will receive a copy of the information sheet and a signed consent form to keep for your personal records.

Thank you very much for taking time to read this document!
We appreciate your interest in this study and hope to welcome you at the School of Health, Sport and Rehabilitation Sciences, University of Salford.

Appendix 3: Letter of acceptance

Dr Sarah Tyson
School of Health, Sport and Rehabilitation Research

The University of Salford
Allerton Building
Salford, Greater Manchester
M6 6PU United Kingdom

T +44(0)161 295 7028
s.tyson@salford.ac.uk

23rd April 2010

THE UNIVERSITY OF SALFORD

Dear Sir,

I have reviewed the protocol document for the SSHOES – diabetic footwear project and that it addresses an important question which is of value to clinicians and to people with diabetes. It is of good scientific quality with an appropriate and feasible design and testing protocol and will be undertaken by an experienced, expert multi-disciplinary team with an international reputation in the field. The proposed statistical methods are appropriate, optimal and feasible.

Yours truly,

Sarah F Tyson

Dr Sarah Tyson PhD, MSc, MCSP
Reader in Rehabilitation

Appendix 4: University of Salford ethics form

University of Salford

Research Ethics Panel

Ethical approval from staff

Ethical approval must be obtained by all staff prior to starting research with human subjects, animals or human tissue. The member of staff must show and if necessary discuss the content of this form with the Research Institute Director before it is 'signed off'. If the application for ethical approval is part of a bid for external funding, the form must be completed as a supplement to the Budget Approval Form.

The signed Ethical Approval Form must be forwarded to the Contracts Office and an electronic copy MUST be e-mailed to the Panel via Tim Clements (t.w.clements@salford.ac.uk). The forms are processed online therefore without the electronic version, the application cannot progress.

PLEASE ENSURE THAT THE ELECTRONIC VERSION OF THIS FORM ONLY CONTAINS YOUR NAME ON THIS PAGE (WHERE IT HAS BEEN REQUESTED) PRIOR TO SENDING IT TO TIM CLEMENTS. I.E. ALL OTHER REFERENCES TO YOU OR ANYONE ELSE INVOLVED IN THE PROJECT MUST BE REMOVED FROM THE ELECTRONIC VERSION. THE REASONS IS THAT THE FORM HAS TO BE ANONIMISED BEFORE THE ETHICS PANEL CONSIDERS IT. THEREFORE PLEASE ALSO ENSURE THAT ANY REFERENCES TO YOUR NAME AND THOSE OF OTHER COLLEAGUES INVOLVED IN CARRYING OUT THE RESEARCH PROJECT, ARE REMOVED FROM THE ELECTRONIC VERSION OF ANY ADDITIONAL DOCUMENTATION YOU SUBMIT WITH THIS FORM, FOR EXAMPLE INFORMED CONSENT FORMS, LEAFLETS ETC. WHERE YOU HAVE REMOVED YOUR NAME, YOU CAN REPLACE WITH A SUITABLE MARKER SUCH AS [.....] OR [XYZ], [YYZ] AND SO ON FOR OTHER NAMES YOU HAVE REMOVED TOO. THIS IS ONLY FOR THE PURPOSE OF THE ETHICS PANEL DISCUSSIONS AS THE PROCEDURE REQUIRES THAT THE APPLIXCANT IDENTITY IS NOT REVEALED TO THE PANEL EXCEPT IN SPECIFIC CIRCUMSTANCES. YOU SHOULD RETAIN NAMES AND CONTACT DETAILS ON THE HARDCOPIES HOWEVER AS THESE WILL BE KEPT IN A SEPARATE FILE FOR POTENTIAL AUDIT PURPOSES.

Please refer to the 'Notes for Guidance' if there is doubt whether ethical approval is required.

(The form can be completed electronically; the sections can be expanded to the size required)

Name of member of staff: Dr Stephen Preece

Jonathan Chapman PhD Student

School : School of Health, Sport and Rehabilitation Science

Research Institute : Health and Social Care

Name of Research Council or other funding organisation (if applicable):

1a. Title of proposed research project

SSHOES Project

1b. Is this Project Purely literature based?

NO

2. Project focus

Foot ulceration is one of the most common complications to affect people with diabetes. If not detected early, this condition can lead to full or partial amputation of the foot. Given the potential severity of foot ulceration, most diabetic patients are prescribed therapeutic shoes, known as diabetic shoes, which are designed to reduce the risk of skin breakdown. This breakdown often results from localised regions of high pressure under the foot and therefore, diabetic shoes are normally designed to reduce pressure during walking. This reduction is typically achieved using one or more footwear modifications, such as a specially designed sole unit, known as a rocker sole.

A rocker shoe has a number of unique design features. Specifically, the heel of the shoe is raised, the sole at the front of the shoe curved upwards and the flexibility of the outsole reduced. The combined effect of these features is to reduce pressure under the forefoot and toes. Previous research has shown that optimal pressure reduction requires individual adjustment of some of the design parameters, such as degree of curvature. However, at present there is no systematic approach for determining the best design for a rocker shoe for an individual diabetic patient, other than for them to try on a very large number of different shoes.

In this project we will first investigate the effect of four separate footwear design parameters which characterise a rocker shoe. We will then develop a system which allows the best design, i.e. the one which minimises pressure, to be predicted from a simple biomechanical assessment of barefoot walking. It is envisaged that this research will lead to a system which can be used in shops and clinics to prescribe shoes for diabetic patients.

3. **Project objectives** (maximum of three)

There are two principal aims, both focused around the pressure reducing effects of a rocker sole shoe. For the first, we will investigate the effect of independently varying four different design features of a rocker sole shoe on plantar pressure (pressure under the foot). For the second, we aim to create a database which will allow us to predict the combination of footwear design features which minimises plantar pressure from a simple biomechanical assessment.

4. **Research strategy**

(For example, where will you recruit participants? What information/data collection strategies will you use? What approach do you intend to take to the analysis of information / data generated?)

We will recruit n=100 participants (n=50 diabetic and n=50 healthy) to take part in both phase I and II. These will be recruited from the University of Salford via email and a poster advertisement (see attached documents). Diabetic participants who respond to either the poster or the email will be screened by a trained community podiatrist prior to arriving for testing.

We propose to carry out a two-phase laboratory-based study to address the two aims outlined above. All data will be collected at the human performance laboratory at the University of Salford. Phase I will involve collecting data on patient’s foot shape and investigating the effect of the four design features on foot pressures. Phase II will produce an algorithm which can predict optimal footwear features to minimise pressure from a simple biomechanical assessment.

Phase I: (visit 1)

During this phase we will collect data on foot shape from all participants and also study the effect of four footwear design features on in shoe pressures across subset of the participants. In order to understand the effect of the different features we will use a within subject, randomised controlled cross over design in which the participants will walk in 16 different pairs of shoes in a randomised order. After informed consent has been taken, participants will undergo neuropathy testing which will involve three separate tests designed to assess the sensation of vibration and pressure and the presence of a reflex. Participants will then undergo a rapid foot scan from which a 3D image of their foot will be constructed. This data will be used to inform the design of the shoes used during the 2nd and 3rd laboratory visits. After the foot scan, we will investigate the effect of four footwear design features on in shoe pressures in a subset of the participants. This subset will be those who have size 9 feet (male) or size 5.5 feet (female) as these are the standardised size of the experimental shoes.

The four footwear design features are: (see Figure 1 in the protocol):

1. Rocker angle (RA)
2. Stiffness of the outsole (SS)
3. Rocker apex position (AP)
4. Apex angle (AA)

The aim of this study is to understand the effect of independently varying each of the four parameters. We propose to define a ‘reference shoe’ which has a 20º rocker angle, a full length stiffened sole, an apex position of 60% of the length of the shoe and an apex angle of 80º. We will then manipulate the four design features across 15 pairs of rocker soled shoes by varying each feature separately whilst keeping the others constant. For example, we will investigate the effect of rocker angle with four shoes with rocker angles of 10º, 15º, 25º and 30º but all other design features the same. In addition to the 15 pairs of shoes, we will also use an off the shelf (Oxford style) shoe as the control. Every participant will wear each of the 16 pairs of shoes, in a randomised order, whilst we record in shoe pressures using the Novel Pedar system. This consists of an instrumented insole, placed under the normal insole, connected to a transmitter unit strapped to the participant’s ankle. After wearing each pair of shoes the participant will complete a brief questionnaire to measure perceived comfort, which has been developed INESCOP (Technological Institute for Footwear and Related Industries) in Spain, the SSHOES lead partner (see attached copy)

The experimental data will be used to calculate in shoe pressures in eight of regions of the foot: the heel, midfoot, 1st metatarsal head, 2nd metatarsal head, lateral metatarsals, hallux (big toe), 2nd toe and lateral toes. For each shoe, we will calculate the peak pressure in each foot region and the pressure time integral across a single gait cycle. The primary outcome will be the peak pressure under the 1st metatarsal head with the other pressure related parameters being secondary outcomes. Repeated measures ANOVA and Tukey's post hoc tests for pair wise comparisons will compare each of the design features with the control shoes, and with each other. Additionally, we will use the Kruskal–Wallis test, to investigate differences in perceived comfort with each of the different design features.

Phase II: (visit 2 and 3)

This study will investigate whether optimal footwear design features (to minimise pressure) can be predicted from biomechanical measures of an individual's walking pattern. After analysing the results of phase I, we will understand how manipulating each of the individual footwear design features affects in shoe pressures. However, in practice we need to understand how best to combine different footwear features to minimise pressures. Therefore, using the results of phase I, we will define another 16 pairs of shoes which have differing combinations of design features which we hypothesise will minimise pressure at different areas of the foot. During the experimental work, we will perform a biomechanical analysis to derive parameters which quantify each participant's barefoot walking pattern (visit 2). Participants will then walk in each of the 16 pairs of shoes to evaluate the effect on in shoe pressures (visits 2 and 3). An Artificial Neural Network will subsequently be created to investigate whether optimal footwear design can be predicted from the barefoot walking pattern.

After reviewing the information sheet, the participant will undergo a gait analysis. This will involve attaching small reflective markers to the participant's feet (heels, midfoot and toes) and legs (see Figure 2 in the protocol). Participants will then walk across a force platform and pressure sensitive matt whilst the motion of the reflective markers is tracked by movement sensors mounted on the walls. In shoe pressures will be collected as described in phase I for the 16 pairs of shoes in a randomised order. Data from the first six pairs of shoes will be collected during the laboratory visit 2 with the remaining 11 pairs being tested during visit 3. After wearing each pair of shoes, the participant will complete the comfort questionnaire.

In shoe pressure data will be used to calculate the peak pressure in each foot region (described above) during walking and then to identify the shoe (for each participant) which minimises pressure in each region. The primary outcomes are the design features which minimise pressure under the 1st metatarsal head. Data from the barefoot biomechanical assessment will be used to define biomechanical parameters relating to joint kinematics (joint motions), kinetic data (combined force and kinematic data) and pressure data. A neural network will then be used to formulate an algorithm which is able to predict optimal footwear design features from a subset of the biomechanical parameters.

5. What is the rationale which led to this project

(for example, previous work – give references where appropriate)

One of the major complications with Diabetes Mellitus is neuropathy which is thought to result from a number of factors, such as microvascular disease. As a result of neuropathy and microvascular disease, diabetic patients become increasingly susceptible to the formation of ulcers on the soles of their feet. Furthermore, the body's ability to heal is considerably impaired with diabetes which means that relatively minor ulceration can rapidly deteriorate into a major problem.

Complications which result from ulceration can often lead to full or partial amputation in diabetic patients. Given the severity of this problem, most patients with diabetes are prescribed therapeutic shoes, known as diabetic shoes which are specially designed to reduce the risk of skin breakdown (Cavanagh, 2004). In order to achieve this objective, diabetic shoes are normally designed to minimise pressure under certain areas of the foot during walking. As the most common site of ulceration is under the forefoot and toes, the footwear is primarily designed to reduce pressure in these areas.

Different approaches have been proposed to reduce pressure under the forefoot, with a number of studies demonstrating a rocker sole to be the most effective design (Praet and Louwerens, 2003). This type of shoe has a number of unique design features. Specifically, the heel of the shoe is raised, the sole at the front of the shoe curved upwards and the flexibility of the outsole reduced (Hutchins et al., 2009). The combined effect of these features is to reduce motion at the metarasal joints during walking and to reduce pressure under the forefoot and toes (Brown et al 2004).

There are four design features which are used to specify a rocker shoe. These are the rocker angle (the angle of upward curvature at the front of the outsole unit), the stiffness of the outsole, the position of the rocker apex (the position along the shoe at which the outsole begins to curve upwards) and the apex angle (the angle of the apex relative to a line across the width of the shoe) (see Figure 1 in the study protocol). Although rocker shoes are commonly used in clinical practice, there has been very little research carried out to determine how pressure under the foot changes as each of these four design features is varied. A single study has investigated the effect of systematically varying two of the parameters; apex position and rocker angle, (van Schie et al., 2000). However, this study was

performed on healthy participants and an outmoded rocker sole shoe and so further research is needed on diabetic patients with more up to date footwear. Specifically, there is a need to understand the precise effect the four footwear features have on pressure under the forefoot across a range of individuals. This investigation will form the first principal research aim in the proposed study.

van Schie et al (2000) demonstrated that healthy participants respond to variation in footwear design features in different ways. Specifically, they found that there was no standardised apex position which could be used to minimise pressure under the forefoot for every patient. Rather, each patient required a different apex position and therefore a customised shoe. There is however no method to predict the required values of each of the four footwear design features for a given patient. This means that to find the shoe design which most effectively minimises pressure under the forefoot every patient must try out many shoes (covering all the footwear design features) whilst undergoing in shoe pressure measurement. Clearly, this would be impractical in a clinical setting and therefore a system which can predict optimal footwear design features after a relatively short assessment is required.

When walking in a rocker shoe, the resulting pressure under the forefoot is determined by a complex interaction of the patient's intrinsic walking pattern, foot geometry and the design of the footwear (Morag et al., 1997). Using established biomechanical measurement techniques many aspects of a patient's walking pattern can be quantified including joint motions, joint torques and pressures under the forefoot as well as changes in foot shape. Any system to specify individual footwear design needs to analyse these aspects of a patient's walking pattern and then calculate the optimal design. To develop this system, a mathematical algorithm linking different walking patterns with optimal footwear design features needs to be created, which requires data from a range of diabetic patients. We propose to collect data from a wide range of diabetic patients to construct such an algorithm. Each patient would firstly undergo a barefoot walking assessment to characterise their walking pattern and then walk in several different shoes which span the range of footwear design features. Whilst doing so, an in shoe pressure measurement system will quantify the pressure under the forefoot and toes. These data will then be analysed to construct the algorithm and identify the optimal pair of shoes (i.e. those with lead to minimal in shoe pressures). The creation of this database will address second aim of the study.

An algorithm linking a patient's walking pattern with an accurate prescription for bespoke footwear has the potential to considerably improve diabetic foot care. In current clinical practice, standardised footwear design features are often used for all patients, regardless of their individual walking pattern and needs. Such an approach has been shown to lead to minimal pressure reduction in some patients and in some cases elevated pressures (van Schie et al., 2000).

In contrast, an algorithm which is able to individualise footwear design prescription should lead to more effective pressure relief for all patients, with consequent improved outcomes and reduction in serious complications, such as amputation. On completion of this project, the research team will undertake further work to develop an inexpensive portable gait laboratory which could be situated in a shop or orthopaedic clinic to measure patients' walking pattern and prescribe the most effective footwear design.

1. Brown D, Wertsch J J, Harris G F, Klein J and Janisse D 2004 Effect of rocker soles on plantar pressures Archives of Physical Medicine and Rehabilitation 85 816

2. Cavanagh P R 2004 Therapeutic footwear for people with diabetes Diabetes Metab.

Res. Rev. 20 S51S5

3. Hutchins S, Bowker P, Geary N and Richards J 2009 The biomechanics and clinical efficacy of footwear adapted with rocker profiles—Evidence in the literature The Foot 19 16570

4. Morag E, Pammer S, Boulton A, Young M, Deffner K and Cavanagh P 1997 Structural and functional aspects of the diabetic foot Clinical biomechanics (Bristol, Avon) 12 S9S10

5. Praet S F and Louwerens J W 2003 The influence of shoe design on plantar pressures in neuropathic feet Diabetes care 26 4415

6. van Schie C, Ulbrecht J S, Becker M B and Cavanagh P R 2000 Design criteria for rigid rocker shoes Foot & Ankle International 21 83344

6. **If you are going to work within a particular organisation do they have their own procedures for gaining ethical approval**

   for example, within a hospital or health centre?

   NO

   If YES – what are these and how will you ensure you meet their requirements?

7. Are you going to approach individuals to be involved in your research?

YES

If YES – please think about key issues – for example, how you will recruit people? How you will deal with issues of confidentiality / anonymity? Then make notes that cover the key issues linked to your study

We aim to recruit 100 participants which will consist of 50 diabetic and 50 healthy. We propose three potential methods of recruiting participants for this study. Initially we will approach the staff and students of the University of Salford either in person or via email. We anticipate being able to recruit more healthy participants via this route. If we unable to recruit sufficient participants with diabetes via this route, then we will contact individuals who have previously participated in research studies at the University of Salford and who have given permission to be contacted again with details of other research studies.

In order to recruit participants from within the university, we will approach staff/students working in the Faculty of Health and Social Care both in person and via email asking them if they would like to participate. All participants will be given a detailed verbal (or emailed) description of what the project involves before they agree to participate. (A copy of the email, which will be sent to all staff/students, has been included with this application) When they visit the laboratory they will then be given a detailed written description of the project and, if they are still willing to participate, will be required to sign the consent form.

If it is necessary to contact individuals who have participated in previous research studies, then a letter will be sent out with full details on the study to potential participants. Anyone willing to participate will be required to contact the one of the lead researchers, either ******* or ******, via phone or email. They will then be given the opportunity to ask questions regarding the study before they agree to participate. When they visit the laboratory they will then be given a detailed written description of the project and if they are still willing to participate will be required to sign the consent form.

Each subject who participates in the study will complete a consent form and will be allocated a unique participant number. This number will be used to identify that particular subject for all subsequent data collection and analysis purposes and the consent form will be stored separately in a paper format. There will be no personal information on each subject stored in electronic format. Once the study has been completed and the results written up, accepted and published the consent forms will be destroyed using the University of Salford's procedure for dealing with confidential waste. This process will ensure confidentiality and anonymity. If a subject decides to withdraw partway through the study, then their personal information will be destroyed immediately.

8. More specifically, how will you ensure you gain informed consent from anyone involved in the study?

Each subject will complete a consent form after reading a full written description of the project and the activities they will be required to perform. Participants will be free to withdraw at any time during the study.

9. Are there any data protection issues that you need to address?

YES

If YES what are these and how will you address them?

The only data protection issues relate to the information on the subject consent form. We will only record the patient's name and signature and this information will not be stored on any electronic format. The consent forms will be stored in a locked filing cabinet and destroyed once the study has been completed and the results written up, accepted and published. These sheets will be destroyed according to the University of Salford's procedure for dealing with confidential waste. This process will ensure confidentiality and anonymity. If a subject decides to withdraw partway through the study, then their personal information will be destroyed immediately.

10. Are there any other ethical issues that need to be considered? For example - research on animals or research involving people under the age of 18.

No

11. ***(a) Does the project involve the use of ionising or other type of "radiation"***
NO

(b) Is the use of radiation in this project over and above what would ***<u>normally</u> be expected (for example) in diagnostic imaging?***

NO

(c) Does the project require the use of hazardous substances?

NO

(d) Does the project carry any risk of injury to the participants?
NO

(e) Does the project require participants to answer questions that may cause disquiet / or upset to them?
NO

If the answer to any of the questions 11(a)-(e) is** YES**, a risk assessment of the project is required.

12. **How many subjects will be recruited/involved in the study/research? What is the rationale behind this number?**

Phase I: We will collect footscan data on all 100 participants and will ensure that foot pressure data is collected on at least 30 participants. Allowing for 10% attrition, this will provide 27 datasets, above the minimum required for statistical power.

Phase II: We will collect data on all 100 participants. Allowing for 10% attrition, this will provide sufficient data to train our neural network.

<u>Phase I:</u>

A sample size calculation was performed for a repeated measures ANOVA test to detect an effect size of 0.25 with and alpha=0.05 and beta = 0.8. Assuming 4 different repeat tests and moderate (r=0.5) correlations between the repeated measures, then 24 subjects are required.

In addition, the literature was consulted and a paper published by Van Schie et al (2000) identified. This study was similar in design to the proposed study but looked at a outdated rocker shoe and included only health participants. Van Schie et al recruited n=17 participants into their study and were able to show significant ($P<0.05$) differences in pressure between shoes with different rocker angles and rocker apex positions. With n=27 we should be able to detect similar differences in our study.

van Schie C, Ulbrecht J S, Becker M B and Cavanagh P R 2000 Design criteria for rigid rocker shoes Foot & Ankle International 21 83344

Phase II:

No previous studies have been performed investigating the link between biomechanical parameters and optimal design features of footwear on which to base a sample size estimate. Furthermore, it is difficult to perform a conventional power analysis for an Artificial Neural Network Analysis. Artificial Neural Networks are able to cope with either very small or very large data sets. However, the amount of training data available sets an upper bound for the complexity of the network design. With data from 90 participants, we should be able to develop a network with three hidden layers. Similar networks have previous been shown to provide good results from much smaller number in other areas of biomechanical modelling (Savelberg and Herzog, 1997)

Savelberg H H and Herzog W 1997 Prediction of dynamic tendon forces from electromyographic signals: an artificial neural network approach Journal of neuroscience methods 78 6574

Please attach:

- A summary in clear / plain English (or whatever media/language is appropriate) of the material you will use with participants explaining the study / consent issues etc.
- A draft consent form – again in whatever media is suitable for your research purposes / population.
- A copy of any posters to be used to recruit participants: email and newspaper advert.

Remember that informed consent from research participants is crucial, therefore your information sheet must use language that is readily understood by the general public.

Projects that involve NHS patients, patients' records or NHS staff, will require ethical approval by the appropriate NHS Research Ethics Committee. The University Research Ethics Panel will require written confirmation that such approval has been granted. Where a project forms part of a larger, already approved, project, the approving REC should be informed about, and approve, the use of an additional co-researcher.

I certify that the above information is, to the best of my knowledge, accurate and correct. I understand the need to ensure I undertake my research in a manner that reflects good principles of ethical research practice.

Signed by Member of Staff	

Date	

In signing this form I confirm that I have read the contents and I am satisfied that the project can proceed subject to approval by the University of Salford RESEARCH ETHICS PANEL.

Signed by RI Director	

Date	

Appendix 5: SSHOES work package 2 project brief (relevant to this project)

Work package number	2		**Start date or starting event:**					Month 1			
Work package title	Footwear and components product										
Activity Type[1]	RTD										
Participant number	1	2	3	4	5	6	7	8	9	10	11
Participant short name	INESCOP	TPSP	USAL	C2I2	DUNA	SOLETEC	UNIVPM	UNI SPORTS	CNR-ITIA	KOPITAR NA	AYCN
Person-months per participant:	23	15	8	0	15	13	4	6	0	7	2

Objectives 1) To define a fully informed design criteria for footwear development. 2) To study the efficiency of system outsole-insole-footwear in relation to the possible combinations of materials and user adjustability. 3) To define which functional characteristics determine fit for purpose of materials used in footwear. 4) Research the possible range of activities a diabetic person may participate in to define adaptive materials and footwear for the intended purpose 5) Research shoe upper- foot interaction in a virtual way

Description of work (possibly broken down into tasks), and role of participants

- *To define a fully informed design criteria for footwear development.*

The work will be leaded by INESCOP with the participation of UNI.SPORTS, USAL, and all footwear and insole SMEs and will consist on the creation of a repository of the selected parameters in WP1 with the aim of establishing a link with footwear, considering the following parameters:

- Foot volume and geometry
- Foot pressure distribution (3D)
- Footwear shape (last)
- Footwear recommended materials and construction

The deliverable is a matching software which gets as input biomechanical data and foot geometry, foot pressure distribution and last shape and produces as output a

[1] Please indicate one activity per work package:
RTD = Research and technological development; DEM = Demonstration; MGT = Management of the consortium; OTHER = Other specific activities, if applicable (including any activities to prepare for the dissemination and/or exploitation of project results, and coordination activities).

recommendation for a last (shape) and list of materials. The information about materials comes from Wp41 and the foot data from Wp32.

- *To study the efficiency of system outsole-insole-footwear in relation to the possible combinations of materials and user adjustability.*

This is one of the more innovative approaches of the project, to consider the system outsole-insole to analyse the efficency of treatments, as well as consider the change of footwear as key element for foot orthoses. The work will be leaded by UNIVPM with the participation of SOLETEC, INESCOP DUNA and TPSP. The work will consist in the design and building of combinations of materials (PU, rubber, EVA, Polyetilene) of at least 5 densities and hardness modifying the thickness of different layers to simulate a real footwear configuration.

TESTS	**STANDARDS**
Apparent Density	ISO 845:1988
Asker Hardness	INESCOP Method
Resilience	UNE 53604:1990
Stress/strain in compresion	ISO 3386-1:1986
Compression set	ISO 1856:2000, method C
Compression fatigue	INESCOP Method
Water vapour permeability	UNE 59035:1994
Perspiration resistance	EN 12801:2000

In addition, different configurations, following the same criteria, will be designed and manufactured and tested inside different shoe types (5 suitable for diabetics). The comfort protocol from CEN TC 3090 will be used with additional measurement of pressure distribution in the interface shoe-insole-foot.

The deliverable is a set of criteria for insole-outsole combination (materials and properties) with respect to the individual (fit for individual) and the type of shoe. This activity could provide a contribution to CEN TC 309) if new methods arise from the protocol deployment.

- *To define which functional characteristics determine fit for purpose of materials used in footwear.*

Once defined the behaviour of different material combinations and shoes that fit better, a system to determine when the footwear is no longer fit for the defined purpose is to be developed, based on the use of sensors integrated in a device that will inform the user or the prescriptor. The device is intended to be a sensor system composed by piezoresistive, temperature and humidity sensors which would measure pressure, temperature and humidity in specific points (to be defined at WP1) of the footwear. As an in-shoe device with autonomy for a period of 3 months and sampling frequency of 1 data set every minute of footwear use. Activity is not considered here as well as activity patterns and will be studied in Wp3. The delivery is a compact device which shows data record and one alarm when some of the parameters are over set points. INESCOP is in charge of this task, in collaboration with TPSP, DUNA, KOPITARNA and USAL, which will support the decision process to determine set points and criteria.

- *Research the possible range of activities a diabetic person may participate in to* *define adaptive materials and footwear for the intended purpose*

This activity is leaded by USAL and supported by UNI.SPORTS and INESCOP and will consist on the research about activities a diabetic person may perform. The definition will be done by literature search and by measuring activity patterns by using a market accelerometer in a control group of 10 diabetics per country (UK, Italy, Slovenia and Spain) and 5 normal feet condition individuals, with a reference shoe system provided by the SMEs. Possible foot tissues and biomechanical changes will be analysed to define level of adaptability of materials and footwear. This activity is feeded with results from WP1.

- *Research shoe upper- foot interaction in a virtual way*

The deformation of a shoe upper during walking and its interaction with individual feet is going to be modelled by using FE techniques. The algorithm to be used is based on preliminary work developed at Polytechnic University of Valencia (LAB HUMAN), which will be modified with proper mechanical characterisation (tensile strength and modulus according to CEN TC 309) of different leather and textile materials used as uppers for shoes. This task will be leaded by INESCOP and SMEs will provide materials for characterisation. The delivery will be a virtual simulator shoe upper-foot.

This WP takes into consideration basic elements defined in WP1 and produces useful info for the KB tool capable of generating a product for one individual in WP4 and WP5.

Partners' role in WP2:

TASK LEADER	**INESCOP**	**MAIN RTD PERFORMERS**	**MM**	**ROLE**
WP2 Footwear and components product		INESCOP	23	Software development. Characterisation of combinations. Device for fit-for-purpose. Search on materials and characterisation. Development of simulator for foot-upper interaction simulation.
		USAL	8	Contribution to comparison between parameters for footwear and component selection. Design of assessment protocol. Protocol for activity measurements and data calculation.

			Contribution to simulator development.
	UNIVPM	4	Software development. Contribution of different insole-sole configurations. Software for data treatment.
	UNI.SPORTS	6	Contribution to comparison between parameters for footwear and component selection. Design of assessment protocol. Protocol for activity measurement and data calculation. Contribution to simulator development.
	INDUSTRY PARTNERS	**MM**	**ROLE**
	TPSP	15	Contribution to matching algorithm. Design of materials combinations. Materials combinations assessment in real life. Activity monitoring of patients. Validation of simulator.
	DUNA	15	Contribution to matching algorithm. Preparation of different insole-sole configurations. Materials combinations assessment in real life. Activity monitoring of patients. Validation of simulator.
	SOLETEC	13	Contribution to matching algorithm. Preparation of different insole-sole configurations. Materials combinations assessment in real life. Activity monitoring of patients. Validation of simulator.
	KOPITARNA	7	Contribution to matching algorithm. Materials combinations assessment in real life. Validation of simulator.
	AYCN	2	Contribution to matching algorithm.

Deliverables

D21 Software: matching software which gets as input biomechanical data and foot geometry, foot pressure distribution and last shape and produces as output a recommendation for a last (shape) and list of materials. Month 15

D22 Report: set of criteria for insole-outsole combination (materials and properties) with respect to the individual (fit for individual) and the type of shoe. Month 12.

D23 Prototype: device which shows data record and one alarm when some of the parameters are over set points. Month 18.

D24 Report: Results about activity pattern measurement in control group. Month 12.

D25 Prototype: virtual simulator of shoe upper-foot. Month 18

References

ABATE, M., SCHIAVONE, C., SALINI, V. & ANDIA, I. 2013. Management of limited joint mobility in diabetic patients. *Diabetes, metabolic syndrome and obesity : targets and therapy,* 6**,** 197-207.

Abbott C., Paisley A., van Schie C, & Boulton A. 2002. A comparison of the Neuropen against standard quantitative sensory-threshold measures for assessing peripheral nerve function. *Diabetic Medicine,* 19**,** 400-405

ABBOTT, C. A., VILEIKYTE, L., WILLIAMSON, S., CARRINGTON, A. L. & BOULTON, A. J. 1998. Multicenter Study of the Incidence of and Predictive Risk Factors for Diabetic Neuropathic Foot Ulceration. *Diabetes Care,* 21**,** 1071-1075.

ABOUAESHA, F., VAN SCHIE, C. H. M., GRIFFTHS, G. D., YOUNG, R. J. & BOULTON, A. J. M. 2001. Plantar tissue thickness is related to peak plantar pressure in the high-risk diabetic foot. *Diabetes Care,* 24**,** 1270-1274.

ABUFARAJ, Z. O., HARRIS, G. F., ABLER, J. H. & WERTSCH, J. J. 1997. A Holter-type, microprocessor-based, rehabilitation instrument for acquisition and storage of plantar pressure data. *Journal of Rehabilitation Research and Development,* 34**,** 187-194.

ALLET, L., ARMAND, S., GOLAY, A., MONNIN, D., DE BIE, R. A. & DE BRUIN, E. D. 2008. Gait characteristics of diabetic patients: a systematic review. *Diabetes/Metabolism Research and Reviews,* 24**,** 173-191.

ARMSTRONG, D. G., PETERS, E. J., ATHANASIOU, K. A. & LAVERY, L. A. 1998. Is there a critical level of plantar foot pressure to identify patients at risk for neuropathic foot ulceration? *Journal of Foot and Ankle Surgery,* 37**,** 303-7.

ARNOLD, J. B. & BISHOP, C. 2012. Quantifying foot kinematics inside athletic footwear: a review. *Footwear Science,* 5**,** 55-62.

ASHRY, H. R., LAVERY, L. A., MURDOCH, D. P., FROLICH, M. & LAVERY, D. C. 1997. Effectiveness of diabetic insoles to reduce foot pressures. *The Journal of Foot and Ankle Surgery,* 36**,** 268-271.

BACARIN, T. A., SACCO, I. C. & HENNIG, E. M. 2009. Plantar pressure distribution patterns during gait in diabetic neuropathy patients with a history of foot ulcers. *Clinics,* 64**,** 113-20.

BARTON, G. 1999. Interpretation of gait data using Kohonen neural networks. *Gait & Posture,* 10**,** 85.

BARTON, J. G. & LEES, A. 1996. Comparison of shoe insole materials by neural network analysis. *Medical and Biological Engineering and Computing,* 34**,** 453-459.

BARTON, J. G. & LEES, A. 1997. An application of neural networks for distinguishing gait patterns on the basis of hip-knee joint angle diagrams. *Gait & Posture,* 5**,** 28-33.

BIRTANE, M. & TUNA, H. 2004. The evaluation of plantar pressure distribution in obese and non-obese adults. *Clin Biomech,* 19**,** 1055-9.

BOADA, A. 2012. Skin Lesions in the Diabetic Foot. *Actas Dermo-Sifiliográficas,* 103**,** 348-356.

BONTRAGER, E. L., BOYD, L. A., HEINO, J. G., MULROY, S. J. & PERRY, J. 1997. 5 Determination of novel pedar masks using harris mat imprints. *Gait & Posture,* 5**,** 167-168.

BOULTON, A. J., HARDISTY, C. A., BETTS, R. P., FRANKS, C. I., WORTH, R. C., WARD, J. D. & DUCKWORTH, T. 1983. Dynamic foot pressure and other studies as diagnostic and management aids in diabetic neuropathy. *Diabetes Care,* 6**,** 26-33.

BOULTON, A. J. M. 2004. Pressure and the diabetic foot: clinical science and offloading techniques. *American Journal of Surgery,* 187**,** 17S-24S.

BOULTON, A. J. M. 2008. The diabetic foot: grand overview, epidemiology and pathogenesis. *Diabetes/Metabolism Research and Reviews,* 24**,** S3-S6.

BOULTON, A. J. M. 2013. The Pathway to Foot Ulceration in Diabetes. *Medical Clinics of North America,* 97**,** 775-+.

BOULTON, A. J. M., CONNOR, H. & CAVANAGH, P. R. 1994. *The foot in diabetes,* J. Wiley & Sons.

BOUTEN, C. V., OOMENS, C. W., BAAIJENS, F. P. & BADER, D. L. 2003. The etiology of pressure ulcers: Skin deep or muscle bound? *Archives of Physical Medicine and Rehabilitation,* 84**,** 616-619.

BOYKO, E. J., AHRONI, J. H., STENSEL, V., FORSBERG, R. C., DAVIGNON, D. R. & SMITH, D. G. 1999. A prospective study of risk factors for diabetic foot ulcer. The Seattle Diabetic Foot Study. *Diabetes Care,* 22**,** 1036-42.

BRAUNSTEIN, B., ARAMPATZIS, A., EYSEL, P. & BRÜGGEMANN, G.-P. 2010. Footwear affects the gearing at the ankle and knee joints during running. *Journal of Biomechanics,* 43**,** 2120-2125.

BROWN, D., WERTSCH, J. J., HARRIS, G. F., KLEIN, J. & JANISSE, D. 2004. Effect of rocker soles on plantar pressures. *Archives of Physical Medicine and Rehabilitation,* 85**,** 81-86.

BUS, S. A. 2008a. Foot structure and footwear prescription in diabetes mellitus. *Diabetes/Metabolism Research and Reviews,* 24**,** S90-S95.

BUS, S. A. 2008b. Foot structure and footwear prescription in diabetes mellitus. *Diabetes-Metabolism Research and Reviews,* 24**,** S90-S95.

BUS, S. A. 2012. Priorities in offloading the diabetic foot. *Diabetes-Metabolism Research and Reviews,* 28**,** 54-59.

BUS, S. A., HASPELS, R. & BUSCH-WESTBROEK, T. E. 2011. Evaluation and Optimization of Therapeutic Footwear for Neuropathic Diabetic Foot Patients Using In-Shoe Plantar Pressure Analysis. *Diabetes Care,* 34**,** 1595-1600.

BUS, S. A., ULBRECHT, J. S. & CAVANAGH, P. R. 2004. Pressure relief and load redistribution by custom-made insoles in diabetic patients with neuropathy and foot deformity. *Clin Biomech (Bristol, Avon),* 19**,** 629-38.

BUS, S. A., VALK, G. D., VAN DEURSEN, R. W., ARMSTRONG, D. G., CARAVAGGI, C., HLAVACEK, P., BAKKER, K. & CAVANAGH, P. R. 2008a. The effectiveness of footwear and offloading interventions to prevent and heal foot ulcers and reduce plantar pressure in diabetes: a systematic review. *Diabetes-Metabolism Research and Reviews,* 24**,** S162-S180.

BUS, S. A., VALK, G. D., VAN DEURSEN, R. W., ARMSTRONG, D. G., CARAVAGGI, C., HLAVACEK, P., BAKKER, K. & CAVANAGH, P. R. 2008b. Specific guidelines on footwear and offloading. *Diabetes Metab Res Rev,* 24 Suppl 1**,** S192-3.

BUS, S. A., VAN DEURSEN, R. W., KANADE, R. V., WISSINK, M., MANNING, E. A., VAN BAAL, J. G. & HARDING, K. G. 2009. Plantar pressure relief in the diabetic foot using forefoot offloading shoes. *Gait Posture,* 29**,** 618-22.

BUS, S. A. & WAAIJMAN, R. 2012. The value of reporting pressure–time integral data in addition to peak pressure data in studies on the diabetic foot: A systematic review. *Clinical Biomechanics,* 28**,** 117-121.

BUS, S. A., WAAIJMAN, R., ARTS, M., DE HAART, M., BUSCH-WESTBROEK, T., VAN BAAL, J. & NOLLET, F. 2013. Effect of Custom-Made Footwear on Foot Ulcer Recurrence in Diabetes A multicenter randomized controlled trial. *Diabetes Care,* 36**,** 4109-4116.

CAPPOZZO, A., CATANI, F., LEARDINI, A., BENEDETTI, M. G. & DELLA CROCE, U. 1996. Position and orientation in space of bones during movement: experimental artefacts. *Clinical Biomechanics,* 11**,** 90-100.

CARL, H. D., PFANDER, D. & SWOBODA, B. 2006. Assessment of plantar pressure in forefoot relief shoes of different designs. *Foot Ankle Int,* 27**,** 117-20.

CASELLI, A., PHAM, H., GIURINI, J. M., ARMSTRONG, D. G. & VEVES, A. 2002. The Forefoot-to-Rearfoot Plantar Pressure Ratio Is Increased in Severe Diabetic Neuropathy and Can Predict Foot Ulceration. *Diabetes Care,* 25**,** 1066-1071.

CAVANAGH, P. R. 2004. Therapeutic footwear for people with diabetes. *Diabetes-Metabolism Research and Reviews,* 20**,** S51-S55.

CAVANAGH, P. R. & BUS, S. A. 2011. Off-Loading the Diabetic Foot for Ulcer Prevention and Healing. *Plastic and Reconstructive Surgery,* 127**,** 248S-256S.

CAVANAGH, P. R., HEWITT JR, F. G. & PERRY, J. E. 1992. In-shoe plantar pressure measurement: a review. *The Foot,* 2**,** 185-194.

CAVANAGH, P. R., MORAG, E., BOULTON, A. J. M., YOUNG, M. J., DEFFNER, K. T. & PAMMER, S. E. 1997. The relationship of static foot structure to dynamic foot function. *Journal of Biomechanics,* 30**,** 243-250.

CAVANAGH, P. R. & ULBRECHT, J. S. 1994. Clinical plantar pressure measurement in diabetes: rationale and methodology. *The Foot,* 4**,** 123-135.

CAVANAGH, P. R., ULBRECHT, J. S. & CAPUTO, G. M. 2000. New developments in the biomechanics of the diabetic foot. *Diabetes Metab Res Rev,* 16 Suppl 1**,** S6-S10.

CAVANAGH, P. R., ULBRECHT, J. S., ZANINE, W., WELLING, R. L., LESCHINSKY, D. & VAN SCHIE, C. 1996. A method for the investigation of the effects of outsole modifications in therapeutic footwear. *Foot Ankle Int,* 17**,** 706-708.

CHANG, W. N., TSIRIKOS, A. I., MILLER, F., SCHUYLER, J. & GLUTTING, J. 2004. Impact of changing foot progression angle on foot pressure measurement in children with neuromuscular diseases. *Gait Posture,* 20**,** 14-9.

CHANTELAU, E., KUSHNER, T. & SPRAUL, M. 1990. How effective is cushioned therapeutic footwear in protecting diabetic feet? A clinical study. *Diabet Med,* 7**,** 355-9.

CHANTELAU, R. 2004. Effectiveness of a new brand of stock 'diabetic' shoes to protect against diabetic foot ulcer relapse (vol 21, pg 647, 2004). *Diabetic Medicine,* 21**,** 807-807.

CHAO, C. Y. L., ZHENG, Y.-P. & CHEING, G. L. Y. 2011. Epidermal thickness and biomechanical properties of plantar tissues in diabetic foot. *Ultrasound in Medicine and Biology,* 37**,** 1029-1038.

CHAPMAN, J. D., PREECE, S., BRAUNSTEIN, B., HOHNE, A., NESTER, C. J., BRUEGGEMANN, P. & HUTCHINS, S. 2013. Effect of rocker shoe design features on forefoot plantar pressures in people with and without diabetes. *Clin Biomech,* 28**,** 679-85.

CHEER, K., SHEARMAN, C. & JUDE, E. B. 2009. Managing complications of the diabetic foot. *BMJ,* 2.

CORNWALL, M. & MCPOIL, T. 2000. Velocity of the center of pressure during walking. *Journal of the American Podiatric Medical Association,* 90**,** 334-8.

CRAWFORD, F., INKSTER, M., KLEIJNEN, J. & FAHEY, T. 2007. Predicting foot ulcers in patients with diabetes: a systematic review and meta-analysis. *QJM,* 100**,** 65-86.

DANIEL, R. K., PRIEST, D. L. & WHEATLEY, D. C. 1981. Etiologic factors in pressure sores: an experimental model. *Arch Phys Med Rehabil,* 62**,** 492-8.

DELIANG, W. 1993. Pattern recognition: neural networks in perspective. *IEEE Expert,* 8**,** 52-60.

DESHPANDE, A. D., HARRIS-HAYES, M. & SCHOOTMAN, M. 2008. Epidemiology of Diabetes and Diabetes-Related Complications. *Physical Therapy,* 88**,** 1254-1264.

DI CARLI, M. F., BIANCO-BATLLES, D., LANDA, M. E., KAZMERS, A., GROEHN, H., MUZIK, O. & GRUNBERGER, G. 1999. Effects of autonomic neuropathy on coronary blood flow in patients with diabetes mellitus. *Circulation,* 100**,** 813-9.

DINGWELL, J. B. & CAVANAGH, P. R. 2001. Increased variability of continuous overground walking in neuropathic patients is only indirectly related to sensory loss. *Gait & Posture,* 14**,** 1-10.

DINH, T., TECILAZICH, F., KAFANAS, A., DOUPIS, J., GNARDELLIS, C., LEAL, E., TELLECHEA, A., PRADHAN, L., LYONS, T. E., GIURINI, J. E. & VEVES, A. 2012. Mechanisms Involved in the Development and Healing of Diabetic Foot Ulceration. *Diabetes,* 61**,** 2937-2947.

FENG, Y., SCHLOSSER, F. J. & SUMPIO, B. E. 2009. The Semmes Weinstein monofilament examination as a screening tool for diabetic peripheral neuropathy. *J Vasc Surg,* 50**,** 675-82.

FERNANDO, D. J. S., MASSON, E. A., VEVES, A. & BOULTON, A. J. M. 1991. Relationship of Limited Joint Mobility to Abnormal Foot Pressures and Diabetic Foot Ulceration. *Diabetes Care,* 14**,** 8-11.

FIEDLER, K. E., STUIJFZAND, W. J. A., HARLAAR, J., DEKKER, J. & BECKERMAN, H. 2011. The effect of shoe lacing on plantar pressure distribution and in-shoe displacement of the foot in healthy participants. *Gait & Posture,* 33**,** 396-400.

FOUNDATION, W. D. & FEDERATION, I. D. 2006. *Diabetes Atlas*, IDF Executive Office.

FRYKBERG, R. G. 1998. Diabetic foot ulcers: Current concepts. *The Journal of Foot and Ankle Surgery,* 37**,** 440-446.

FULLER, E., SCHROEDER, S. & EDWARDS, J. 2001. Reduction of peak pressure on the forefoot with a rigid rocker-bottom postoperative shoe. *Journal of the American Podiatric Medical Association,* 91**,** 501-507.

GARROW, A. P., VAN SCHIE, C. H. & BOULTON, A. J. 2005. Efficacy of multilayered hosiery in reducing in-shoe plantar foot pressure in high-risk patients with diabetes. *Diabetes Care,* 28**,** 2001-6.

GEFEN, A., MEGIDO-RAVID, M., AZARIAH, M., ITZCHAK, Y. & ARCAN, M. 2001. Integration of plantar soft tissue stiffness measurements in routine MRI of the diabetic foot. *Clin Biomech,* 16**,** 921-5.

GENOVA, J. & GROSS, M. 2000. Effect of Foot Orthotics on Calcaneal Eversion During Standing and Treadmill Walking for Subjects With Abnormal Pronation. *Journal of Orthopaedic & Sports Physical Therapy,* 30**,** 664-675.

GIOFTSOS, G. & GRIEVE, D. W. 1995. The use of neural networks to recognize patterns of human movement: gait patterns. *Clinical Biomechanics,* 10**,** 179-183.

GOLDMANN, J. P., SANNO, M., WILLWACHER, S., HEINRICH, K. & BRUGGEMANN, G. P. 2013. The potential of toe flexor muscles to enhance performance. *J Sports Sci,* 31**,** 424-33.

GOULERMAS, J. Y., FINDLOW, A. H., NESTER, C. J., HOWARD, D. & BOWKER, P. 2005. Automated design of robust discriminant analysis classifier for foot pressure lesions using kinematic data. *Ieee Transactions on Biomedical Engineering,* 52**,** 1549-1562.

GRUNDY, M., TOSH, P. A., MCLEISH, R. D. & SMIDT, L. 1975. An investigation of the centres of pressure under the foot while walking. *J Bone Joint Surg Br,* 57**,** 98-103.

GULDEMOND, N. A., LEFFERS, P., SANDERS, A. P., SCHAPER, N. C., NIEMAN, F. & WALENKAMP, G. H. I. M. 2007a. Daily-life activities and in-shoe forefoot plantar pressure in patients with diabetes. *Diabetes Research and Clinical Practice,* 77**,** 203-209.

GULDEMOND, N. A., LEFFERS, P., SCHAPER, N. C., SANDERS, A. P., NIEMAN, F., WILLEMS, P. & WALENKAMP, G. H. 2007b. The effects of insole configurations on forefoot plantar pressure and walking convenience in diabetic patients with neuropathic feet. *Clin Biomech (Bristol, Avon),* 22**,** 81-7.

HASTINGS, M. K., GELBER, J. R., ISAAC, E. J., BOHNERT, K. L., STRUBE, M. J. & SINACORE, D. R. 2010. Foot progression angle and medial loading in individuals with diabetes mellitus, peripheral neuropathy, and a foot ulcer. *Gait & Posture,* 32**,** 237-241.

HAYKIN, S. S. 1999. *Neural Networks: A Comprehensive Foundation,* Prentice Hall International.

HEALY, A., DUNNING, D. N. & CHOCKALINGAM, N. 2010. Materials used for footwear orthoses: A review. *Footwear Science,* 2**,** 93-110.

HEALY, A., NAEMI, R. & CHOCKALINGAM, N. 2013. The effectiveness of footwear as an intervention to prevent or to reduce biomechanical risk factors associated with diabetic foot ulceration: A systematic review. *Journal of Diabetes and its Complications,* 27**,** 391-400.

HETHERINGTON, V. J., JOHNSON, R. E. & ALBRITTON, J. S. 1990. Necessary dorsiflexion of the first metatarsophalangeal joint during gait. *The Journal of foot surgery,* 29**,** 218-222.

HILLS, A. P., HENNIG, E. M., MCDONALD, M. & BAR-OR, O. 2001. Plantar pressure differences between obese and non-obese adults: a biomechanical analysis. *Int J Obes Relat Metab Disord,* 25**,** 1674-9.

HOLZREITER, S. H. & KÖHLE, M. E. 1993. Assessment of gait patterns using neural networks. *Journal of Biomechanics,* 26**,** 645-651.

HSI, W. L., CHAI, H. M. & LAI, J. S. 2004. Evaluation of rocker sole pressure-time curves in insensate forefoot during gait. *American Journal of Physical Medicine & Rehabilitation,* 83**,** 500-506.

Accuracy and precision of two in-shoe pressure measurement systems, 2002. Article. Directed by HSIAO, H., GUAN, J. & WEATHERLY, M.: Taylor & Francis Ltd.

HURLEY, L., KELLY, L., GARROW, A. P., GLYNN, L. G., MCINTOSH, C., ALVAREZ-IGLESIAS, A., AVALOS, G. & DINNEEN, S. F. 2013. A prospective study of risk factors for foot ulceration: The West of Ireland Diabetes Foot Study. *Qjm-an International Journal of Medicine,* 106**,** 1103-1110.

HUTCHINS, S., BOWKER, P., GEARY, N. & RICHARDS, J. 2009. The biomechanics and clinical efficacy of footwear adapted with rocker profiles—Evidence in the literature. *The Foot,* 19**,** 165-170.

JANISSE, D. J. 1995. Prescription insoles and footwear. *Clin Podiatr Med Surg,* 12**,** 41-61.

JAYAPRAKASH, P., BHANSALI, S., BHANSALI, A., DUTTA, P. & ANANTHARAMAN, R. 2009. Magnitude of foot problems in diabetes in the developing world: a study of 1044 patients. *Diabetic Medicine,* 26**,** 939-942.

JOHNSON, S. T., TUDOR-LOCKE, C., MCCARGAR, L. J. & BELL, R. C. 2005. Measuring Habitual Walking Speed of People With Type 2 Diabetes: Are they meeting recommendations? *Diabetes Care,* 28**,** 1503-1504.

JONELY, H., BRISMEE, J.-M., SIZER, P. S., JR. & JAMES, C. R. 2011. Relationships between clinical measures of static foot posture and plantar pressure during static standing and walking. *Clinical Biomechanics,* 26**,** 873-879.

KAVROS, S. J., VAN STRAATEN, M. G., WOOD, K. A. C. & KAUFMAN, K. R. 2011. Forefoot plantar pressure reduction of off-the-shelf rocker bottom provisional footwear. *Clinical Biomechanics,* 26**,** 778-782.

KEIJSERS, N. L. W., STOLWIJK, N. M., LOUWERENS, J. W. K. & DUYSENS, J. 2013. Classification of forefoot pain based on plantar pressure measurements. *Clinical Biomechanics,* 28**,** 350-356.

KHOURY, M., WOLF, A., DEBBI, E. M., HERMAN, A. & HAIM, A. 2013. Foot center of pressure trajectory alteration by biomechanical manipulation of shoe design. *Foot & ankle international. / American Orthopaedic Foot and Ankle Society [and] Swiss Foot and Ankle Society,* 34**,** 593-8.

KNOWLES, E. A. & BOULTON, A. J. M. 1996. Do people with diabetes wear their prescribed footwear? *Diabetic Medicine,* 13**,** 1064-1068.

KOSIAK, M. 1961. Etiology of decubitus ulcers. *Arch Phys Med Rehabil,* 42**,** 19-29.

KUMAR, P. & CLARK, M. L. 2009. *Kumar and Clark's Clinical Medicine, International Edition*, Elsevier Health Sciences UK.

LAVERY, L. A., ARMSTRONG, D. G., VELA, S. A., QUEBEDEAUX, T. L. & FLEISCHLI, J. G. 1998. Practical criteria for screening patients at high risk for diabetic foot ulceration. *Archives of Internal Medicine,* 158**,** 157-162.

LAVERY, L. A., PETERS, E. J. G. & ARMSTRONG, D. G. 2008. What are the most effective interventions in preventing diabetic foot ulcers? *Int Wound J,* 5**,** 425-33.

LAVERY, L. A., VELA, S. A., FLEISCHLI, J. G., ARMSTRONG, D. G. & LAVERY, D. C. 1997. Reducing plantar pressure in the neuropathic foot. A comparison of footwear. *Diabetes Care,* 20**,** 1706-10.

LEDOUX, W. R., SHOFER, J. B., COWLEY, M. S., AHRONI, J. H., COHEN, V. & BOYKO, E. J. 2013. Diabetic foot ulcer incidence in relation to plantar pressure magnitude and measurement location. *Journal of Diabetes and its Complications,* 27**,** 621-626.

LEUNG, P. C. 2007. Diabetic foot ulcers - a comprehensive review. *Surgeon-Journal of the Royal Colleges of Surgeons of Edinburgh and Ireland,* 5**,** 219-231.

LEVIN, M. E. & O'NEAL, L. W. 1988. *The Diabetic foot,* Mosby.

LIDTKE, R. H., MUEHLEMAN, C., KWASNY, M. & BLOCK, J. A. 2010. Foot Center of Pressure and Medial Knee Osteoarthritis. *Journal of the American Podiatric Medical Association,* 100**,** 178-184.

LITZELMAN, D. K., MARRIOTT, D. J. & VINICOR, F. 1997. The Role of Footwear in the Prevention of Foot Lesions in Patients With NIDDM: Conventional wisdom or evidence-based practice? *Diabetes Care,* 20**,** 156-162.

LONG, J. T., KLEIN, J. P., SIROTA, N. M., WERTSCH, J. J., JANISSE, D. & HARRIS, G. F. 2007. Biomechanics of the double rocker sole shoe: Gait kinematics and kinetics. *Journal of Biomechanics,* 40**,** 2882-2890.

LORD, M. & HOSEIN, R. 2000. A study of in-shoe plantar shear in patients with diabetic neuropathy. *Clinical Biomechanics,* 15**,** 278-283.

MACFARLANE, D. J. & JENSEN, J. L. 2003. Factors in diabetic footwear compliance. *Journal of the American Podiatric Medical Association,* 93**,** 485-491.

MACFARLANE, R. M. & JEFFCOATE, W. J. 1997. Factors contributing to the presentation of diabetic foot ulcers. *Diabetic Medicine,* 14**,** 867-870.

MACIEJEWSKI, M. L., REIBER, G. E., SMITH, D. G., WALLACE, C., HAYES, S. & BOYKO, E. J. 2004. Effectiveness of diabetic therapeutic footwear in preventing reulceration. *Diabetes Care,* 27**,** 1774-82.

MALUF, K. S. & MUELLER, M. J. 2003. Novel Award 2002. Comparison of physical activity and cumulative plantar tissue stress among subjects with and without diabetes mellitus and a history of recurrent plantar ulcers. *Clin Biomech (Bristol, Avon),* 18**,** 567-575.

MALUF, K. S., MUELLER, M. J., STRUBE, M. J., ENGSBERG, J. R. & JOHNSON, J. E. 2004. Tendon Achilles lengthening for the treatment of neuropathic ulcers causes a temporary reduction in forefoot pressure associated with changes in plantar flexor power rather than ankle motion during gait. *J Biomech,* 37**,** 897-906.

MARTINEZ-NOVA, A., HUERTA, J. P. & SANCHEZ-RODRIGUEZ, R. 2008. Cadence, age, and weight as determinants of forefoot plantar pressures using the Biofoot in-shoe system. *Journal of the American Podiatric Medical Association,* 98**,** 302-310.

MENZ, H. B. & MORRIS, M. E. 2006. Clinical determinants of plantar forces and pressures during walking in older people. *Gait & Posture,* 24**,** 229-236.

MOKDAD, A. H., FORD, E. S., BOWMAN, B. A. & ET AL. 2003. PRevalence of obesity, diabetes, and obesity-related health risk factors, 2001. *Jama,* 289**,** 76-79.

MØLLER, M. F. 1993. A scaled conjugate gradient algorithm for fast supervised learning. *Neural Networks,* 6**,** 525-533.

MORAG, E. & CAVANAGH, P. R. 1999. Structural and functional predictors of regional peak pressures under the foot during walking. *J Biomech,* 32**,** 359-70.

MORAG, E., PAMMER, S., BOULTON, A., YOUNG, M., DEFFNER, K. & CAVANAGH, P. 1997. Structural and functional aspects of the diabetic foot. *Clin Biomech (Bristol, Avon),* 12**,** S9-S10.

MUELLER, M. J., HASTINGS, M., COMMEAN, P. K., SMITH, K. E., PILGRAM, T. K., ROBERTSON, D. & JOHNSON, J. 2003. Forefoot structural predictors of plantar pressures during walking in people with diabetes and peripheral neuropathy. *Journal of Biomechanics,* 36**,** 1009-1017.

MUELLER, M. J., SINACORE, D. R., HOOGSTRATE, S. & DALY, L. 1994. Hip and ankle walking strategies: effect on peak plantar pressures and implications for neuropathic ulceration. *Arch Phys Med Rehabil,* 75**,** 1196-200.

MUELLER, M. J., ZOU, D., BOHNERT, K. L., TUTTLE, L. J. & SINACORE, D. R. 2008. Plantar stresses on the neuropathic foot during barefoot walking. *Phys Ther,* 88**,** 1375-84.

MUGAMBI-NTURIBI, E., OTIENO, C. F., KWASA, T. O. O., OYOO, G. O. & ACHARYA, K. 2009. Stratification of persons with diabetes into risk categories for foot ulceration. *East African medical journal,* 86**,** 233-9.

MURRAY, H. J., YOUNG, M. J., HOLLIS, S. & BOULTON, A. J. 1996. The association between callus formation, high pressures and neuropathy in diabetic foot ulceration. *Diabet Med,* 13**,** 979-82.

MYERS, K. A., LONG, J. T., KLEIN, J. P., WERTSCH, J. J., JANISSE, D. & HARRIS, G. F. 2006. Biomechanical implications of the negative heel rocker sole shoe: Gait kinematics and kinetics. *Gait & Posture,* 24**,** 323-330.

NAIR, S. P., GIBBS, S., ARNOLD, G., ABBOUD, R. & WANG, W. 2010. A method to calculate the centre of the ankle joint: a comparison with the Vicon Plug-in-Gait model. *Clin Biomech,* 25**,** 582-7.

NATHER, A., BEE, C. S., HUAK, C. Y., CHEW, J. L. L., LIN, C. B., NEO, S. & SIM, E. Y. 2008. Epidemiology of diabetic foot problems and predictive factors for limb loss. *Journal of Diabetes and its Complications,* 22**,** 77-82.

NAWOCZENSKI, D. A., BIRKE, J. A. & COLEMAN, W. C. 1988. Effect of rocker sole design on plantar forefoot pressures. *Journal of the American Podiatric Medical Association* 78**,** 455-60.

NESTER, C., JONES, R. K., LIU, A., HOWARD, D., LUNDBERG, A., ARNDT, A., LUNDGREN, P., STACOFF, A. & WOLF, P. 2007. Foot kinematics during walking measured using bone and surface mounted markers. *Journal of Biomechanics,* 40**,** 3412-3423.

NESTER, C. J., LIU, A. M., WARD, E., HOWARD, D., COCHEBA, J. & DERRICK, T. 2010. Error in the description of foot kinematics due to violation of rigid body assumptions. *Journal of Biomechanics,* 43**,** 666-672.

NGIA, L. S. H. & SJOBERG, J. 2000. Efficient training of neural nets for nonlinear adaptive filtering using a recursive Levenberg-Marquardt algorithm. *Signal Processing, IEEE Transactions on,* 48**,** 1915-1927.

OWINGS, T. M., APELQVIST, J., STENSTROM, A., BECKER, M., BUS, S. A., KALPEN, A., ULBRECHT, J. S. & CAVANAGH, P. R. 2009a. Plantar pressures in diabetic patients with foot ulcers which have remained healed. *Diabet Med,* 26**,** 1141-6.

OWINGS, T. M., APELQVIST, J., STENSTROM, A., BECKER, M., BUS, S. A., KALPEN, A., ULBRECHT, J. S. & CAVANAGH, P. R. 2009b. Plantar pressures in diabetic patients with foot ulcers which have remained healed. *Diabetic Medicine,* 26**,** 1141-1146.

OWINGS, T. M., WOERNER, J. L., FRAMPTON, J. D., CAVANAGH, P. R. & BOTEK, G. 2008. Custom therapeutic insoles based on both foot shape and plantar pressure measurement provide enhanced pressure relief. *Diabetes Care,* 31**,** 839-844.

OYIBO, S. O., JUDE, E. B., TARAWNEH, I., NGUYEN, H. C., ARMSTRONG, D. G., HARKLESS, L. B. & BOULTON, A. J. M. 2001a. The effects of ulcer size and site, patient's age, sex and type and duration of diabetes on the outcome of diabetic foot ulcers. *Diabetic Medicine,* 18**,** 133-138.

OYIBO, S. O., JUDE, E. B., TARAWNEH, I., NGUYEN, H. C., HARKLESS, L. B. & BOULTON, A. J. M. 2001b. A Comparison of Two Diabetic Foot Ulcer Classification Systems: The Wagner and the University of Texas wound classification systems. *Diabetes Care,* 24**,** 84-88.

PAI, S. & LEDOUX, W. R. 2010. The compressive mechanical properties of diabetic and non-diabetic plantar soft tissue. *Journal of Biomechanics,* 43**,** 1754-1760.

PAYNE, C., TURNER, D. & MILLER, K. 2001. Determinants of plantar pressures in the diabetic foot. *Journal of Diabetes and its Complications,* 16**,** 277-283.

PERRY, J. E., ULBRECHT, J. S., DERR, J. A. & CAVANAGH, P. R. 1995. The use of running shoes to reduce plantar pressures in patients who have diabetes. *The Journal of bone and joint surgery* 77**,** 1819-28.

PHAM, H., HARKLESS, L. B., ARMSTRONG, D. G., GIURINI, J. M., HARVEY, C. & VEVES, A. 2000. Screening techniques to identify people at high risk for diabetic foot ulceration - A prospective multicenter trial. *Diabetes Care,* 23**,** 606-611.

PITEI, D. L., FOSTER, A. & EDMONDS, M. 1999. The effect of regular callus removal on foot pressures. *J Foot Ankle Surg,* 38**,** 251-5.

POLLARD, J. P., LEQUESNE, L. P. & TAPPIN, J. W. 1983. Forces under the foot. *Journal of Biomedical Engineering,* 5**,** 37-40.

PRAET, S. F. & LOUWERENS, J. W. 2003. The influence of shoe design on plantar pressures in neuropathic feet. *Diabetes Care,* 26**,** 441-5.

RAMANATHAN, A. K., KIRAN, P., ARNOLD, G. P., WANG, W. & ABBOUD, R. J. 2009. Repeatability of the Pedar-X in-shoe pressure measuring system. *Foot Ankle Surg,* 16**,** 70-3.

RAO, S., SALTZMAN, C. & YACK, H. J. 2006. Ankle ROM and stiffness measured at rest and during gait in individuals with and without diabetic sensory neuropathy. *Gait & Posture,* 24**,** 295-301.

RAO, S., SALTZMAN, C. & YACK, H. J. 2007. Segmental foot mobility in individuals with and without diabetes and neuropathy. *Clinical Biomechanics,* 22**,** 464-471.

RAO, S., SALTZMAN, C. L. & YACK, H. J. 2010. Relationships between segmental foot mobility and plantar loading in individuals with and without diabetes and neuropathy. *Gait & Posture,* 31**,** 251-255.

RAO, S., SONG, J., KRASZEWSKI, A., BACKUS, S., ELLIS, S. J., DELAND, J. T. & HILLSTROM, H. J. 2011. The effect of foot structure on 1st metatarsophalangeal joint flexibility and hallucal loading. *Gait & Posture,* 34**,** 131-137.

REIBER, G., LIPSKY, B. & GIBBONS, G. 1998. The burden of diabetic foot ulcers. *The American Journal of Surgery,* 176**,** 5S-10S.

REIBER, G. E. 1992. Diabetic foot care. Financial implications and practice guidelines. *Diabetes Care,* 1**,** 29-31.

REIBER, G. E., SMITH, D. G., WALLACE, C., SULLIVAN, K., HAYES, S., VATH, C., MACIEJEWSKI, M. L., YU, O., HEAGERTY, P. J. & LEMASTER, J. 2002. Effect of therapeutic footwear on foot reulceration in patients with diabetes: a randomized controlled trial. *Jama,* 287**,** 2552-8.

REIBER, G. E., VILEIKYTE, L., BOYKO, E. J., DEL AGUILA, M., SMITH, D. G., LAVERY, L. A. & BOULTON, A. J. 1999. Causal pathways for incident lower-extremity ulcers in patients with diabetes from two settings. *Diabetes Care,* 22**,** 157-162.

RICHARDS, J. 2008. *Biomechanics in Clinic and Research: An Interactive Teaching and Learning Course,* Churchill Livingstone/Elsevier.

ROBERTSON, D. D., MUELLER, M. J., SMITH, K. E., COMMEAN, P. K., PILGRAM, T. & JOHNSON, J. E. 2002. Structural changes in the forefoot of individuals with diabetes and a prior plantar ulcer. *Journal of Bone and Joint Surgery-American Volume,* 84A**,** 1395-1404.

ROBERTSON, D. G. & DOWLING, J. J. 2003. Design and responses of Butterworth and critically damped digital filters. *J Electromyogr Kinesiol,* 13**,** 569-73.

ROBERTSON, D. G. E. 2004. *Research Methods in Biomechanics,* Human Kinetics.

ROSENBAUM, D., HAUTMANN, S., GOLD, M. & CLAES, L. 1994. Effects of walking speed on plantar pressure patterns and hindfoot angular motion. *Gait & Posture,* 2**,** 191-197.

ROZEMA, A., ULBRECHT, J. S., PAMMER, S. E. & CAVANAGH, P. R. 1996. In-shoe plantar pressures during activities of daily living: implications for therapeutic footwear design. *Foot Ankle Int,* 17**,** 352-9.

RUBIN, R. J., ALTMAN, W. M. & MENDELSON, D. N. 1994. Health care expenditures for people with diabetes mellitus, 1992. *The Journal of Clinical Endocrinology & Metabolism,* 78**,** 809A-809F.

RUPEREZ, M. J., GINER, E., MONSERRAT, C. & MONTIEL, E. 2012. Simulation of the behavior of the calfskin used as shoe upper material in footwear CAD. *Computer-Aided Design,* 44**,** 1205-1216.

RUPÉREZ, M. J., MARTÍN-GUERRERO, J. D., MONSERRAT, C. & ALCAÑIZ, M. 2012. Artificial neural networks for predicting dorsal pressures on the foot surface while walking. *Expert Systems with Applications,* 39**,** 5349-5357.

SAITO, M., NAKAJIMA, K., TAKANO, C., OHTA, Y., SUGIMOTO, C., EZOE, R., SASAKI, K., HOSAKA, H., IFUKUBE, T., INO, S. & YAMASHITA, K. 2011. An in-shoe device to measure plantar pressure during daily human activity. *Medical Engineering & Physics,* 33**,** 638-645.

SAWACHA, Z., GABRIELLA, G., CRISTOFERI, G., GUIOTTO, A., AVOGARO, A. & COBELLI, C. 2009. Diabetic gait and posture abnormalities: A biomechanical investigation through three dimensional gait analysis. *Clinical Biomechanics,* 24**,** 722-728.

SAZONOV, E. S., BUMPUS, T., ZEIGLER, S., MAROCCO, S. & IEEE 2005. Classification of plantar pressure and heel acceleration patterns using neural networks. *Proceedings of the International Joint Conference on Neural Networks.* New York: Ieee.

SCHAFF, P. S. & CAVANAGH, P. R. 1990. Shoes for the insensitive foot: the effect of a "rocker bottom" shoe modification on plantar pressure distribution. *Foot & Ankle International,* 11**,** 129-40.

SCHÖLLHORN, W. I. 2004. Applications of artificial neural nets in clinical biomechanics. *Clinical Biomechanics,* 19**,** 876-898.

SEGAL, A., ROHR, E., ORENDURFF, M., SHOFER, J., O'BRIEN, M. & SANGEORZAN, B. 2004. The effect of walking speed on peak plantar pressure. *Foot & Ankle International,* 25**,** 926-933.

SICREE, R. & SHAW, J. 2007. Type 2 diabetes: An epidemic or not, and why it is happening. *Diabetes & Metabolic Syndrome: Clinical Research & Reviews,* 1**,** 75-81.

SOULIER, S. M. 1986. The use of running shoes in the prevention of plantar diabetic ulcers. *J Am Podiatr Med Assoc,* 76**,** 395-400.

STESS, R. M., JENSEN, S. R. & MIRMIRAN, R. 1997. The role of dynamic plantar pressures in diabetic foot ulcers. *Diabetes Care,* 20**,** 855-858.

STEWART, L., GIBSON, J. N. & THOMSON, C. E. 2007. In-shoe pressure distribution in "unstable" (MBT) shoes and flat-bottomed training shoes: a comparative study. *Gait Posture,* 25**,** 648-51.

TAYLOR, R. 1990. Interpretation of the Correlation Coefficient: A Basic Review. *Journal of Diagnostic Medical Sonography,* 6**,** 35-39.

UCCIOLI, L., FAGLIA, E., MONTICONE, G., FAVALES, F., DUROLA, L., ALDEGHI, A., QUARANTIELLO, A., CALIA, P. & MENZINGER, G. 1995. Manufactured shoes in the prevention of diabetic foot ulcers. *Diabetes Care,* 18**,** 1376-8.

VAN BOGART, J. J., LONG, J. T., KLEIN, J. P., WERTSCH, J. J., JANISSE, D. J. & HARRIS, G. F. 2005. Effects of the toe-only rocker on gait kinematics and kinetics in able-bodied persons. *IEEE Trans Neural Syst Rehabil Eng,* 13**,** 542-50.

VAN SCHIE, C., ULBRECHT, J. S., BECKER, M. B. & CAVANAGH, P. R. 2000. Design criteria for rigid rocker shoes. *Foot & Ankle International,* 21**,** 833-844.

VAN SCHIE, C. H., WHALLEY, A., ARMSTRONG, D. G., VILEIKYTE, L. & BOULTON, A. J. 2002. The effect of silicone injections in the diabetic foot on peak plantar pressure and plantar tissue thickness: a 2-year follow-up. *Arch Phys Med Rehabil,* 83**,** 919-23.

VEVES, A., FERNANDO, D. J. S., WALEWSKI, P. & BOULTON, A. J. M. 1991. A study of plantar pressures in a diabetic clinic population. *The Foot,* 1**,** 89-92.

VEVES, A., MURRAY, H. J., YOUNG, M. J. & BOULTON, A. J. 1992. The risk of foot ulceration in diabetic patients with high foot pressure: a prospective study. *Diabetologia,* 35**,** 660-3.

W. G. MEIJER, J. T., S. M. H. J. JAEGERS, T. P. LINKS, A. J. SMITS, J. W. GROOTHOFF, W. H. EISMA, J. 2001. Quality of life in patients with diabetic foot ulcers. *Disability and Rehabilitation,* 23**,** 336-340.

WAAIJMAN, R., ARTS, M. L., HASPELS, R., BUSCH-WESTBROEK, T. E., NOLLET, F. & BUS, S. A. 2012. Pressure-reduction and preservation in custom-made footwear of patients with diabetes and a history of plantar ulceration. *Diabet Med,* 29**,** 1542-9.

WAAIJMAN, R. & BUS, S. A. 2012. The interdependency of peak pressure and pressure-time integral in pressure studies on diabetic footwear: no need to report both parameters. *Gait Posture,* 35**,** 1-5.

WILLIAMS, A. E. & NESTER, C. J. 2006. Patient perceptions of stock footwear design features. *Prosthetics and Orthotics International,* 30**,** 61-71.

WU, G. & CAVANAGH, P. R. 1995. ISB recommendations for standardization in the reporting of kinematic data. *J Biomech,* 28**,** 1257-61.

WU, W.-L., ROSENBAUM, D. & SU, F.-C. 2004. The effects of rocker sole and SACH heel on kinematics in gait. *Medical Engineering & Physics,* 26**,** 639-646.

XU, H., AKAI, M., KAKURAI, S., YOKOTA, K. & KANEKO, H. 1999. Effect of shoe modifications on center of pressure and in-shoe plantar pressures. *American Journal of Physical Medicine & Rehabilitation,* 78**,** 516-524.

YAVUZ, M., OCAK, H., HETHERINGTON, V. J. & DAVIS, B. L. 2009. Prediction of Plantar Shear Stress Distribution by Artificial Intelligence Methods. *Journal of Biomechanical Engineering-Transactions of the Asme,* 131.

YOUNG, M. J., BOULTON, A. J. M., MACLEOD, A. F., WILLIAMS, D. R. R. & SONKSEN, P. H. 1993. A multicentre study of the prevalence of diabetic peripheral neuropathy in the United Kingdom hospital clinic population. *Diabetologia,* 36**,** 150-154.

ZEQUERA, M., STEPHAN, S. & PAUL, J. 2007. Effectiveness of moulded insoles in reducing plantar pressure in diabetic patients. *Conf Proc IEEE Eng Med Biol Soc,* 2007**,** 4671-4.