Podiatrists' and orthotists' views and experiences of using plantar pressure measurement in the assessment and treatment of diabetic foot syndrome

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Declaration

I declare that this thesis has been composed by myself and embodies the results of my own course of study and research. All sources and material have been acknowledged.

Abbreviation

PPA: Plantar Pressure Assessment

DFU: Diabetic Foot Ulcer

CAD-CAM: Computer aided design-Computer aided manufacture

IWGDF: International working Group on the Diabetic Foot

PAD: Peripheral Arterial disease

LOPS: Loss of Protective Sensation

VPT: Vibration Perception Threshold

SWF: Semmes-Weinstein monofilament

ROM: Range of motion

BAF: Before and after

RCT: Randomised controlled trial

TCI: Total contacts insert

ROI: Region of interest

CPD: Continued professional training

MSK: Musculoskeletal

Abstract

Background: The measurement of plantar pressure is recommended as a clinical tool for risk assessment, prevention and treatment of diabetic foot ulceration. To first assess comprehensively the available evidence on the use of plantar pressure assessment (PPA) to guide footwear and insole design and modification in people with diabetic foot disease, a systematic review was undertaken. Although the current evidence supports the use of PPA in diabetic foot management, the implementation of the technology in a clinical setting faces barriers such as competency, cost, time, etc. Therefore, a qualitative study was conducted to determine the barriers and facilitators of clinical usage of PPA according to podiatrists' and orthotists' views and experiences in the assessment and treatment of diabetic foot syndrome.

Method: The literature search for the systematic review utilised Medline/Pubmed, Scopus, Cochrane, Clinical Trials, and CINAHL databases.

In terms of qualitative study, 4 Podiatrists and 2 Orthotists with and without experience of using plantar pressure measurement were recruited. Six semi-structured online interviews were conducted; the audio was recorded and transcribed. Then, inductive thematic analysis was used to analyse transcribed texts.

Result: The systematic review provides support for the use of PPA to optimise footwear and insole for the prevention of ulcer recurrence, and plantar pressure reduction in the diabetic foot.

The qualitative study revealed some barriers and facilitators to improve the clinical implementation of PPA. As a result, six themes have been defined: 1. The importance of training and education in clinical implementation of PPA, 2. Providing evidence for the NHS to prove the benefits of PPA, 3. Time and space, 4. Human resources 5. Specific triage 6. Cost. Clinicians were overwhelmingly in support of plantar pressure measurement to demonstrate high areas of pressure in people with diabetes. However, lack of knowledge, time and space were considered as the main barriers in clinical implementation of PPA.

Conclusion: The advantages of the use of plantar pressure data for insole and footwear modifications in people with diabetes have been supported by the evidence. However, the barriers to implementation of PPA include lack of knowledge and education about the use and interpret of plantar pressure data, shortage of time and space in routine clinical practice, and high cost of purchase and implementation of this technology.

Training in using plantar pressure device and interpreting the data is a key factor. Besides, providing evidence for the NHS is an important thing to bring the effectiveness of PPA into consideration. The NHS can allocate specific clinics and time to facilitate the clinical use of PPA.

1.0 Chapter 1: Introduction

1.1 Introduction

10-15% of people with diabetes will suffer from foot ulceration at some point in their life [1]. PPA has been frequently considered as a tool in literature to support diagnosis, treatment, and research of diabetic foot conditions [2-9]. However, we do not fully understand the barriers and facilitators of using PPA as a clinical tool for outcome measurement, decision making and insole and footwear design.

Diabetes is recognised as a major public health problem worldwide. In the UK, the prevalence is estimated to be around 4 million people and is expected to increase further to about 5 million people in the next decade [10].

Uncontrolled diabetes may cause metabolic changes in the body and lead to the development of peripheral neuropathy and/or arterial disease [11]. Peripheral neuropathy, arterial disease or a combination of these can lead to the development of diabetic foot syndrome [11, 12].

Diabetic foot ulcers (DFU) are a serious complication which can alter an individual's life. Five to seven percent of patients with diabetes currently or previously have suffered from foot ulcers. About 50% of people with diabetes pass away within five years of acquiring a diabetic foot ulcer, and the lifetime risk of foot ulceration in people with diabetes is believed to be around 25% [12]. Diabetic foot ulcers are the reason for 80 % of amputations and have become the most common reason for non-traumatic limb amputation in the UK [13]. Diabetic foot care has a significant financial burden on health services in the UK that has been estimated to be around £580 million in 2010–2011 and between £837 million and £962 million in 2014–2015 [14, 15].

Diabetic foot ulceration risk factors include peripheral neuropathy, peripheral arterial disease (PAD), foot deformities, reduced foot and ankle range of motion (ROM), elevated plantar pressure, minor trauma, prior ulceration or amputation, and vision impairment [16]. Increased plantar foot pressure is believed to be one of the most common reasons for the development of plantar DFU, which are reinforced by two main factors, foot deformity and limited joint range of motion [16].

Clinical evidence suggests that, in patients who suffer from diabetes mellitus, abnormal amount or pattern of loading may be indicators of foot pathology. Therefore, the clinical use of PPA is developing in the clinical assessment and treatment of diabetic foot syndrome. The important roles of this technology are risk assessment, prescription, predicting insole effects, and the measurement of outcomes from practice [17-21]. PPA can

identify the individuals who may be at risk of developing an ulcer, recurrence of a healed ulcer, or further worsening of an existing ulcer due to high plantar pressure [22-24].

Although the value and benefits of PPA are appreciated by many practitioners and they agree that this technology has the potential to enhance all aspects of orthotic practice, it is absent from most clinical practice [25]. It is believed that technology has to advance and improve clinical practice without increasing the workload [25].

Professional skills for podiatrists and orthotists vary greatly across countries. As part of the professional skills and qualifications for podiatrists and orthotists in the UK, competency in the assessment of the biomechanics of the foot/lower limb is included. PPA is an important part of biomechanical assessment of the diabetic foot, because strong evidence suggests that excessive pressures might induce foot ulcers in individuals with diabetes [26].

An initial literature review was conducted (Chapter 2) to provide an overview of diabetic foot syndrome, the current knowledge about the role of PPA in diabetic foot management and the key barriers regarding the adoption of new technologies in the healthcare sector. Following these two aims and associated studies were designed to explore (1) whether and how PPA can be used as a clinical tool to guide and optimise design and modifications of footwear and insoles through a systematic review (chapter 3) and (2) the opinions of podiatrists and orthotists relating to the use of

PPA in people with diabetic foot syndrome through qualitative analysis (chapter 4).

2.0 Chapter 2: Literature review

2.1 Introduction

In this chapter, diabetic foot syndrome is defined and described in terms of epidemiology and impact on life. This is followed by a review of current knowledge about the role of PPA in diabetic foot management including risk assessment, prescription and predicting insole effects. Despite the awareness and value of PPA for the measurement of outcomes in research studies, the technology remains largely absent from the clinical settings. Therefore, key barriers regarding the adoption of new technologies in the healthcare sector are also reviewed.

2.2 Diabetes

Diabetes mellitus is considered a great public health problem across the world. In the UK, the prevalence is estimated to be around 4 million people and is expected to rise further to about 5 million people in the next decade [10].

2.3 **Diabetic foot syndrome**

Uncontrolled diabetes may cause metabolic changes in the body and lead to the development of peripheral neuropathy and/or arterial disease [11]. Peripheral neuropathy, arterial disease or a combination of these may contribute to the development of diabetic foot syndrome. Complications related to the diabetic foot include Loss of Protective Sensation (LOPS), Peripheral Arterial Disease (PAD), foot deformity, skin changes, and calluses at high-pressure areas on the foot, and foot ulcerations [27].

2.3.1

Loss of protective sensation

Peripheral neuropathy is one of the most common issues in patients with diabetes and has serious implications for lower limb/foot health. Diabetic peripheral neuropathy is a nerve disorder in diabetes caused by chronic poorly diabetes [28, 29]. Diabetic neuropathy condition typically affects the arms, hands, fingers, legs, and feet. One of the most common symptoms is loss of sensation in the feet and can be very dangerous [28-30]. Unnoticed minor wounds like burns or cuts can develop into significant limb threatening pathology if they become infected. Numbness or insensitivity to mechanical stresses or temperature is two symptoms of the loss of protective sensation in the feet. Over time, it is also linked to developing foot deformities and ulcers [31]. Blisters and ulcers may form on insensate regions of the foot due to persistent mechanical loading and even accidental actual wounds caused by incision, puncture or other

trauma that are not detected by these patients as they are unable to feel pain [31].

2.3.2

Peripheral arterial disease (PAD)

Epidemiological evidence has shown that Peripheral Arterial Disease (PAD) is a common problem in patients with diabetes the prevalence is approximately between 20 and 40 % [32]. In people with diabetes, PAD is frequently a sign of generalised atherosclerosis that usually affects distal segments and has high cardiovascular morbidity and mortality [33, 34]. PAD indicates that atherosclerosis has blocked one or more arteries either partially or fully in lower limbs [35]. Therefore, PAD can be a cause of foot ulceration and amputation of lower limbs in people with diabetes [36].

2.3.3

Foot deformities

Previous studies show that motor neuropathy in diabetes can alter the muscle functions between the extrinsic and intrinsic muscles of the foot that result in foot deformity and limited joint mobility. The prevalence of foot deformity in people with diabetes has been reported as 30–40 % [37]. Plantar pressure may increase over a small area during walking due to the foot deformities and limited joint mobility which cause foot ulceration in people with diabetes [38-40].

2.3.4

Skin changes and calluses

Certain foot deformities cause changes in weight-bearing and plantar pressure distribution which has been demonstrated to then lead to callus formation in 56% of patients. Callus is a hyperkeratotic lesion which is tough and hard with no physiological function of protection [41]. The limited joint mobility and deformities occurring at forefoot, mid-foot, and sub-talar joint have also been shown to contribute to increased plantar pressure in several studies [42, 43]. Therefore, great toe, first metatarsal head, fifth toe, and heel have been found as common areas of callus formation [44]. For example, fixed hammer/claw toes and hallux limitus have been significantly associated with skin changes and callus formation in forefoot area [38]. Also, forefoot varus deformity (arched foot) is thought to result in calluses at the outside margin of the foot, and forefoot valgus (flat foot) may result in calluses under the middle of the forefoot [45]. Additionally, in rearfoot calcaneus eversion is associated with high plantar pressure on medial metatarsal, while calcaneus inversion is associated with high plantar pressure on lateral metatarsal head [38].

People with diabetes are at risk for developing foot ulcers in calluses if they have lack of awareness of pressure and pain [46]. Due to the lack of elasticity of the callus tissue, mechanical overload of the foot causes separation of the callus from the underlying tissue which leads to skin tears or blisters, and developing an ulcer [41].

Additionally, even after the resolution of a foot ulcer, recurrence is common due to the weakness of skin. Unfortunately, in the first months

after an ulcer has healed, the skin and underlying tissue are still regaining strength and remain vulnerable for breakdown which can increase the rate of ulcer recurrence. Armstrong et al (2017) reviewed 19 studies on incidence rates for ulcer recurrence and estimated that roughly ulcers can be recurrent within 1 year after ulcer healing in 40% of patients, within 3 years in about 60%, and within 5 years in 65% of patients with diabetes (38).

2.3.5

Diabetic foot ulcerations

Between five and seven per cent of patients with diabetes have had or currently have a foot ulcer, which is a serious condition with potentially life-altering consequences [13]. The lifetime risk of having foot ulcers for a person with diabetes is believed to be around 25 %, and in the UK, 50 % of those with diabetes pass away within five years of developing a diabetic foot ulcer [12].

Diabetic foot ulcers are the reason for 80 % of amputations, and have become the most common reason for non-traumatic limb amputation [13]. Diabetes-related foot problems also have a remarkable financial burden on health services that has been estimated to be around £580 million [11].

Elevated mechanical stress is the most common aetiology of the plantar diabetic foot ulcers which increases plantar foot pressures by two main factors, deformity of foot and reduced joint mobility. The main extrinsic mechanism of tissue breakdown is mechanical stress. The mechanical stress

can be prolonged force over a small surface such as hallux abducto-valgus deformity resulting in ischemia and tissue breakdown or frequent moderate pressure leading to inflammation such as occurs when walking barefoot which can cause skin breakdown over a metatarsal head [47]. This should not be surprising since cyclic loading is the most common trigger for material failure [47]. This engineering phenomenon, called fatigue failure, indicates that most material breakdowns result from frequent, repetitive loading at a stress level below the material's strength [47]. Body tissues such as plantar foot skin are no exception and applying this phenomenon can break down the plantar skin after cyclic loading. The plantar surface experiences cyclic loading during walking that might yield to fatigue failure in the skin and the underlying tissues. In fact, investigations have suggested fatigue failure as a reason for the formation of diabetic ulcer [48].

2.4 **Diabetic foot assessment and management**

Foot assessment is an important part of diabetic foot care. In a clinical practice guideline, the American Podiatric Medical Association, the Society for Vascular Surgery, the Society for Vascular Medicine, and NICE guideline in the UK suggested that every people with diabetes needs to get a thorough annual foot examination to find risk factors for ulceration and amputations [16, 49].

The risk factors for diabetic foot ulceration which can be evaluated during a comprehensive lower limb examination include neuropathy, PAD, foot

deformity, limited ankle range of motion (ROM), high plantar pressures, minor trauma, and previous ulceration or amputation [16].

The International working Group on the Diabetic Foot (IWGDF) has been developing evidence-based guidelines on the prevention and management of diabetic foot problems since 1999. In 2019, all IWGDF Guidelines have been updated, according to systematic reviews of studies and recommendations made by interdisciplinary specialists from around the world [27]. An individual with diabetes who has at least LOPS or PAD but no active foot ulcers are referred to as an at-risk patient in the guideline (IWGDF 2019 update). In patients without risk factors, the likelihood of developing a foot ulcer is quite low at 0.36% while for patients with risk factors the risk is 29.4% [50]. Hence, prevention of foot ulcers in at-risk patients is specifically the aim of interventions [27].

Table 1 Routine, basic foot assessment for people with diabetes adapted from Bus et al (2020) [27]

Neurological assessment	**Vascular assessment**	**Dermatological assessment**	**Musculoskeletal assessment**
screening with 10g monofilament Vibration using 128Hz tuning fork	Check foot pulses Audible Doppler waveforms Ankle–brachial pressure index, if indicated	Skin status: colour, thickness, dryness, cracking/sweating Infection: check between toes for fungal infection Ulceration Calluses or blistering	Check for deformity, e.g. claw toes, prominent metatarsal heads Charcot joint Muscle wasting

Having been comprehensively assessed, the patients will be assigned a foot risk category. A comprehensive assessment includes taking history about previous ulcer/lower extremity amputation, foot pain, numbness, and claudication. Also, physical examination including neurological, vascular, dermatological and musculoskeletal assessment need to be undertaken (Table 1) [27].

Accordingly, patients with ulcer risk factors need to be referred for receiving subsequent management or need more frequent follow-up than patients without risk factors. The higher risk category, the increased risk of ulceration, hospitalisation and amputation [27, 51].

Based on the IWGDF Risk Stratification System [27] recommended as the most complete and up-to-date tool for clinicians who treat people with diabetes [52, 53], people with diabetes are classified into four risk categories as shown in Table 2 [27].

Table 2 The IWGDF Risk Stratification System and corresponding foot screening and examination frequency adapted from Bus et al (2020) [27].

Category	Ulcer Risk	Characteristics	Frequency
0	Very low	No LOPS and No PAD	Once a year
1	Low	LOPS or PAD Once	Every 6-12 months
2	Moderate	LOPS + PAD, or LOPS + foot deformity or PAD + foot deformity	Once every 3-6 months
3	High	LOPS or PAD, and one or more of the following: • history of a foot ulcer • a lower-extremity amputation (minor or major) • end-stage renal disease	Once every 1-3 months

There are various interventions to prevent or treat a diabetic foot ulcer such as identification and screening of people at high risk of diabetic foot, patient education in order to promote foot self-care, podiatry care, and appropriate footwear and insole to offload foot [54-56].

According to research, it's challenging to maintain ulcer healing. Armstrong et al (2017) reviewed 19 studies on incidence rates for ulcer recurrence and estimated that DFU can be recurrent within approximately 1 year after ulcer healing in 40% of patients, within 3 years in about 60%, and within 5 years in 65% of patients with diabetes. Five key elements of prevention include: (a) recognising the at-risk foot; (b) regular examination of the at-risk foot; (c) educating the patients, their family, and carer; (d) using appropriate footwear; and e) reducing ulcer risk factors [27].

People with diabetes categorised as moderate or high risk for foot ulceration, suffer from loss of protective sensation which leads to inaccurate neurological feedback from the foot with respect to foot pressure or shoe fit. Therefore, it is vital that the footwear fits and protects the foot correctly. Ill-fitting footwear can cause repetitive stresses from rubbing on the skin and increase the risk of ulceration [57]. This may require footwear or insoles made from a 3D impression of feet (custom-made) to decrease the pressure between the foot and surface and prevent the mechanical stress on the foot dorsum [27, 58].

Crawford et al (2020) conducted a systematic review of the published cost–utility analyses of the prevention of DFUs and reported that therapeutic

footwear with offloading modifications could be cost-effective to treat all people with diabetes mellitus regardless of their ulcer risk [59]. However, the cost-effectiveness of the treatments is likely to vary according to the patient risk, and the treatment is considered more cost-effective in the subgroup of patients at high risk [59].

Also, in the presence of a foot deformity or pre-ulcerative sign including abundant callus, blisters, thickened nails, and fungal infections [60], changing foot biomechanics and reducing plantar pressure become even more important for at-risk locations [27, 61]. Research has demonstrated that a strong multidisciplinary foot care team (MDFT) has a significant impact on the reduction of the risk of amputation, the rate of hospitalisation and subsequent rate of re-ulceration in the frequency of major amputations for patients with diabetic foot disease [13, 62].

2.5 **The role of orthotists and podiatrists in the current clinical pathway**

Professional skills vary greatly across countries because their level of training and education would be different according to their level of resource, finance, and facilities [63]. Podiatrists and orthotists qualifications in the UK include training in relation to the biomechanics of the foot. The UK curriculum is competency-based, and the specifications of biomechanics-related modules emphasize the various aspects of lower limb/foot biomechanics knowledge and skills to be learned through a range of methods such as lectures, tutorials, workshops, and seminars.

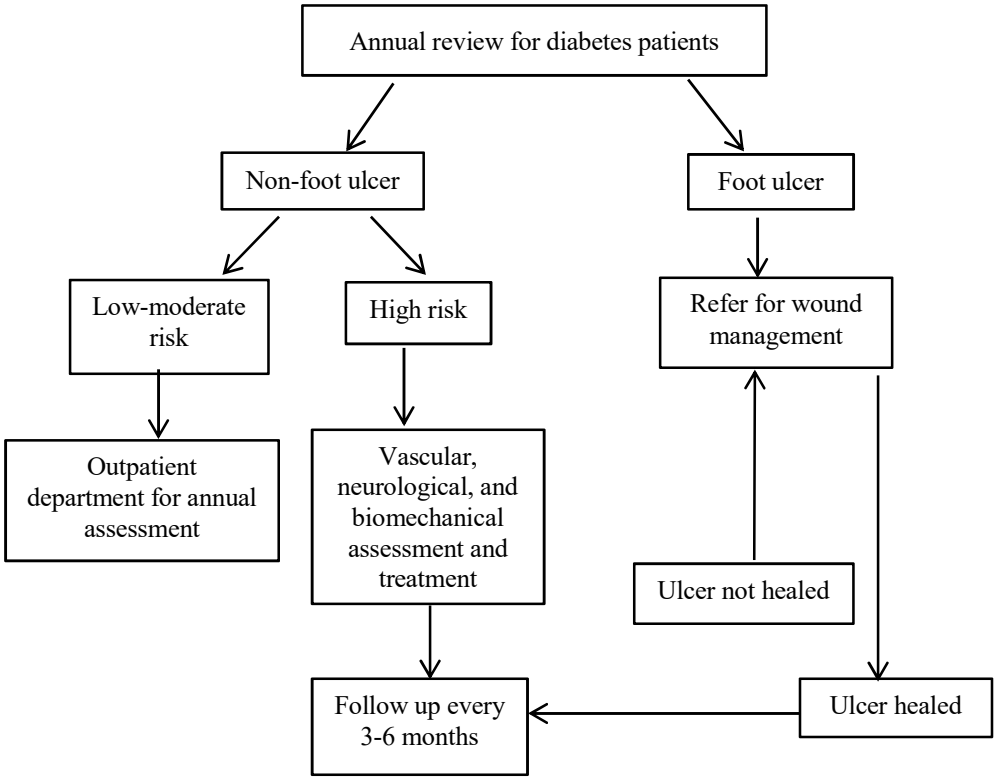
These professions in the UK typically play a role in the management of foot/lower limb biomechanics, as part of the diabetic foot management team [49, 64, 65].

A senior podiatrist, specialist in diabetic foot care, should be the first contact practitioner for any patient with diabetes and foot ulceration. Also, if they are seen by other healthcare professional such as GP or physiotherapist, after a rapid diabetic foot examination they may require to be referred to a podiatrist for further examination and treatment. The problems and risk factors are covered by a podiatrist's examination of diabetic feet [49].

Following evaluation, the multidisciplinary foot team will develop a comprehensive foot management plan with regular reassessment, involving other members of the team as needed, to promote recovery and prevent recurrence (Figure 1).

As a member of the core specialist foot care team, orthotists recommend and design orthoses including footwear and insoles for the management of diabetes, considering tissue mechanics and biomechanical principles [49, 51, 66].

Figure 1 Diabetes patient assessment and treatment flow chart, adapted from Wang et al (2016) [67]



The assessment and treatment of diabetic foot require an understanding of foot biomechanics [68]. Therefore, orthotist and podiatrist as interdisciplinary team members should have biomechanical knowledge and competency to prevent recurrences of foot ulcer while providing intervention [58].

Lázaro-Martínez et al (2014) reported that biomechanical foot assessment should include, recording foot deformities and, examining joint range of motion, determining foot posture index (FPI), foot plantar pressure

measurement, and also demographics and medical history of the patient or presence of calluses or other skin lesions [58].

2.6 **Plantar pressure measurement or Pedobarography**

Pedobarography is the measurement of plantar pressure which is the force between the plantar aspect of foot and supporting surface in weight bearing conditions. PPA has had substantial advancements over recent decades. Technology advancement in measurement has facilitated a better understanding of the generation of the pressure on foot plantar during human locomotion [69, 70]. The assessment of plantar pressures can be undertaken in either a laboratory setting for research purposes or a clinical setting, as the kit is largely mobile it can be done in most clinical settings. Although mid-gait (8 m walkway) protocol was the most common method to collect pressure platform data, due to clinic space restrictions and worries about patient safety, this technique cannot be optimal because it would necessitate far more patient steps to complete data collection and would lead to more trials being rejected due to targeting [71]. Bus et al (2005) suggested that for measuring barefoot plantar pressure in the diabetic foot, the 2-step protocol is a valid method and requires the fewest number of trials for obtaining reliable pressure data[72]. Also, when the only required outcome is peak pressure or minimal barefoot loading is needed, the 1-step protocol can be a good approach [72]. Pedobarography is widely used to characterize foot function in biomechanical assessment of diabetic foot and can provide

valuable information about the foot and ankle during functional activities such as walking and load-bearing function of the foot.

Plantar pressure systems have a number of common components including sensors mounted on a platform or inside a shoe; a computer for gathering, storing, and retrieving data for analysis; and a monitor to display data. In general, according to the sensors configuration, PPA systems are classified into platform systems and in-shoe systems. Platform and in-shoe measurement systems have their own pros and cons, and it is the clinician or researcher who should select the system based on the functional abilities of a patient or the activity that they want to study [73]. A limitation in most pressure classification systems is that these systems only measure a perpendicular force to the sensor surface and cannot measure the anterior-posterior or medial-lateral shear forces, while research data shows shear forces have a great contribution in developing new ulcers or re-ulceration.

2.6.1

Outcome variables from PPA systems

The variables from plantar pressure measurement include the maximum force, peak pressure, average pressure, impulse, and pressure-time integral. The highest amount of pressure recorded by each sensor during the stance phase is defined as peak pressure this measure is often used as a primary outcome to understand of the amount of pressure reduction when a cushioned foot orthoses is used. The average pressure value is often of interest in determining the typical pressure exerted on a particular anatomical region during the walking cycle [18].

Reports of data on the pressure-time integral (PTI) are also popular. The area under the peak pressure-time curve is the most common definition of the pressure-time integral [74]. As it is believed that both time and pressure are crucial in the development of ulcers and PTI considers both of which, the PTI is often even seen as a more pertinent metric than the peak pressure [75]. Nonetheless, the available data indicates that in patients with diabetes, peak pressure and PTI are interdependent [76]. They came to the conclusion that reporting pressure-time integral data in addition to peak pressure data in the same study provides small value [76].

2.6.2

Plantar pressures in Diabetes

Plantar pressure is a critical outcome variable in biomechanical assessment of the diabetic foot, because strong evidence suggests that pressures above threshold value which has been reported from 200 to 700kPa in different studies might induce foot ulcers and skin damage in individuals with sensory impairment [26]. This variation in threshold value in various studies is due to differences in their methodology for example different plantar pressure devices (barefoot or in-shoe) have been used or their inclusion criteria were set and some included patients with neuropathy or healed ulcer while others excluded these factors. Also, regions of interest were different across various studies [47, 68, 77-80]. PPA in a range of foot studies in people with diabetes showed that plantar pressure in these patients is increased in comparison with healthy populations [26, 69, 70, 81]. This high plantar pressure can be the result of

a combination of morphological, muscular, and sensory abnormalities [17, 19-21, 81, 82].

In clinical practice, PPA can be used as a clinical tool for the evaluation and management of foot impairments in patients with diabetes [17-21]. This can help identify those who may be more vulnerable to developing or exacerbating a plantar surface injury as a result of elevated plantar pressure [22-24].

Deformities of the foot and toe may increase the localised plantar pressure, especially at the metatarsal heads [81]. Theoretically, when plantar foot pressures are higher, soft tissue breakdown can start with less repetitive stress [47]. According to the concept of fatigue failure, when higher pressure is applied to the sole of foot, less repetitive stress is needed to fail the material or initiate soft-tissue breakdown [47]. Therefore, it should come as no surprise that elevated plantar pressure is strongly correlated with foot ulcers [47].

PPA can also provide useful information as part of the patient's management program, such as the prescription and the design of footwear and foot orthoses, exercise program, and restrictions in the amount of weight bearing activity [83]. High plantar foot pressures at locations of foot deformity are believed to be the primary cause of the majority of diabetic ulcers, sometimes in conjunction with unsuitable or ill-fitting footwear [77, 84].

Caselli et al (2002), Qiu et al (2015) reported a forward shifting of weight-bearing during walking in patients with diabetes can lead to a higher maximum force, peak pressure, impulse, and pressure time integral levels in the second to forth metatarsal heads and lower maximum pressure levels under the lateral part of the heel compared to the participants without diabetes [78, 85].

Currently, there are two types of Pedobarography applications for diabetic foot care: 1) as a clinical tool in risk assessment and management [16, 80], and 2) as a means for design and/or modification of footwear and insoles [3, 86-89].

2.6.2.1 Plantar pressure as a clinical tool in evaluation, periodic monitoring, and risk management

Although the consequences of diabetic foot ulceration can be disastrous, ulcer development could be prevented [27]. Therefore, as the most important step to decrease the rate of foot ulceration, the at-risk patients need to be identified. As a result, different screening techniques including vibration perception threshold (VPT), PPA, joint mobility, and 5.07 Semmes-Weinstein monofilament (SWF) testing have been suggested in IWGDF and are implemented clinically [27, 90-92].

Several studies have shown that Pedobarography as a clinical tool can show the presence of high plantar pressures and be used for screening patients with diabetes. Therefore, Pedobarography can play an important role in prediction of foot ulceration in patients with diabetes. Higher peak

plantar pressures can indicate an increased risk of foot ulceration [85, 93]. Therefore, PPA can potentially help clinicians to prevent ulceration by discovering areas of high pressure that could otherwise go overlooked. A practical combination of sensitivity and specificity of plantar pressure threshold was found by Pham et al in a large sample of patients for screening neuropathic ulcers [94]. It is crucial for screening tests to have a high sensitivity level because identifying at-risk people is their main goal [94]. However, the sensitivity and specificity for peak plantar pressure are approaching 59% and 69 %, respectively [94]. Therefore, it is believed that PPA is not a particularly useful tool for anticipating skin breakdown and foot ulcers by themselves [94].

It is highly likely that there are additional factors that boost predictive power in the prediction of DFU when used in conjunction with plantar foot peak pressure assessment, including the pressure time integral (The cumulative effect of pressure over time in a certain area of the foot) [95, 96]. Research has shown that patients with diabetes exhibit higher impulse and pressure time integral levels in certain forefoot regions especially in the second, third, and forth metatarsal heads and hallux than the sample of participants without diabetes [96].

Clinical examination tests including evaluation of vibration perception threshold (VPT), joint mobility, and 5.07 Semmes-Weinstein monofilament (SWF) testing as screening techniques are the most sensitive method (99%) for identifying the patient at risk for foot ulceration [94]. The sensitivity of foot pressure measurement was remarkably lower compared with the combination of clinical examination. However, in comparison to

screening tests, PPA has a significantly greater specificity, making it more appropriate as second-line test [94]. Therefore, foot pressure measures can be utilised as a post-screening test and have a significantly greater specificity [94].

Clearly, determining an optimal system threshold value below which the risk of ulceration is decreased would be a valuable tool to help practitioners to classify people with diabetes according to risk [47]. Various studies have identified different threshold values for the risk of ulceration in the diabetic foot (Table 3) Stess et al (1997), found that the possible threshold for forefoot ulceration is approximately above 400 kPa in diabetics with peripheral neuropathy [77]. Armstrong et al (1998) suggested that the optimal threshold is 700 kPa with 70.0% sensitivity and 65.1% specificity [47]. However, Caselli et al. (2002) in another study reported that a peak plantar pressure threshold higher than 6kg/cm^2 (588.6 kPa) is the pressure threshold which can develop soft tissue injury in people with diabetes with high-risk of ulceration [78].

Owing et al (2009) reported that in people with diabetes with the mean barefoot plantar peak pressure at healed ulcer site was 556 kPa which was lower than the previous studies [79]. On the other hand, Fawzy et al (2014) reported that the optimal threshold value of peak plantar pressure (PPP) for risk ulceration at forefoot is 335 kPa and rearfoot is 245 kPa in Egyptian Patients with Diabetes with or without foot ulceration [68].

Recently Abbott et al (2022) reported a site-specific relationship between high PPP measurement in barefoot participants and a history of DFU for

'high-risk' patients. They have determined a barefoot peak plantar pressure threshold value of >402 kPa, with optimal sensitivity to predict the 'high-risk' sites at the plantar aspect of the foot [80]. This study shows that PPP threshold of 402 kPa was the most reliable prediction method for DFU at any plantar site, and remarkably better than the established >588.6 kPa threshold. The highest sensitivity of the 402 kPa threshold was at the metatarsal heads and mid-foot sites (73%) and increased to 100% at mid-foot alone. They recommended this highly sensitive plantar pressure threshold value (402kPa) to identify specific plantar sites of previous DFU occurrence in daily clinical practice [80]. Their reported threshold value is the same as that proposed by Stess and colleagues for forefoot ulceration (>400 kPa) [77]. However, the threshold value reported in their study is lower than >588kPa which was previously reported for barefoot walking by Caselli et al (2002) [78]. In the study conducted by Caselli et al, PPPs were obtained for the entire foot regardless considering specific location [78].

In summary, the reported threshold values for the diabetic foot in barefoot conditions are varied across the previous studies [47, 68, 77-80, 97]. As they used different plantar pressure devices with different size of sensors and resolution the comparison of results across studies is not possible. Also, participants and the anatomical region of interest assessed were different across studies. In terms of participants, diabetic characteristics and risks were different in various studies. Some considered the presence of neuropathy and categorised patients with different level of neuropathy, some included patients with healed ulcers

and did not consider neuropathy. The lack of consensus means there could be a potential limitation of use of threshold value in clinical practice.

Due to the larger exposure of bony prominences and greater influence of foot deformities in a barefoot condition than within a cushioned in-shoe condition, barefoot PPPs may be higher than in-shoe PPP up to four times, therefore, threshold for in-shoe cannot be translated to barefoot walking [87].

Owing et al (2009) used in-shoe to determine the plantar pressure threshold at high-risk regions [79]. Accordingly, in at-risk patients, the PPP should be maintained below 200 KPa as the target in-shoe pressure threshold in footwear and insole prescription [79]. Jones et al (2021) also reported that in the design and modification of footwear, insoles, and orthoses, 200 kPa was largely used as a threshold, however, further research is required to consider this threshold as a standard [98].

Table 3 Summary of studies defining a PP threshold

Study	Author	Shod condition and type of PP device and means of capture	Threshold
The role of dynamic plantar pressures in diabetic foot ulcers	Stess RM, et al. (1997)	Barefoot on platform device EMED-SF system (Novel)	400 kPa PPP at prior ulceration site
Is there a critical level of plantar foot pressure to identify patients at risk for neuropathic foot ulceration?	Armstrong DG, et al. (1998)	Barefoot on platform device EMED-SF system (Novel)	700 kPa PPP at existing ulceration site
The Forefoot-to-Rearfoot Plantar Pressure Ratio Is Increased in Severe Diabetic Neuropathy and Can Predict Foot Ulceration	Caselli et al. (2002)	Barefoot on platform device Mat system (Tek scan)	588.6 kPa PPP at forefoot (F) and rearfoot (R) and the ratio F/R in different severity of neuropathy to predict ulceration
Plantar pressures in diabetic patients with foot ulcers which have remained healed.	Owings et al. (2009)	Barefoot on platform device EMED-SF system (Novel)	556 kPa PPP at prior ulceration site
Plantar Pressure as a Risk Assessment Tool for Diabetic Foot Ulceration in Egyptian Patients with Diabetes	Fawzy, et al. (2014)	Barefoot on platform device Mat system (Tek scan)	335 kPa PPP at current ulceration at forefoot 245 kPa PPP at current ulceration site at rearfoot
Site-Specific, Critical Threshold Barefoot Peak Plantar Pressure Associated with Diabetic Foot Ulcer History: A Novel Approach to Determine diabetic foot ulcer Risk in the Clinical Setting.	Abbott CA, et al (2022)	Barefoot on a validated carbon footprint system, Pressure Stat™ formerly known as Podotrack	402 kPa PPP at current ulceration site at rearfoot
Plantar pressures in diabetic patients with foot ulcers which have remained healed.	Owings et al. (2009)	Within therapeutic footwear with in-shoe device Both Pedar and Pliance	207 kPa PPP at prior ulceration site

2.7 **Clinical implementation of technology**

The healthcare sector is technologically innovative, and the emergence of new technologies is expanding. Large investments have been made in research and development to fund the development of innovative medical technologies, and these are being used in innovative ways to improve the medical experience of patients [88].

PPA is a developing technology in the clinical assessment and treatment of the diabetic foot. The important functions of this technology are risk assessment, prescription and predicting insole effects, and the measurement of outcomes from practice. Although the value and benefits of PPA are appreciated by many practitioners and it is agreed that technology has the ability to improve every aspect of orthotic practice, it is absent from most clinical practice [99]. It is believed that technology has to advance and improve clinical practice [99].

Previous research found five key barriers including competency, cost, time, fear of change, and complexity regarding the adoption of technology in healthcare such as electrical medical record, rehabilitation technology and biomechanical assessment [89, 99-103].

Competency: Healthcare professionals need enough competencies to provide technology-based services in clinical practice and avoid technology misuse and minimize errors. In fact, clinic staff knowledge is one of the key factors in determining whether they have proficiency with technology and digital skills to use systems effectively, communicate professionally, and

record medical information accurately. Inadequate medical staff competence can compromise patient safety and increase the frequency of errors [104]. Efficacy and appropriate use of technology requires regular evaluation and training of practitioners [105-107].

In addition, lack of competency can cause negative experiences with the use of technology, which may cause frustration and influences perspectives on implementing other technologies [108, 109]. Buntin et al. (2011) also found a link between the experience of dissatisfaction and the negative consequences of technical implementation [110]. Santos et al. (2016) also reported that in a focus group of podiatrists and orthotists, practitioners have attempted to implement technology in their clinical practice, however, due to their negative experiences they are not using the devices (plantar pressure measurement device or 3D scanner) anymore [99].

Cost: The second most common obstacle identified is cost. Both start-up and maintenance costs for new technologies can be exorbitant and high expenses limit new technology implementation within the healthcare pathway [111]. The existing practice has a cost because it includes time for clinical assessment and cost-benefit savings from new technologies in patient care need to be justified to support investment in a new technology [86]. For example, diabetic foot screening can be delivered with minimal cost such as monofilament for sensory assessment or palpable pulse for artery assessment versus increased cost such as neurothesiometer or Ultrasonic Doppler Scan (£5000) with acceptance that more sensitivity requires higher cost. Other example is PPA which can

be done without cost via skin observation to see if there is a callus or with a plantar pressure measurement device (Pedar-X £12000). However, it should be considered that more than half of the diabetic foot cost (£307m) is spent on care for ulceration in 2010-2011 which may justify the use of technology to increase the accuracy of assessment to prevent foot ulceration and further cost.

It is also believed that these sorts of technologies should be reasonably priced to justify the cost-benefits and be able to afford by the typical clinics. However, it is important to consider that costs are spread across multiple patients and assessments, especially, in the case of private clinics which have as many patients as to compensate the cost of purchasing the technology which may justify the use of technology on the basis of a marketable benefit to attract increased patient numbers and compensate the cost of purchase.

Time: Time is another important barrier from the healthcare provider's point of view. In general, time barriers focus on acquiring, training, and implementing new technologies. Healthcare professionals, especially those with direct patient care, believe that they usually do not have enough time to learn about new technologies [89, 112]. In clinical practice, there is a time restriction for each patient, thus technology should aim to expedite the diagnosis and prescription procedures by providing both the practitioner and the patient with clear, understandable data. Before healthcare providers embrace the new technology, they need to be confident that the new technology is easy to use and set up, with reliable data collection and will seamlessly fit into the current workflow, rather

than increasing the amount of work and time spent treating the patient [89, 99, 107].

Research has shown that, although clinicians appreciate the value of technology and believe that it can improve clinical practice, plantar pressure measurement is reported as complex and time-consuming which is why it is not widely used in clinical practice. They indicated that they need to be convinced regarding the real added value from plantar pressure measurement to their practice in order to invest in new technology [99].

Santos et al. (2016) suggested that time limitation is one of the main issues that practitioners are faced with. Plantar pressure measurement devices are too time-consuming to set up and use and also the provided results are too complex to interpret within the consultation time [99].

Complexity: Technology needs to be user-friendly to optimise its effectiveness and sustainability. Most clinicians believe the device and output should be easy to set up and interpret [111].

Additionally, Guldemond et al. (2006) et al. came to the concluded that there are not enough user-friendly clinical devices such as plantar pressure measurement systems that consider the improvement of patients' outcomes [113]. Also clinicians in Santos et al study believed that the current available technology does not improve their practice and “they have cabinets stuffed with unused devices” [99].

2.8 **Conclusion to literature review**

The initial review of the literature revealed that high plantar pressure might induce foot ulcers and skin damage in patients with diabetes. Therefore, PPA can potentially be used as a clinical tool for risk monitoring or prediction of foot ulcerations and subsequent management of the diabetic foot. Patients with diabetes who may be more vulnerable to developing or exacerbating a plantar surface injury as a result of elevated plantar pressure can be identified by discovering areas of high pressure that could otherwise go overlooked. PPA can also provide useful information in modification and design of footwear and insole to optimise offloading in these patients.

The threshold value of PPP above which the risk of foot ulceration is increased would be a valuable tool to help practitioners to classify people with diabetes according to risk. The threshold value depends on the measurement systems and has been reported different in various studies ranging from 207 kPa to 700 kPa [47, 68, 77-80].

The literature review provided an initial and general understanding of the clinical use of PPA. A detailed and systematic review would be valuable to focus on the effect of PPA as a clinical tool to guide design and modification of footwear and insole in diabetic foot management.

Although the current evidence has shown that PPA has positive effects on clinical management of diabetic foot, current orthotic practice does not

incorporate the technology, and the clinical process for identifying elevated plantar pressure by professionals appears to be inadequate.

Generally, the adoption of technology in healthcare currently faces some key barriers including competency, cost, time, fear to change, and complexity. It would be valuable to explore the barriers to the clinical implementation of plantar pressure measurements are and how to improve the implementation of this technology in practice. The perception of relevant clinicians, podiatrists and orthotists, would be relevant to capture in order to conduct this exploration.

3.0 Chapter 3: Systematic review

PPA as a clinical tool for to guide design and modification of footwear and insole: a systematic literature review

3.1 Introduction

Footwear and insole interventions have a long clinical history to relieve pressure at ulcer sites or areas at risk for developing DFU [82]. Although there are numerous studies employing plantar pressure measurement to assess the effectiveness of the intervention applied [114-116], clinical observation shows that the suggested offloading interventions are frequently based on clinician opinion and prior experience rather than evidence-based techniques in which PPA is used to guide offloading features of footwear and insoles [3].

To gain further understanding of the current evidence base pertaining to the effectiveness of footwear and insole interventions guided by plantar pressure data in patients with diabetes, the researcher conducted a detailed review of the literature. The main goal of this review was to systematically evaluate the evidence on the use of PPA to guide design and modifications of footwear and insoles for plantar pressure reduction,

ulcer prevention and ulcer healing in the diabetic foot. The results of this systematic review will enable us to understand whether and how PPA as a clinical tool can be used to guide and optimise design and modifications of footwear and insoles, and its effect on plantar pressure reduction, ulcer prevention and ulcer healing in the diabetic foot. This information will contribute to improvement in clinical management of foot and ankle in people with diabetes. This might include providing evidence to establish guidelines for implementation of PPA in clinical settings, innovative design of footwear and insoles, and also incorrect or ineffective interventions may be prevented.

Aim:

Our aim was to systematically review the literature to understand whether and how PPA as a clinical tool can be used to guide and optimise design and modifications of footwear and insoles, and its effect on plantar pressure reduction, ulcer prevention and ulcer healing in the diabetic foot.

3.2 **Methods**

This review follows the PRISMA guidelines [117].

Search strategy: A search was conducted for papers published prior to March 2022 on the effectiveness of footwear and insoles with modifications guided by PPA in foot ulceration healing, prevention, or plantar foot pressure reduction in people with diabetes. Search strategies, shown in table 4, were defined using the following databases:

PubMed, CINAHL, Medline, Scopus, Cochrane, and ClinicalTrials.gov. Additionally, a hand search of the included papers was done.

Study selection: Patients with diabetes were the target population for this systematic review. Main outcomes were key priorities and themes relevant to clinical outcomes in this patient group: ulcer healing, ulcer prevention (first or recurrent foot ulcer), Peak Plantar Pressure, and Pressure Time Integral (PTI).

The interventions considered were design or modification of footwear or insole interventions guided by plantar pressure measurement and analysis. These consisted of incorporating plantar pressure data from static or dynamic assessments or from in-shoe or barefoot measurements into design of characteristics of the insole or footwear. This included: the local removal or softening of material in the insole; post-plug removal (square or cylindrical), replacement of top cover of the insole; the addition of an arch support, metatarsal pad, hallux pad, or metatarsal bar on the insole; customised bar location and shape or the modification of the shoe's insole or outsole's rocker or roller, which represent common clinical interventions in adults with diabetes.

The design of the included studies was randomised controlled trials (RCTs), crossover studies, control before-and-after (CBA) studies, cross-sectional studies, and case studies published in the English language. The references in each article were hand-screened to find studies that might be pertinent, however this approach yielded no papers that satisfied the review's inclusion criteria.

Table 4 Search strategy (PICO) for literature search of key databases

#1	Diabetes	OR	"Diabetic foot"				
#2	Pressure	OR	Pedobarograph				
#3	Footwear	OR	insole	OR	Orthotic	OR	shoe
	#1	**AND**	**#2**	**AND**	**#3**		

Data Extraction and Collection Process: Following a primary search of the databases and compiling a list of identified papers, the title and abstract of papers were screened by two reviewers (ART and DP) to determine possible eligibility. In case of two papers, there were disagreements on eligibility, we discussed with a third reviewer (CP) to reach a consensus and finally included the papers which met inclusion criteria. Then the reviewers assessed full-text papers of identified articles for eligibility according to patient group, outcome, and intervention. As with initial screening the final papers were discussed between the co-reviewers of study, the 3rd reviewer acted to resolve any conflicts between reviewers.

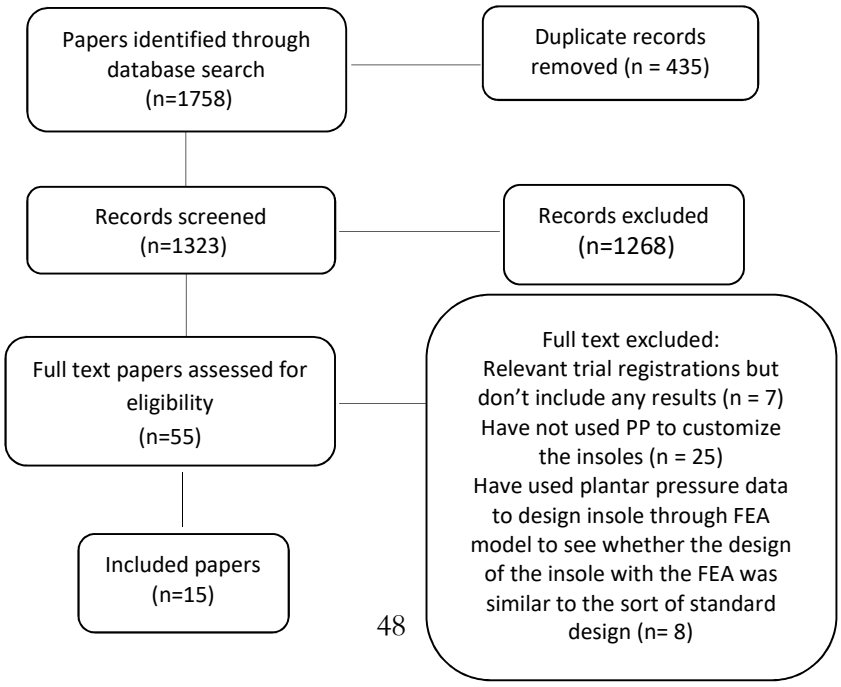
Methodological Quality Evaluation: Each included article was assessed for methodological quality using the PEDro scale for Randomised Clinical Trials (RCT) and the Joanna Briggs Institute (JBI) critical appraisal tool for Non-controlled Trial Studies. PEDro scores of 6 to 10 were regarded excellent quality, 4 to 5 were considered moderate quality, and 0 to 3 were rated low quality for literature [118]. Literatures with JBI scores of 7 to 8 were considered high quality, of 4 to 6 were considered moderate quality, and of 0 to 3 were considered low quality [119].

3.3 Results

A total of 1758 articles were identified in the database search and after review of the title and abstract 55 of these articles were potentially considered eligible. At secondary assessment, 15 studies had eligibility as final papers (Figure 2: PRISMA flowchart). 40 papers did not meet the inclusion criteria of the systematic review. 7 studies were relevant trial registrations but didn't include any results, 25 studies did not use PP to customize the insoles, 8 studies used plantar pressure data to design insole through FEA model to see whether the design of the insole with the FEA was similar to the sort of standard design. They did not have an actual biomechanical assessment and did not go to test the insole.

Figure 2 PRISMA flowchart illustrating the process of study selection

[117]



Evidence was found to support the use of PPA to guide footwear and insoles design and pressure relief modifications for ulcer prevention, and plantar pressure reduction in people with diabetic foot.

The characteristics of the included studies were summarised in tabular format (Table 5) and described on a study-by-study narrative basis. Finally, based on the quality of available evidence evaluations were made according to three primary outcomes including “ulcer healing”, “ulcer prevention” and reduction of plantar pressure.

Table 5 Study characteristics of included studies within the systematic review

Reference	Setting	Type of study	population	Intervention	Comparison	Duration	Region of interest	Outcome	Findings	Quality Score
DJ Parker et al[2]	Hospital	RCT	57 participants with diabetes were randomly allocated to each supply chain traditional (handmade)versus digital (CAD/CAM) - Moderate to high risk of ulceration	Digital supply chain foot (3D scan and plantar pressure distribution data)	Traditional supply chain (a foam impression box)	6 months	all regions which had a mean peak pressure>200 kpa in the control insole were designated as regions of interest (ROI)	- The percentage reduction in peak plantar pressure at the site of highest forefoot plantar pressure - the number of regions of interest (ROI) where plantar pressure was > 200 kPa - the percentage peak pressure reduction for all ROI	The digital supply chain was determined to be more efficient, but after six months of use, there was no statistically significant difference between the supply chains.	8
Owing et al[3]	Research laboratory	A randomised crossover design	20 participants with diabetes and peripheral neuropathy - Low risk of ulceration	Foam box impressions of the participants' feet, and Plantar pressure data	Foam box impressions of the participants' feet	Immediate effect	First MTH, second MTH, lateral MTH (MTH3–5), and mid-foot.	Peak pressure and force-time integral	The combination of foot shape and Bare foot plantar pressure data provides improved offloading of high-pressure zones under the forefoot compared to insoles based just	4

									on shape.	
M D Amico et al[4]	Research laboratory	Cross-sectional	30 neuropathic diabetic patients - Low to high risk of ulceration	CAD-CAM insoles	Flat insole (FI); Traditional shape based total contact customised insoles	Immediate effect	Any single cell of the obtained mean peak pressure greater-equal than 200 kPa	peak pressure	Compared to the conventional shape-only technique, the CAD-CAM strategy achieves superior offloading performance.	8
MLJ Arts et al[5]	Hospital	Repeated Measure	85 people with diabetic neuropathy and a recently healed plantar foot ulcer - High risk of ulceration	Custom-made footwear modifications when peak pressure was ≥ 200 kPa.	Pre-modification levels	At three-monthly intervals for 15 months or until a foot ulcer developed	Any location distal to the heel showed a mean peak pressure ≥ 200 kPa.	peak pressure	By modifying the footwear under the guidance of in-shoe plantar pressure measurements, offloading in custom-made footwear can be significantly improved in diabetics with recently healed plantar foot ulcers.	4
SA Bus et al[6]	Hospital	Randomised controlled trial	171 neuropathic diabetic patients with a recently healed plantar foot ulcer - High risk of ulceration	Custom-made footwear with improved and subsequently preserved offloading based on in-shoe plantar pressure measurement and analysis	Usual care (i.e., nonimproved custom-made footwear)	18 months or until plantar foot ulceration	- The previous ulcer location with peak pressure >200 kPa - The two forefoot or mid-foot locations that showed the highest peak pressures >200 kpa	The percentage of patients with a plantar foot ulcer in 18 months.	Unless they are worn as advised, specially made shoes with improved offloading based on in-shoe PPA do not significantly lower the incidence of plantar foot ulcer recurrence in diabetes compared to specially-designed shoes that do not undergo	10

									such improvement. These results imply that both offloading, and adherence affect the effectiveness of footwear.	
M Zequera et al [7]	Rehabilitation clinic	A crossover design	10 patients at the early stage of neuropathy with no history of foot ulceration. - Low risk of ulceration	customised insoles designed for each patient using clinical data, and in-shoe plantar pressure measurements fabricated by 1) by a CAD/CAM system 2) a traditional method	1) flat insole (Plastazote). 2) a commercially prefabricated insole	Once a week for five months	10 different foot regions	Peak pressure	According to the findings of this study, the computer model used to create the insoles using PPA as a design guide was the most effective insole for reducing plantar pressure.	3
JBJ Zwaferink et al[120]	Rehabilitation clinic	Randomised crossover	24 neuropathic diabetic patients at high risk of foot ulceration - Moderate to high risk of ulceration	Four data-driven custom-made footwear conditions	An athletic shoe	Immediate effect	- Any forefoot location with a mean peak pressure ≥ 200 kPa. - Metatarsal heads with peak pressure at regions with a dynamic barefoot peak pressure >450	Mean Peak pressure	Proved the offloading effectiveness of a data-driven, personalised footwear design technique based on in-shoe plantar to prevent plantar foot ulcers.	6
RL Actis [121]	Research laboratory	Case study	A male volunteer with a history of diabetes	Typical full contact insert was modified based on the	Standard TCI and single plug design	Immediate effect	35 mm proximal and 30 mm distal from the center of the metatarsal	Peak pressure	the modification of total contact inserts (TCIs) with a specific number of	1

			and peripheral neuropathy - Low risk of ulceration	results of finite element analyses, by inserting 4 mm diameter cylindrical plugs of softer material in the regions of high pressure			head of the 2nd ray of the diabetic participant		4 mm diameter cylindrical plugs of softer material implanted in the areas of high plantar pressure in the forefoot area to further reduce its loading through the use of in-shoe pressure assessment.	
SA Bus et al[122]	Diabetic foot clinic	Cross-sectional	20 neuropathic diabetic participants with foot deformity - Moderate to high risk of ulceration	Each custom-made insole was specifically fabricated for this project by a CAD-CAM process in which the barefoot plantar pressure data, footprints and tracings of the participant's feet	Flat insole	Immediate effect	MTH1 was chosen as the Region of Interest because it was the most common region for prior ulcers	peak pressure (PP) and force–time integral (FTI)	Although there was a lot of individual variation, custom-made insoles were more effective than flat insoles in off-loading the first metatarsal head region.	6
TL Lin et al[123]	Hospital	before-and-after study	26 patients with diabetic neuropathic feet - Low to high risk of ulceration	After determination of the ROIs with in-shoe plantar pressure, the plugs corresponding to the ROIs were then	Pre-plug removal	Immediate effect	The forefoot region with the highest mean peak pressure (MPP) value of each foot was considered to be the region of interest (ROI).	Mean peak pressure (MPP), maximum force, and contact area beneath the ROI area	Following removal of the insole plugs, a substantial decrease in MPP was seen among the 26 ROIs (32.3%, P<0.001). The pre- and post-plug removal conditions did not significantly	5

				removed for the post-plug removal and post-plug removal plus arch support conditions.					differ in MPP at non-ROIs.	
SA Bus[8]	Research laboratory	BAF	23 neuropathic diabetic foot patients - Moderate to high risk of ulceration	The prescribed therapeutic footwear consisted of fully customised footwear (n = 22) or custom molded insoles in an extra depth shoe (n = 1).	Non-modified footwear	Immediate effect	- The locations of previous ulceration, severe foot deformity, or pre-ulcerative signs, all in which the measured peak pressure was >200 kPa. -Other regions showing peak pressures >300 kPa were also targeted. A maximum of three ROIs per foot were selected	In-shoe peak pressures and force-time integrals	According to these results, in-shoe plantar pressure analysis is a useful tool for evaluating and guiding footwear changes that significantly reduce pressure on the neuropathic diabetic foot.	4
R Waaijman et al[124]	Hospital	Non-randomised Controlled Trial	117 patients with diabetes, neuropathy, and a healed plantar foot ulcer - High risk of ulceration	Pressures were measured and, if needed, footwear was modified	No footwear modifications based on pressure analysis.	At three-monthly intervals for 12 months	- The previous ulcer location and if present - Per foot, the two highest peak pressure locations in the midfoot and	Peak pressure	This study demonstrates that after changing bespoke footwear based on in-shoe pressure analysis, plantar pressures at high-pressure zones can be significantly	4

							forefoot with peak pressure > 200 kPa.		lowered.	
JS Ulbrecht et al[125]	Podiatry clinic	RCT	130 men and women with diabetes, peripheral neuropathy, and at least one recently healed sub metatarsal head plantar ulcers - High risk of ulceration	Shape- and pressure-based insoles	Standard-of care insole manufactured on the basis of shape and clinical information alone	15 months, until or a study end point (forefoot plantar ulcer or non-ulcerative plantar forefoot lesion)	Forefoot with peak barefoot plantar pressure in the area of previous ulcer >450 k	Peak barefoot plantar pressures	According to the current study's findings, Shape- and pressure-based insoles are preferable to those made just using foot shape and clinical knowledge.	8
S Telfer et al[126]	Research laboratory	A randomised crossover design	20 participants with Type 2 diabetes and peripheral neuropathy and at-risk feet - Low risk of ulceration	Based on a design derived from shape, the in-shoe pressure, and ultrasound data which underwent a finite element analysis-based virtual optimisation procedure	based on shape data and subsequently manufactured via direct milling	Immediate effect	Forefoot regions (1st MTH, 2nd MTH and 3-5th MTHs) where the localised peak barefoot plantar pressure, > 450 kPa	Peak pressure	The performance of offloading was enhanced compared to conventional, shape-based devices as a result of the incorporation of virtual optimisation into the insole design process.	6

A Martinez-Santos et al[9]	Research laboratory	Randomised crossover design	60 people with diabetes and neuropathy - Low risk of ulceration	Metatarsal bar location and shape customised according to in-shoe plantar pressure data.	Flat insole	Immediate effect	The 1st MTP joint, 2-4th metatarsal heads (MTH), the hallux, and 5th metatarsal head	Peak plantar pressures	The pressure was most frequently reduced when the anterior edge of the metatarsal bar was positioned at 77% of the peak pressure values. Individual patient feet and design choices made for orthotic insoles affect plantar pressure reduction.	5

3.3.1

Characteristics of included studies

15 studies (3 RCT, 3 crossover designs, 3 cross-sectional designs, 4 before and after (BAF) design, 1 non-RCT, 1 case study) met the inclusion criteria and were selected for methodological assessment and analysis following full text review as reported in Table 5. After assessment for methodological quality, four studies had high quality, nine studies were considered as moderate quality, and two studies had low quality. A factor that affected the quality of majority of the studies was that they did not control. The nine moderate quality and two low quality studies were non-controlled trials and did not control the intervention. While three out of four high quality studies were RCTs. The other factor affecting the quality of studies was identifying confounding factors or the strategies to deal with them. One out of the four high quality studies scored highly despite being non-controlled trial; because it considered confounding factors and the strategies to deal with them.

Detailed results and study ratings of the 15 studies are shown in Table 5. These studies were undertaken in hospitals (n = 5), rehabilitation clinics (n = 2), Diabetic foot clinics (n = 1) or podiatry clinics (n = 1) and university laboratories (n = 6). Applying the IWGDF risk stratification system (Table 2), 5 studies recruited low risk participants, 4 studies recruited moderate to high-risk participants, and 2 studies recruited low to high-risk participants whilst 4 studies only recruited high risk participants with diabetic foot disease. Follow-up time periods ranged

from no follow-up to 18 months. Sample size of the studies ranging from 1 to 171 (in total: 794) and there was no recruitment bias.

3.3.2

Ulcer healing

No studies on the effectiveness of footwear and insoles modifications guided by PPA in ulcer healing in the diabetic foot were found.

3.3.3

Ulcer prevention

No eligible studies were found for primary prevention of diabetic foot ulcer. Two RCTs with very low risk of bias have assessed the effects of footwear and insoles modifications guided by PPA on ulcer recurrence in the diabetic foot (i.e., secondary prevention) [125].

In the first high-quality RCT [6], 171 patients who had history of plantar foot ulceration in the 18 months preceding randomisation, were randomly assigned to either custom-made footwear with optimised offloading features guided by in-shoe PPA or to the same custom-made footwear without such optimisation. Plantar pressure distribution was measured using a Pedar-X in-shoe pressure measurement system (Novel GmbH) at a sampling rate of 50 Hz while comfortable walking. For each

foot, the two forefoot or midfoot areas that showed the highest peak pressures (greater than 200 kPa) and the preceding ulcer location with peak pressure higher than 200 kPa were identified and targeted for pressure reduction. The shoe technician made modifications to the shoes until the peak pressure at these regions of interest was lowered by 25% or to an absolute level of 200 kPa. The shoe technician had complete discretion over the footwear modifications, and up to three changes might be made in a single round. After 18 months of follow-up, in comparison to the standard treatment group, the improved footwear group had considerably less complicated foot ulcers (i.e., Texas depth 3 or grade C and D ulcers). There was no significant difference between the groups in terms of the recurrence of plantar foot ulcers: 38.8% vs. 44.2% ($p = 0.48$). Nevertheless, 79 patients in the group using pressure-improving footwear who used their footwear for at least 80% of their recorded activity demonstrated a significantly reduced incidence of recurrence of ulceration compared with the control group: 25.7% vs. 47.8% ($p = 0.045$). These findings suggest that footwear performance depends on both effective offloading and adherence [6].

In the second high quality RCT [125], 130 patients with the history of metatarsal head ulceration (>1 week but <4 months) were randomly assigned to either foot shape and barefoot pressure-based custom-made insoles or foot shape-based custom-made insoles, worn in double extra-depth and extra-depth. Foot shape was captured using foam boxes. A Novel Emed D platform at a sampling frequency of 50 Hz (Novel GmbH, Munich, Germany) was used to detect the peak barefoot plantar pressure using the average of five trials and a first walking step protocol

[3]. Based on defined algorithms and the peak barefoot plantar pressure distribution contours, experimental insoles were modified using computer-aided design. The metatarsal bars and reliefs on each experimental insole were patient-specific. Over the course follow-up period, the composite outcome of pre-ulcer lesions and recurrent foot ulcers showed a trend in favor of insoles guided by both foot shape and pressure data (P = 0.13). The use of these insoles resulted in significantly fewer recurrent plantar ulcers than insoles designed only based on foot shape data (9.1% vs 25.0%, p = 0.007) after 15 months of follow-up. The results of this study show that customised insoles made based on the shape of foot and plantar pressure data have much better outcomes in reducing ulcer recurrence, than insoles made based on foot shape and clinical opinion alone [125].

3.3.4

Plantar pressure reduction

For the purpose of plantar pressure reduction, three types of pressure-based custom-made footwear and insoles have been developed and studied, differentiated by the source of the plantar pressure data. These three sources are; in-shoe, barefoot or both. Irrespective of the plantar pressure data being used, they all use PPA to identify high-pressure locations for customisation of footwear and insoles. A total of 13 studies that report on plantar pressure reduction for various footwear and

insoles modifications guided by PPA interventions were included in this review.

3.3.4.1 In-shoe plantar pressure data-driven footwear and insole design and modifications:

One type of pressure relief optimisation uses in-shoe plantar pressure measurements to guide design and modifications of footwear and insoles. Eight studies [4, 5, 7, 8, 121, 123, 124, 126] used in-shoe PPA to modify footwear and insoles (also known as footwear customisation or optimisation). All the studies measured peak plantar pressure (PPP) as the primary outcome. Six studies were of moderate quality and two studies had low quality.

In a randomised crossover study [126], the pressure offloading performance of the insoles was optimised through numerical simulation techniques, which were designed based on the shape of foot, in-shoe pressure and ultrasound data, which underwent a virtual optimisation procedure based on finite element analysis. Foam boxes were used to capture feet shapes. Using the Pedar-X system (Novel GmbH, Munich, Germany), in-shoe plantar pressures were measured while level walking at the comfortable walking speed (within +/-10%). A minimum of 12 steps per foot were recorded at 50 Hz. To modify insoles based on plantar pressure data, insole design underwent a standardised modification procedure in which a metatarsal bar was raised, and

material was removed from the region under each metatarsal head until predicted regional peak plantar pressures were under 200 kPa. Direct milling was used to make one pair, while 3D printing was used to make a second pair. Then optimised insoles were compared against a control foot shape-based only insoles produced by direct milling in a sample of 18 participants with Type 2 diabetes and peripheral neuropathy and at-risk feet. In comparison to foot shape-based devices, the use of milled and 3D printed virtually tailored insoles reduced the peak plantar pressure in 88% and 74% of the forefoot regions of interest. In comparison to shape-based only insoles, the virtually optimised insoles significantly decreased peak pressures by the average of 41.3 kPa (95% CI [31.1, 51.5]) for milled devices and 40.5 kPa (95% CI [26.4, 54.5]) for printed devices [126].

In one study of 85 people [5] with diabetic neuropathy whose plantar foot ulceration recently healed, participants' footwear was modified on any location distal to the heel with a mean peak pressure ≥ 200 kPa. Using the Pedar-X system, in-shoe plantar pressures were measured while walking at a sample frequency of 50 Hz (Novel GmbH, Munich, Germany). When any site distal to the heel displayed a mean peak pressure more than 200 kPa, participants had their footwear modified. The kind and number of modifications made to the footwear were at the discretion of the shoe technicians. Orthopaedic shoe technicians frequently use modifications that are both accommodating (such as local cushioning, insole material removal, and insole top cover replacement) and corrective (such as metatarsal pads, bars, and rocker outsoles). This protocol was repeated a maximum of three times during a single session

until the in-shoe peak pressure at each target region was less than 200 kPa or decreased by more than 25% from the initial measurement at study entry. It was always targeted for pressure reduction if this was the site of the prior ulcer. They reported that peak pressure at the target locations in all footwear modifications significantly decreased compared with pre-modification levels (range –6.7% to –24.0%, $P < 0.001$) [5].

In a before and after study [123] of 26 patients who had diabetic neuropathic feet, a region of interest (ROI) was considered as the highest mean peak pressure (MPP) value of each foot measured through in-shoe plantar pressure measurement protocol in forefoot region while walking at a self-selected speed using Pedar®-X at a sample frequency of 50 Hz. A minimum of 30 steps were recorded from eight walking trials for each patient. The removal of 1 cm X 1 cm2 plugs from beneath regions of interest (ROI) resulted in reductions of PPP at ROI in the forefoot by 72 kPa, from 221.4 (50.3) kPa to 149.9 (34.8) kPa [123].

In one clinical trial [124], the use of in-shoe PPA to guide modification of the offloading of the prescribed custom-made footwear was investigated in 32 patients with diabetes, neuropathy and with a recently healed plantar ulcer. In-shoe plantar pressures were recorded while walking at a comfortable speed, a minimum of 20 mid-gait steps for each foot, using the Pedar-X system (Novel, Munich, Germany) with a sample frequency of 50 Hz. Regions of interest were chosen based on the average peak pressure images captured across numerous steps. They included the site

of the prior ulcer and, if present, the forefoot and midfoot two highest peak pressure regions, both of which had peaks more than 200 kPa. In order to lower peak pressure at the regions of interest, the shoe specialist subsequently modified the footwear. The shoe technician and/or rehabilitation specialist made the decision regarding any modifications to the insoles or shoes. It was possible to make multiple changes at once. There were established standards for successful offloading improvement. They were either a reduction to an absolute level below 200 kPa or a peak pressure reduction at the region of interest of 25% compared to baseline levels. Pressure modified footwear led to significant of peak pressure reduction at the previous ulcer location (23%) and the highest (21%) and second highest (15%) pressure locations. This was recorded in 32 patients with diabetes, neuropathy and with a recently healed plantar ulcer. These decreased pressures were sustained at or further decreased over the course of a year and were significantly lower, by 24-28%, than pressures in the control group (32 patients who had no footwear modifications based on pressure analysis) [124].

A study suggested a new quantitative-statistical framework (QSF) for the evaluation and optimisation of the offloading insoles guided by in-shoe pressure measurement [4]. The PEDAR-X system (Novel GmbH, Munich, Germany) was used to measure the in-shoe dynamic plantar pressure while sampling at 50 Hz. In a controlled laboratory environment, participants walked in repeated trials along a 15-m corridor at their comfortable walking speeds. The CAD-CAM foot orthoses were created

by a foot orthotist using the subject's foot scan and mean peak pressure maps (MPPM). In the area of the insole beneath regions of excessive local pressure of 200 kPa, an automatic design algorithm defined the high-pressure contours along which the 3D scan shape is modified, providing a proportional pressure deepening. The primary offloading technique used for the CAD-CAM insoles was the removal of material under the regions of excessive local pressure (>200 kPa). In their suggested strategy, each 5mm x 5mm grid element that had a statistically significant peak pressure greater than 200 kPa was regarded to be a component of a risk-region of interest (R-ROI). The QSF method was applied to compare the offloading efficiency of a novel shape and pressure-based insole (CAD-CAM) with traditional shape-based total contact customised insoles (TCCI). The primary offloading technique used for the CAD-CAM insoles was the removal of material under the regions of excessive local pressure (>200 kPa). In comparison with flat insoles (20.6±12.9 cm2), both the TCCI (7±8.7 cm2) and the CAD-CAM (5.5 ±7.3 cm2) approaches reduced R-ROIs mean areas ($p<0.0001$). The CAD-CAM approach performed better than the TCCI in terms of a mean pressure reduction of 37.3 kPa (15.6%) compared to flat insole. In terms of significantly reducing the sizes of R-ROIs, the CAD-CAM technique performed better than the TCCI. The R-ROIs should be completely removed when they are present in order to get the best offloading insole results, according to their suggestion, and QSF can help lead these improvements. According to their research, the shape and pressure-based CAD-CAM strategy performs better offloading than the conventional foot shape-only strategy [4].

In an experiment with a crossover design [7] including 10 diabetes patients in the early stages of the disease, customised insoles were designed for each patient using clinical data, insole technical information, anthropometrical measurements data and in-shoe plantar pressure measurements to identify high plantar pressure areas (>150 kPa) in order to design the appropriate insole for plantar pressure reduction. The Parotec system (Paromed, Australia) was used to record plantar pressure distribution data at a sampling rate of 100Hz. The patient walked along a 10 m-long corridor at their comfortable walking speed, and pressure data from five steps was used in the analysis for each foot. They reported that customised insoles reduce peak pressure in areas such as the Hallux, metatarsal heads and heel significantly in comparison with flat and prefabricated insoles [7].

A proof-of-principle study [8] of 23 neuropathic diabetic foot patients reported that after footwear modification guided by in-shoe plantar pressure analysis peak pressure decreased by 30%. Patients repeatedly walked along a 12-m corridor at a self-chosen speed while in-shoe plantar pressures were measured with the Pedar-X system (Novel, Munich, Germany). In four walking trials, a minimum of 15 midgait steps were recorded at a sample frequency of 50 Hz. The target regions for pressure optimisation were identified from the peak pressure image as regions of interest (ROIs). These ROIs had measured peak pressures of more than 200 kPa and were located in areas where there had previously been ulceration, significant foot deformity (Charcot osteoarthropathy),

or pre-ulcerative symptoms. Targeted areas also included any others with peak pressures exceeding 300 kPa. There was a maximum of three ROIs per foot chosen. The options for modification were made by the shoe technician and/or physician and included replacing the insole top cover, the local removal or softening of material in the insole, adding a metatarsal pad, hallux pad, or metatarsal bar to the insole, or adjusting the rocker or roller in the shoe outsole. In 35 defined regions of interest with peak pressure more than 200 kPa, after an average 1.6 rounds of footwear modifications, mean peak pressure was significantly reduced from 303 (SD 77) to 208 (46) kPa ($P<0.001$) [8].

A numerical study [121] based on the use of finite element models to modify total contact inserts (TCIs) with the multi-plug design, proposed the use of in-shoe pressure assessment to validate FEA models. Their hypothesis was that several little soft plugs inserted beneath the metatarsal heads at the site of greatest pressure would lower these localised high PPP to the equivalent of a single large plug of material, with the added benefit of offering more flexibility for TCI. Cylindrical plugs of softer material inserted in the regions of high plantar pressure in the forefoot area to further reduce its loading. The number of plugs (5–15), plug diameter (2–8 mm), distance between plugs (1–5 mm), plug height (50–100% thickness of TCI), and material characteristics (E=0.25–2.25 MPa) were among the design variations taken into account throughout the numerical simulation. The peak plantar pressure (PPP) under the metatarsal heads was examined while the subject was seated in the loading apparatus and placing a load on their forefoot equal to

50% of their body weight when the F-Scan pressure data was taken. Comparing the numerical findings of the finite element approach with the measured pressure distribution in the area of the metatarsal heads for the shoe and TCI conditions showed that the results of the FEA model and experimental pressure testing were in good agreement. For a male volunteer with a history of diabetes and peripheral neuropathy, a set of four prototype insoles were made based on the results of the numerical studies, and plantar pressure measurement. To investigate the effects of multi-plug design on forefoot pressure, during six walking attempts, plantar pressures were measured using the F-Scan system, and the data was gathered at 50 Hz. During the middle of each walking trial, a mean of 3 representative steps was selected, and a mean of 18 steps was used for the peak pressure. The study showed that these customised inserts with softer plugs reduced the peak plantar pressure occurring in the middle and lateral regions of forefoot (3.3−15.7%) more than the TCI alone [121].

Eight studies [4, 5, 7, 8, 121, 123, 124, 126] used in-shoe PPA to guide design and modifications of insoles through removal of material or plugs, application of softer material, or addition of a corrective feature (such as a pad, bar, or arch support). All included studies reported improved pressure offloading performance in areas such as the Hallux, metatarsal heads and heel compared with pre-modification levels or in comparison with flat and prefabricated insoles.

3.3.4.2 Barefoot plantar pressure data driven footwear and insole design and modifications:

Another type of pressure reduction customisation uses barefoot pressure data input to a design algorithm that uses computer-aided design and manufacturing (CAD-CAM). This is used to create a custom-made insole to reduce pressure in areas of increased loading. One study of high quality and three studies of moderate quality used barefoot PPA to modify footwear and insoles and these were moderate to high quality [2, 3, 9, 122]. All the studies measured peak plantar pressure (PPP) as the primary outcome to investigate the effects of interventions.

There is one high quality RCT study that reports the immediate significant effect of this approach in terms of plantar pressure reduction [2]. This compared a hand-made insole based on 'traditional' foam box casting technique with a CAD-CAM insole based on weight-bearing foot scan technique and recorded plantar pressure data during barefoot standing. F-Mat (Tekscan, USA) was used to record static plantar pressure distribution data while the subject was standing barefoot. Static pressure information was used to guide modifications such as cavities, material additions, or substitutions to CAD-CAM insoles on a patient-by-patient basis. They reported the superiority of CAD-CAM pressure-based strategy versus hand-made one in terms of pressure reduction at the point of supply at which time orthoses reduced the number of regions where plantar pressure was > 200 kPa, by 33% for the CAD-CAM group and 21% for the traditional group. Despite this immediate positive effect,

there was no statistically significant difference between the two groups after 6 months of use [2]. However, the sample of this study may not be of sufficient size to detect statistical significance, and so the finding and conclusion will also be limited by this.

A second randomised crossover study [9] included 60 people with diabetes and neuropathy. This study used barefoot plantar pressure data while standing to customize metatarsal bar location and shape for each participant. Plantar pressure measurements were taken while the individual was standing on a platform (Emed® platform, Novel, Germany), and was used to define the proximal/distal location of a metatarsal bar and a void (large cavity) distal to the bar. When the anterior edge of the metatarsal bar was positioned at a line on the area where plantar pressure was 77% of the peak plantar pressure, the most frequent reductions in pressure occurred. This study demonstrated that optimal clinical results can be achieved when metatarsal bars/pads are placed along peak pressure areas rather than anatomical structure [9].

A randomised crossover design study of 20 participants with diabetes and peripheral neuropathy compared three insole conditions [3]. Foam box impressions were used to capture the shapes of the participants' feet. An Emed-D pressure platform with four sensors per square centimeter was used to measure plantar pressures while walking. Plantar pressure data (Novel) during barefoot walking incorporated into the insole design. In areas of significant excessive local pressure (1,000 kPa), a 3-mm-deep portion of the insole beneath a metatarsal head was removed, and a metatarsal bar was produced along a pressure contour found by an automated design algorithm. Two control insoles were

designed only from Foam box impressions of the participants' feet. The first control insole was made of a molded thin polypropylene shell with Korex, sponge, or Plastazote cover. The second control insole was made of a 45 shore A durometer ethylene vinyl acetate base with Procell or Plastazote top cover. The experimental insole consisted of a 35-shore hardness Microcel Puff ethylene vinyl acetate base and a Poron or P-cell top cover. During baseline measurement, any region that had a peak pressure of more than 450 kPa was considered a region of interest (ROI). The authors claimed that compared to custom insoles manufactured just on the basis of foot shape, those made based on the patient's barefoot plantar pressure profile significantly increase offloading. When compared to the two shape-based insoles, the shape-plus-pressure-based insole offloaded more effectively in 64 of the 70 zones. When compared to the two shape-based insoles, peak pressure was lowered on average by 32 and 21% (both $P< 0.0001$) and force-time integral by 40 and 34% (both $P <0.0001$). This study demonstrated that using foot shape and barefoot plantar pressure measurements to create bespoke insoles results in improved offloading of high-pressure areas under the forefoot compared to solely using shape [3].

In a cross-sectional study of 20 patients who had diabetic neuropathy and foot deformities [122], during level walking, first-step collection was used to gather dynamic barefoot plantar pressures during five barefoot left and right foot contacts on a Novel EMED-SF pressure platform (Novel USA, Minneapolis, MN, USA). The barefoot plantar pressure data, the subject's footprints, and tracings of their feet were sent to a qualified

orthopedic shoemaker who used them to create each CMI particularly for this study using a CAD-CAM method. The shoemaker was not informed about any designated points of interest. The CMIs were designed without the use of any particular algorithm. Instead, the shoemaker's expertise and knowledge were used to create a CMI that was representative of a device that might be created in a clinical context. The main PPA guided modifications employed for the CMIs involved removing material from high-pressure areas and accumulating it in other places of insole that contained a metatarsal pad and a medial longitudinal arch support. Large "heel cups" were another characteristic of the CMIs. In-shoe dynamic pressures sampling at 50 Hz were measured using the Novel Pedar system to compare CAD-CAM insole with a flat insole. During three trials of level walking along a 9-m sidewalk, an average of 30 steps for each insole condition were recorded. They found that, in comparison to a flat insole made of open-cell polyurethane 0.95 mm, custom-made CAD-CAM manufactured insoles guided by barefoot plantar pressure data significantly reduced the PP and force-time integrals at the heel and first metatarsal head [122].

Barefoot peak plantar pressure has been shown to be only of moderate sensitivity and specificity to predict ulcer location. However, increased barefoot plantar pressure has been reported to be predictive of ulceration [91]. The findings of four included studies indicate that using barefoot plantar pressure data to guide the design of insoles can result in enhanced offloading. Considering that the patient wears the footwear for part of weight-bearing activity, in-shoe pressure is likely a more significant predictor of tissue injury than barefoot plantar pressure.

However, it is logical to assume that footwear is a possible confounding factor associated with plantar pressure abnormalities found in related studies.

3.3.4.3 In-shoe and barefoot plantar pressure data driven footwear and insole modifications:

One type of pressure relief customisation uses both in-shoe and barefoot plantar pressure measurements to guide modifications to custom-made footwear and insoles. One study of moderate quality used this method to modify footwear and insoles [120].

Twenty-four neuropathic people with diabetes at high risk of foot ulceration were recruited and provided with four data-driven custom-made footwear in a random order. The first condition (Insole-A) was a handmade insole and used in-shoe plantar pressure guided optimisation. The second condition (Shoe-A) was a handmade and fully custom-made shoe that includes insole-A. Shoe-A and Insole-A were both assessed using in-shoe plantar pressure analysis (Novel Pedar-X) during walking and were adjusted by the shoe technician if forefoot peak pressure was greater than 200 kPa. Third insole condition (Insole-B) used a barefoot plantar pressure measurement device (EMED-X, Novel, Munich, Germany), in-shoe plantar pressure measurement device (F-scan, Tekscan, South Boston, USA), Static weight bearing foot impressions on a blueprint pedograph, 3D foot shape-based design and manufacturing

(CAD-CAM) routine. First, a shoe technician combined the barefoot plantar pressure data, 3D foot scan, and static foot impressions in a CADCAM procedure that activated a milling machine to produce an insole. The technician next assessed the insoles using in-shoe pressure measurement (F-scan) and made improvements until detected high pressure regions' peak pressures were 30% lower than baseline (barefoot) peak pressures. The fourth insole condition (Insole-C) goal was to reduce MTH peak pressure in areas where the dynamic barefoot peak pressure was greater than 450 kPa. An automated design algorithm used 3D foot shape-based CADCAM design and used a barefoot plantar pressure measurement device (EMED-X, Novel, Munich, Germany) to generate a metatarsal bar along high-pressure isobars and remove 3mm of insole material from areas with more than 1000kPa barefoot pressure. They proved that using pressure data, the offloading efficacy of both handmade and CAD-CAM footwear/insole improved. In particular, the study showed that wearing Shoe-A and Insole-A resulted in the lowest metatarsal head peak pressures (mean 112–155 kPa, 90–98% of cases <200 kPa), significantly lower than for Insole-B and Insole-C (mean 119–199 kPa, 52–100% <200 kPa). This study demonstrates the unloading effectiveness of a handmade, in-shoe plantar pressure-guided custom footwear design to enhance diabetic footwear for preventing plantar foot ulcers [120].

3.3.4.4 Discussion

This review systematically evaluated the available evidence on the use of PPA to guide footwear and insoles pressures relieve modifications for ulcer prevention, ulcer treatment, and plantar pressure reduction in the diabetic foot. Three types of pressure-based custom-made footwear and insoles have been developed according to the source of plantar pressure data; in-shoe, barefoot or both for the purpose of pressure reduction. They all use PPA to identify high-pressure locations for customisation of footwear and insoles. There is evidence to support the use of PPA in the development of pressure-relief modifications for ulcer prevention, and plantar pressure reduction in people with diabetic foot syndrome. No studies on the efficacy of PPA-guided modifications of footwear and insoles on the healing of diabetic foot ulcers were found.

The risk of recurrence of ulcer after healing has been reported to be 40% at first year, 60% after 3 years [46]. High plantar pressure during walking plays an important role in the development and recurrence of foot ulcers [87, 127]. Therefore, to prevent ulcer recurrence, the International Working Group on the Diabetic Foot 2015 guideline and the more recent Dutch and Australian 2017 guidelines both recommend using custom-made footwear with a demonstrated at least 30% peak pressure reduction compared to current orthopedic footwear, or a peak pressure of less than 200kPa (if pressure is measured with a valid and reliable device with sensor size of 1cm2) [128]. The findings of two high quality RCT studies in the current systematic review indicates that patient-specific footwear and insoles manufactured according to foot shape and

optimised by in-shoe or barefoot plantar pressure reduces the recurrence of foot ulceration when the shoes are worn for enough hours (adhered to wearing their custom-made footwear), compared to custom-made footwear without such optimisation [6, 125].

13 studies [2-5, 7-9, 120-124, 126] reported that the use of plantar pressure data can effectively guide footwear and/or insoles modifications to improve pressure relief which consequently may reduce the risk for pressure-related diabetic foot ulcers in people with diabetes. All included studies reported improved pressure offloading performance in areas such as the Hallux, metatarsal heads and heel compared with pre-modification levels or in comparison with flat and prefabricated insoles. However, the majority of studies were non-RCT (n = 12) and of moderate (n=9) and low quality (n=2), and generalisability is constrained by numerous potential confounders and particular local factors. Moreover, heterogeneity between studies limits any effective synthesis. The only RCT focuses on pressure reduction results in connection to cost and supply chain analyses [2].

The studies included in this review either made use of pressure platforms or insoles. Nine studies used in-shoe plantar pressure measurement equipment [4-8, 121, 123, 124, 126], five studies used plantar pressure platform systems [2, 3, 9, 122, 125], and one study used both in-shoe and platform systems [120] to measure plantar pressure for the purpose insoles modifications. Most In-shoe plantar pressure systems including Novel Pedar-X (8 studies [4-6, 8, 120, 123, 124, 126]), F-Scan (2studies [120, 121]) and all plantar pressure platforms including Novel Emed D

(5studies [3, 9, 120, 122, 125]) and Tekscan F-Mat (1study [2]) meet the requirement of the guidance (valid and reliable device with sensor size of 2 cm^2) [27, 129-131].

Recently Diabetic Foot guideline on the prevention of foot ulcers in persons with diabetes (IWGDF 2019 update) [27] recommended that the plantar pressure-relieving effect means that in high-pressure areas, the peak pressure during walking should either be reduced by less than or equal to 30% or should be less than 200 kPa to Prevent of recurrent foot ulcers. All studies included in this review analysed plantar pressure data, produced peak pressure maps, and then defined locations with In-shoe plantar pressures greater than 200 kPa (8 studies [4-6, 8, 120, 121, 123, 124]), barefoot plantar pressure greater than 450 KPa (3 studies [120, 125, 126]), barefoot plantar pressure greater than 1000 KPa (1 study [3]), barefoot plantar pressure greater than 77% of highest peak pressure (1 study [9]). 3 studies did not explain exactly how they used peak plantar pressure data to guide insole modifications [2, 7, 122]. Most studies used the same design and modification principles for all their participants. Across studies there was a wide variation in the intervention design. Insole modification features include the removal of 1 cm X 1 cm plugs from beneath the region with excessive pressure [123], the removal of material under the regions of excessive local pressure (>200 kPa) [4-6, 8, 120, 121, 123, 124], removing material under each metatarsal head and increasing the height of a metatarsal bar and until the regional peak plantar pressures were reduced to <200 kPa [126], removal of a 3-mm-

deep portion of the insole beneath a metatarsal head in areas of significant excessive local pressure (1,000 kPa), and adapting a metatarsal bar according to the pressure contour [2, 3, 5, 6, 8, 120, 123, 125, 126], inserts (TCIs) with a certain number of 4 mm diameter cylindrical plugs of softer material in the regions of high plantar pressure in the forefoot area [121], customising metatarsal bar location and shape according to plantar pressure profile [9]. While studies demonstrated these modifications to be effective when guided by plantar pressure, the variation of design and modification approaches has contributed to insufficient evidence on the effects of different types of plantar pressure-guided modifications on pressure relief. Several studies left the choice of modifications to the shoe technician and／or rehabilitation specialist [5, 6, 8, 120, 122-124] which include replacing the insole top cover, the local removal or softening of material in the insole, adding a metatarsal pad, hallux pad, or metatarsal bar to the insole [2, 5, 6, 8, 124]. These studies did not modify the insoles according to established protocols, which could affect the reproducibility and generalisability of their findings.

The results of this systematic review enable us to understand how PPA as a clinical tool can be used to guide and optimise design and modifications of footwear and insole. These results demonstrate that PPA is an effective and efficient tool for assessing and guiding footwear and insole modifications that provides an objective approach for immediate improvement of quality, which should reduce the risk for pressure-related plantar foot ulcers. They provide the evidence for the critical design features of insoles guided by PPA which can reduce excessive plantar pressures and the recurrence of plantar ulcers in people with

diabetic neuropathy. This information might lead to innovative design of footwear and insole, and also incorrect interventions may be prevented.

There are several limitations to this study which need to be considered. The over-riding limitation and challenge to research in this area is the investigation of manageable sample sizes that offer a realistic representation for such a heterogeneous group of people with diabetic foot disease.

In all the included studies in the current systematic review, only vertical plantar pressure data during standing or walking was considered as an individual mechanical factor that makes up plantar tissue stress (PTS) in people with diabetic foot disease. PTS is defined as "the accumulation of all mechanical stresses on an area of plantar foot tissue from all weight-bearing activity over time."[132] It primarily consists of the interaction of the following separate mechanical factors: vertical (normal) pressure (also known as plantar pressure), horizontal pressure (also known as shear stress), and the frequency with which these pressures are applied (also known as weight-bearing activity) [132]. Although the therapeutic value of measuring and modifying vertical plantar pressure as one specific mechanical component of PTS has been proven, it is still a long way from being an accurate representation of a person's full PTS profile. Comprehensive PTS model might assist in the development of interventions such as foot orthotics that are based on all mechanical stresses on the plantar surface of the foot. Further studies are suggested to develop and evaluate appropriate footwear and insole modifications guided by multiple mechanical factors of PTS model.

Irrespective of the plantar pressure data being used, studies predominantly used peak plantar pressure to identify high-pressure locations for customisation of footwear and insoles. These studies solely used pressure data at a single point during the gait cycle where the forefoot experienced its maximal loading, which could have resulted in possible missing of important pressure data. It has been suggested that using a variable like the force-time integral, which accounts for time in the assessment of loading, provides a more accurate representation of cumulative tissue stress than using peak pressure alone [3]. However, only two of included studies reported this variable [6, 122]. Some studies [2, 9] used standing pressure data to guide modifications, which does not provide an accurate picture of dynamic plantar loading, which indicates the potential risk of extrapolating results of standing data to enhance dynamic pressure offloading performance.

It is difficult to determine whether the improved offloading performance of the pressure-based footwear and insoles are due to the incorporation of plantar pressure data into their design, or other design and manufacturing factors such as production process (i.e. source of foot shape data, Milled compared to handmade)[2], material (e.g. The control insoles were made from different materials from the experimental insole)[3], and shoe technician input [7]. These factors make it difficult to determine whether the enhanced offloading performance of experimental insole is due to incorporating plantar pressure data into design, or other factors or combination and interaction of them which makes drawing conclusions difficult.

Foot orthotics and footwear are mostly evaluated according to clinical experience and a “trial-and-error” approach. Although there are more and more assertions regarding the benefits of using existing measuring technology for plantar pressure measurement and 3D shape quantifications, there is still a discussion over how practical these technologies are in the context of ordinary clinical practice [133], and how to reduce plantar pressure objectively and systematically on the basis of a specific pressure distribution profile. Future research should concentrate on creating evidence-based recommendations for standard footwear designs and modifications guided by PPA. Future research should also investigate the association between these chosen modifications, plantar pressure and ulceration outcome measures.

Conclusions

This systematic review provides support for the use of PPA for prevention of ulcer recurrence, and plantar pressure reduction in the diabetic foot. Furthermore, the results of controlled and uncontrolled investigations of PPA treatments designed to prevent first ulceration need to be confirmed by more high-quality studies. Despite the offloading objective, PPA to optimise the pressure-relieving features of customised insoles is still not a widely accepted technique in the management of neuropathic diabetic foot ulcers [133].

Several barriers have been identified to the clinical implementation of technologies in healthcare setting including competency, cost, time, fear to change, and complexity regarding the adoption of technology [89, 99-103]. However, exploring the views of clinicians who are treating the diabetic foot daily could enable a clearer understanding of perceived barriers specific to the implementation of PPA in this clinical setting which is explored in the following chapters.

4.0 Chapter 4: Qualitative Study of Clinician Perceptions

4.1 Introduction

The initial review of the literature explored how PPA is used in diabetic foot management. Then, the researcher conducted a systematic review to gain further information about the effectiveness of footwear and insole interventions guided by plantar pressure data in patients with diabetes. The result of the systematic review supports the advantages of PPA in prevention of ulcer recurrence and plantar pressure reduction in the diabetic foot**.**

However, clinical implementation of technologies in healthcare settings has been facing barriers including competency of health care practitioners in the use of technology, cost, time, fear of change, and complexity of data interpretation. What are not clear within the literature are barriers to use/uptake of plantar pressure measurement in the assessment and treatment of diabetic foot syndrome. Therefore, this study used a qualitative study design to explore the current barriers and facilitators to the implementation of PPA in a clinical setting. Qualitative data is often recommended for a deeper understanding of the participant perspective [134]. It was established that understanding the views and opinions of orthotists and podiatrists involved in diabetic foot management, about the

use of PPA, are essential to understand the barriers and provide recommendation to support clinical uptake.

This qualitative study therefore aimed to explore podiatrists' and orthotists' views and experiences of using plantar pressure measurement in the assessment and treatment of diabetic foot syndrome.

4.2 **Aims of this research**

Explore the current barriers to the implementation of PPA in a clinical setting of diabetic foot care

Explore the facilitators for the implementation of PPA in a clinical setting of diabetic foot care.

4.3 **Potential benefits of the research**

Identify the clinical understanding of PPA, in a sample of Podiatrists and Orthotists.

Identify the barriers and facilitators for clinical implementation of PPA, in order to provide recommendations for integration into clinical practice.

4.4 **Qualitative research**

Qualitative studies focus on insights and understanding of people's experiences. It can be considered as an approach to collect text-based data to understand people's opinions into real-world problems [135, 136].

Qualitative research collects participants' experiences, perceptions, and behaviours instead of collecting numerical data points. Unlike quantitative studies, qualitative research answers how and why, not how many or how much [137].

Qualitative research in nursing and health care dates back to 1995, [138], since then qualitative methods have become more common in the field of health services research and health technology assessment [139], being used in the development of interventions or in understanding barriers and facilitators to their successful implementation [140].

4.4.1

Truth value, Consistency, and Applicability in Qualitative Research

When utilising research findings in health care practice, evaluating the quality of research is taken into consideration. However, unlike quantitative research, statistical methods cannot be applied; establishing validity and reliability of research findings, and alternative frameworks are needed to ensure the 'trustworthiness' of the findings [141].

Truth value, consistency, and applicability are the alternative terminology to validity, reliability, and generalisability respectively in qualitative studies [141].

4.4.2

Truth value (validity)

Truth value or validity in qualitative research refers to the appropriateness of the research method including; the study design, sampling framework and methods used for data analysis, in order to answer the research question [142]. The researcher used the expertise of the research team [SB, DP, CP] who were already experienced in the use of qualitative methodologies to provide guidance and critique throughout the research process [141, 142].

4.4.3

Consistency (reliability)

Reliability is an essential criterion for qualitative research and lies with consistency between the data and the findings. Reliability is dependent on the trustworthiness of research and the clarity and transparency of the researcher's decisions [143].

To enhance validity and truthfulness of the analysis, conducted codes and themes were shown to the other members of the research team [SB, DP, and CP] and developed following discussion to agree with the thematic analysis. It is recognised that our individual world view has an impact on qualitative data analysis and findings and there may be some disagreements. Therefore, an audit trail is essential to clearly explain the

process of data analysis and the decision made throughout the research process, also demonstrates how any disagreements are resolved [144]. Our meeting with supervisory team and any development in thematic analysis were recorded as a means of establishing an audit trail.

4.5 **Data Collection Method**

Data, in qualitative research, can be collected via several techniques including interviews, focus groups, and observation [137]. Interviews, specifically the semi-structured format, are the most commonly used data collection method in healthcare qualitative research [145-148]. As a semi-structured interview is flexible, provides the opportunity to the interviewer to ask follow-up questions based on participants' responses and can promote interchange between the interviewer and participant [146, 148-150].

In the current study, questions were designed to align with the purpose and goal of the study and were carefully worded in a way that was easy to understand. Trust and respect within the interview were considered in order to share personal insights and experiences freely [151, 152]. We allowed the participants to identify what they feel is important and focused on their personal experience instead of interpreting the thoughts, feelings, experiences, and perspectives of others.

An initial draft of questions was devised and forwarded to the research team. During meetings with the research team and based on their experience of qualitative research, pressure measurement and assessment

in diabetes; the final list of questions (demographic and main interview questions) was created (Appendix A).

The interview questions and guide were piloted during a practice interview. The interview was recorded and members of the research team with interview experience provided feedback on the interviewer's technique.

The order of the questions was designed from general to detailed questions. The general initial questions have been identified as tour questions by Rubin and Rubin (2011) were asked before the focused interview questions to prompt a descriptive response and explore the research participants experience [153]. Examples include: "Can you tell me about your perspective of PPA for clinical use?" "Over your career, what is your experience of using PPA?"

These questions were followed with "main questions" which were more specific focusing on the barriers and facilitators of the clinical implementation of PPA and clinically applicable threshold value. To monitor people with diabetes with the risk of foot ulceration or offload the high-pressure area in diabetic foot, identification of an optimal peak plantar pressure cut-point threshold below which the risk of ulceration is reduced would be a valuable tool [47]. Thus, the developed questions aimed to explore the current understanding of this threshold approach amongst clinicians in addition to the technical use of PPA to identify the higher risk areas of foot [80].

The important characteristics of data were focused on the reasons why clinicians do not use plantar pressure and the way that overcoming barriers to use can be facilitated. Follow up questions and probes were based on an interview guide to help keep the interview focused and facilitate a deeper response from research participants.

Focused interview questions could be further developed and expanded over the course of the study as a result of the participant's responses to the questions.

4.6 **Procedure**

Ethical considerations

Ethical approval for the qualitative study was sought as a stand-alone piece of work before undertaking the research project through Ethics Committee of Health and Society at the University of Salford, (Ethics code: 3598) (Appendix B).

Sampling

In qualitative research, to facilitate the in-depth case-oriented analysis that is necessary for this type of studies, sample sizes are usually small. Moreover, samples are recruited according to participants' capacity to provide rich and detailed information relevant to the topic under investigation. Therefore, qualitative studies have purposive sampling which selects 'information-rich' cases [154].

Some qualitative researchers believed that data saturation depends on how rich (high quality) and thick (enough quantity) the data are as well as the sample size. Therefore, selecting a sample size according to information power to provide the best opportunity for the researcher to reach data saturation is important to most researchers.

Additionally, some other qualitative researchers believed that "the concept of data saturation is inconsistent, unrealistic, and practically untenable" [155]. Decision about the number of data items and the time to stop data collection, are inherently subjective and cannot be made (completely) prior to analysis [156].

Namey et al. (2016) reported that reaching to about 80% thematic saturation (i.e. 80% of the total number of codes identified) can be achieved by eight interviews and to achieve 90% saturation by 16 interviews. They recommend a sample size between 8 and 16 interviews can be suggested to reach data saturation [157].

Therefore, in this study, an ideal sample size could be between 8-16 participants. However, this study was an exploratory topic to have different perspective about clinical implementation of PPA and did not aim to develop a theory. Therefore, saturation was not an aim in sampling of this study. We considered information power concept and purposively aimed to sample from people who were "information rich". We targeted orthotists and podiatrists who are responsible for providing orthoses in the diabetic field or managing foot diabetic syndromes.

All interviews were conducted by the primary researcher (ART), a physiotherapist with 10 years of experience in the field of musculoskeletal (MSK), mainly foot and ankle. The interviewer was trained through supervisors' advice, self-taught via several papers and thesis, and educational videos in conducting interviews before starting the data collection phase of the study. Additionally, the interviewer undertook one pilot practice interview to improve techniques. The pilot interview was on a podiatrist practicing in a private clinic and was evaluated by supervisors and the interviewer was provided with feedback, comments, and relevant website/ training materials such as "Designing Effective Projects: Questioning, The Socratic Questioning Technique" to develop interview skills. The first interview of the data collection phase was also reviewed by the supervisors and provided with further feedback with the aim of improving the quality of the following interviews.

Interviewer approached potential participants for both the pilot and main study through supervisors' network links to CoP (College of Podiatry), NOMAG (National Orthotics Managers Advisory Group) and BAPO (British Association of Prosthetist and Orthotists). An invitation email was sent to the networks to circulate, and a brief description message was also posted on twitter and LinkedIn by the supervisors (Appendix C). Potential participants were asked to contact the student via email. Potential participants were informed about the purpose of the research through participant information sheets (Appendix D) and all participants' questions were answered. Potential participants were contacted no less than 24 hours after sending the patient information sheets to confirm their

interests in volunteering, ensure they met inclusion criteria, and arrange the interview.

4.6.1

Participant Inclusion criteria:

Orthotists and podiatrists who are responsible for providing orthoses in the diabetic field or managing foot diabetic syndromes as PP can positively affect orthotic design and modification in management of foot diabetic syndromes

Orthotists and podiatrists who are with and without clinical experience in using of plantar pressure measures (participants with clinical experience in plantar pressure may have different views in terms of barriers and facilitators compared with participants without experience in plantar pressure)

Orthotists and podiatrists who have access to a computer, as interviews were online and conducted on Teams application

Orthotists and podiatrists with a minimum 5 years of post-qualifying experiences.

This study was looking at changing practice and that is required individual to understand the existing practice. We needed them to speak about their clinic as a whole as well as their practice. So having an extended post qualification practice experience can broaden their ability to speak about the clinic changes.

Orthotists and podiatrists who have qualifications in orthotics or podiatry

Orthotists and podiatrists based in the UK as trainings, clinical guidelines and resources in other countries may be different.

4.6.2

Participant Exclusion criteria:

Clinicians who have worked alongside researchers to review pressure use in practice

Clinicians with clinical academic contracts which relate to pressure research

This group of clinicians was excluded because the aim of this qualitative study was to explore the clinicians' views about the implementation of PPA in clinical setting, not in a research or academic setting. Those who have experienced using plantar pressure as a research or teaching tool may not be in a position to speak about the challenges that face them. For example, the time available is a potential barrier for the implementation of technology. However, the clinicians who are involved in research or teaching will typically have time protected to do more detailed analysis and more thorough assessments. Therefore, they do not represent the barriers to use of technology in the clinical setting.

A known conflict of interest or association with a manufacturer/distributor of PPA equipment.

Clinicians who worked in other fields and do not deal with people with diabetes such as clinicians who practice nail surgery, sport injury, Paediatric, etc.

4.7 **Data collection**

All interviews were conducted online via Teams and audio was recorded. At the start of each interview, the researcher explained the aims of the research to the participant. Participants were also informed how anonymity would be maintained via the use of a numerical code for each participant. Then the consent form (Appendix E) was read for the participants and their answers were recorded. Afterwards demographic questions were asked to provide an introduction and an overview to the participants. Then the researcher went through the main interview questions. The interview took around 20 to 30 minutes. As the interviews were conducted online, participants could take part anywhere they had access to a computer, so participants took part at home, clinic, workplace, etc.

No participants dropped out of the study or were required to repeat the interview. Following the interviews, transcription was completed by the researcher within 48 h of the interview and transcripts were returned to the participants for comment. Two participants replied and confirmed the transcripts, while four participants did not reply.

4.8 **Data Analysis Method**

The study used a qualitative design, with thematic analysis of the data to explore barriers and facilitators to the use of plantar pressure measurement in clinical practice. Thematic analysis is a powerful and flexible method to analyse qualitative data by identifying, analysing and reporting themes and patterns within data set [150, 158]. Thematic analysis focuses on the content of what is being said by participants and is a suitable method for the exploration of shared experiences [158].

Within thematic analysis the researcher is considered key to the research process, responsible for the entire analytical process, making decisions on the coding and contextualising data [159]. Coding refers to the identification of common patterns of data within the transcripts and these patterns then form the overall themes. Therefore a theme is created once the researcher sees some form of a pattern within the data; with this process the researcher effectively becomes the analysis tool [160].

In the current study, our thematic analysis was based on the 6 -step approach developed by Braun and Clarke, 2006 (Table 6) [149]. To ensure validity of the data, the thematic analysis framework was suggested to and agreed by the research team.

Thematic analysis is distinguished by its flexibility in research question, sampling size, the method of data collection, and approaches to meaning generation. Thematic analysis can be used to find patterns within and across data in relation to participants' experience and perspectives. This

approach can be utilised to analyse various sample sizes – from case study research with 1-2 participants to large interview studies - whether homogenous or heterogeneous samples. Any data type such as interviews and focus groups to qualitative surveys and story completion can also be analysed with Thematic analysis [161].

Table 6 Braun and Clarke thematic analysis approach

Stage 1	Familiarising with the Data
Stage 2	Generating Initial Codes
Stage 3	Searching for Themes
Stage 4	Reviewing Themes
Stage 5	Defining and Naming Themes
Stage 6	Producing the Report

After the completion of each interview, the interviewer (ART) transcribed the audio recordings verbatim using automatic transcription software (Word 365). Then, the interviewer started reading and re-reading the transcript to immerse with the data and have familiarisation with the depth and breadth of the content at the first step. During this phase, the interviewer made some notes about ideas for coding.

The transcripts were transferred to INVIVO software (QSR International) to manage the data coding. During this phase, the interviewer worked systematically across the data set to identify the sections in the data items that may form the basis of themes as codes. Then, the relevant codes were categorised to extract the themes.

To enhance validity and truthfulness of the analysis, created codes and themes were discussed with the other members of the research team and developed following discussion. In research meeting, we discussed to break down the initial codes and also keep themes whole rather than splitting them into facilitator versus because some of the themes were both facilitators and barriers – for example knowledge was considered one theme as those who had competency to use plantar pressure had been able to use the equipment while those who didn't, found it to be a barrier. Meeting with supervisory team and any development in thematic analysis were recorded as a means of establishing an audit trail. Exemplars from the dialogue were extracted to demonstrate truthfulness of the data within each theme.

5.0 Chapter 5: Findings of qualitative study

5.1 Introduction

The interviews' main aim was to explore podiatrists and orthotists' thoughts and experiences of using PPA in the assessment and treatment of diabetic foot syndrome.

Six clinicians including four podiatrists and two orthotists participated in this study. One podiatrist and two orthotists had prior experience of using PPA in their clinical practice and the others three podiatrists had no experience. In terms of clinicians' work circumstances, three out of six clinicians had worked in both the NHS and private sector, two of them only worked for the NHS and one had worked for the private sector only. Table 7 shows the participants' information.

Transcripts were returned to the participants for comments. 2 out of 6 participants replied and confirmed the transcripts without changes and the researcher did not receive comments from the others.

Table 7 Participants' information and experience

Code	Gender	Experience of using pressure	Work circumstance	Years of experience	Explanation
22-1	M	With exp in PP	Previous experience in the private sector, and current experience in the NHS	16	As a clinician who had experience in both the private sector and NHS and used to use PP in the private clinic, could proposed facilitators for improvement of PP usage in the NHS.
22-2	M	With exp in PP	Private and the NHS	10	As a participant who works in both the private sector and NHS and using PP in the private clinic, could proposed facilitators for improvement of PP usage in the NHS.
22-3	F	Without exp in PP	The NHS	25	The participant was qualified more than 20 years ago and focused on the importance and training and CPD. She used PP for a project many years ago and saw it difficult to use and interpreting.
22-4	F	With exp in PP	Previous experience in the private sector and the NHS. Current experience in university	21	Having experience in different working places, this clinician provided the researcher with the barriers in different working places.
22-5	F	Without exp in PP	The NHS	30	As a manager of a podiatry clinic in an NHS trust provide the researcher with proposed facilitators from a managerial perspective.
22-6	F	Without exp in PP	Private	13	A podiatrist who works in a private clinic

This study was an exploratory topic to have different perspective about clinical implementation of PPA and did not aim to develop a theory. Therefore, saturation was not an aim in sampling of this study. We considered information power concept and purposively aimed to sample from people who were "information rich". Our participants had considerable years of practice in the field of diabetic foot care from occupations, podiatrist and orthotist. They also were varied regarding the practice setting they have worked, private or NHS, in such a way that four participants had worked in both private and NHS practice setting, one in private and one in NHS. Our participants also were varied in terms of experience in working with plantar pressure devices in their clinical practice, three with and three without plantar pressure experience (Table 7).

However, similar barriers and challenges arose for all participants, with no new themes or subthemes were raised in the final 2 interviews highlighting similar experiences and perspectives towards PPA from across the participants interviewed. This may indicate data saturation for this sample; however, it is recognised that further purposive sampling from different contexts such as locations (different regions in the UK) may provide more codes around the topic.

5.2 **Plantar pressure uses for diabetic foot care**

The researcher identified six themes following the thematic analysis of the six interviews. Each theme has subthemes that contribute to the overall theme (Table 8); 1. The importance of training and education in clinical implementation of plantar pressure, 2. Providing evidence for health services to prove the benefits of PPA 3. Time and space, 4. Human resources, 5. Specific triage, 6. Cost.

Clinicians were overwhelmingly in support of PPA to identify high pressure areas in diabetic patients. However, lack of knowledge and education regarding use and interpretation of plantar pressure data, shortage of time and space in routine clinical practice, and high cost of purchase and implementation of this technology were considered as barriers in clinical implementation.

Table 8 Themes and subthemes

THEMES	TITLE OF THEME	SUBTHEMES
Theme 1	The importance of training and education	Lack of knowledge and education about PP Lack of information and interest about PP Continued professional development: in-house training, short courses, and self-taught to get up-dated
Theme 2	Providing evidence and demonstrating the benefits of PP	Providing evidence and prove the benefits of PP to the NHS Showing the clinicians how it works and the advantages
Theme 3	Time and space in clinic to undertake assessment	Limited clinic time and lack of enough room Time consuming Specific time and clinic
Theme 4	Human resource	To train specific people in trust for using PP
Theme 5	Specific triage	Specialised to certain patient groups Inappropriate for some patients
Theme 6	Cost	High cost Cost analysis and justifying the high cost

For the most parts, clinicians remarked that if they can identify the higher pressure in the diabetic foot and offload that pressure it can lead to less incidence of ulceration.

“I think it's fantastic because it gives you so much more information that you can't see, and I think it should be used as a clinical tool (22_6 without PP experience)”.

Two clinicians who have the experience of using plantar pressure devices in their practice described that in addition to identifying high pressure areas to offload, they use PP to assess whether interventions are beneficial to their patients.

“Using a PPA is good to see whether something that you've done or something that you know someone else that did for the good of the patient, Is actually of benefit (22_1 with experience of PP)”.

In addition to offering feedback to the clinicians themselves, one of the clinicians believes that PPA can also provide feedback for the patient, to show them where there's more pressure. In a treatment plan, feedback is important to determine if an intervention will be successful [93, 98, 162].

“Using something as simple as pedobarography to show exactly how the foot is moving and where there's more pressure helps the patient to understand and demonstrate exactly where that pressure is and why it's there. So, there's a huge benefit to that (22_2 with experience of PP)”.

The second part of the interview for the clinicians who had plantar pressure experiences was focused on the method of analysis of plantar pressure data and mainly the application of specific thresholds. However, the clinicians with PP experience described analysis of PP measurement for risk assessment and prescription of orthosis as finding the high plantar pressure area according to the colours of footprint of the visualised data on screen. They interpreted that the red colour in the footprint indicates high risk area and yellow indicates low risk. That is because this approach reduces data from absolute values to grades or conditions, is simple, understandable, and easy to communicate with patients. They were not aware of the application of threshold values and the differences of threshold values across different measurement systems, in clinical practice to monitor the risk; therefore, the discussion of barriers of threshold was limited because knowledge was limited within the participants involved in this study.

5.2.1

Theme 1: The importance of training and education in clinical implementation of plantar pressure

All participants believe that lack of knowledge is the main barrier to clinical implementation of plantar pressure. They believe that most clinicians don't have enough information about PPA and don't believe in the accuracy of the technology. Hence, they see PPA as a challenging measurement. They feel it is a difficult system to use and a complex system in terms of the software to interpret. This perspective causes them not to be confident about using Pedobarography or changing their

assessment and treatment protocol and adopt these new processes. One participant reported that clinicians generally don't know about the benefits and limitations of plantar pressure technology specifically and purchase plantar pressure device for the first time from a sales Representative at a conference.

"There is potentially training involved in using that. I think basically just getting used to the implication of how you use it and interpreting the data and how to translate that into an orthotic device (22_6 without experience of PP)".

One of the participants said that they had a few experiences of the plantar pressure implementation some years ago and they have not had continued training for PPA. They believed that maybe the newer systems are very "user friendly" and easy to use, but they have not directly experienced these.

All participants reported that the reason for lack of knowledge in PPA is that it isn't covered within undergraduate training modules at universities (within the UK). Students are not coming out with any clinical experience in PPA due to insufficient training in PPA at the undergraduate level.

"You don't really get taught at any depth in any of the modules for podiatry (22_2 with experience of PP)".

Participants believe that clinicians need to be trained in PPA, interpreting the data and implementation of plantar pressure in clinics. The training

can be undertaken in different ways including at the undergraduate level, short courses, or self-taught.

Participants reflected on various training offered to them around PPA. Training in the use of PPA needs to be addressed in the undergraduate program so that the students obtain enough experience in the field and then when they are in clinical practice, they can take it forward. In addition, training can be undertaken through some short courses provided by the companies or manufacturers that supply the equipment, through peer provision by other members of the clinical team that have more confidence in using PPA systems or by reading journal articles that support the evidenced based use of PPA and being self-taught.

5.2.2

Theme 2: Providing evidence and demonstrating the benefits of PP

Four participants believe that providing evidence to the NHS regarding the benefits of PPA is an important requirement to facilitate the clinical use of plantar pressure

devices. They reported that funding technology through the NHS is not really a problem and that if valid and reliable research proves that something works; the NHS will always find the money. The more evidence in terms of improved patient outcomes via the use of relevant clinical outcome measures is provided, the more likely the NHS is to invest in these systems.

"If we could really prove that in the long term this did prevent ulcers. Then it would be well worth investing the time (22_3 without experience in PP)".

In addition to the organisational level, two participants believe that introducing the plantar pressure systems to the individual practitioners and demonstrating the clinical benefits of PPA in effective diabetic foot management in person and practically can help some clinicians who do not appreciate the value.

"If you actually physically get it into the clinic with the patients and with the clinicians and get the clinicians physically doing it and showing them how it works and the advantages, that's how you'll get more people to do it (22_4 with experience PP)".

5.2.3

Theme 3: Time and space in clinic to undertake assessment

Lack of time is a considered factor by 5 participants. They reported a limited clinic time in the NHS for the assessment of patients with diabetes. The participants believe that the set-up of plantar pressure device and interpretation of the data is time-consuming and takes the majority of the consultation time. Therefore, clinicians would not have enough time to undertake the standard clinical assessment and use PPA for all patients.

"I think time would be one of them in the NHS. We have limited time per patient in the NHS by the time clinicians have done the full assessment; clinicians wouldn't have enough time then to do plantar pressures (22_5 without experience of PP)".

Lack of space is another barrier highlighted by five participants. Plantar pressure plate needs an appropriate space to be set up and enable the patient to walk over the device. However, most clinicians in the NHS are struggling with the lack of enough room. They usually have to use shared rooms or communal area for setting up the plantar pressure plate which can be problematic.

"We have difficulty finding the clinic rooms because we often use shared clinic rooms with other professions. Everyone is competing for the same space (22_5 without experience of PP)".

Since PPA and interpretation might be time-consuming, allocating specific time for these tasks could be beneficial to develop and facilitate plantar pressure implementation in the NHS clinics. In addition to interpretation of the data, plantar pressure system set up is said to be time-consuming and a barrier for the clinical use of PPA.

"You have to allocate specific clinics and times, through which you can see these patients, then measure plantar pressure and then take the time and analyse the results. I mean it needs its time. It's not something that you have to rush (22_1 with experience of PP)".

Similar to specific time and clinic, a dedicated space for the pressure system to be setup, measurement and interpretation reduce time associated with using PP for each patient. One participant suggested that clinicians can set up the system in a designated room to reduce the number of set ups for individual appointments and save their time.

"*You'd need a dedicated area for that, where it was constantly available for use rather than having to bring it out to for use, and so that the system was set up and you could bring a patient in and within that time (22_3 without experience of PP)".*

5.2.4

Theme 4: Human resource

Two participants in our study believed that specific people within trusts can be targeted and trained regarding the implementation of PPA in clinics. They can be one or two members of staff within the clinical team who are passionate about pedobarography. They can be the only members of staff who are trained to use the PPA for patients and also, they can train other clinicians.

"It might just be one or two members of staff that use it regularly, so it might not need to be the whole team that utilizes it (22_ 6 without experience of PP)".

"It could be done if they'd have to earmark specific people within each department who have a passion for it (22_4 with experience of PP)".

5.2.5

Theme 5: Specific triage

There are various symptoms in diabetic foot syndrome including musculoskeletal, neurological, and dermatological issues that range from mild to severe. PPA might be impossible for some patients with a severe

ulcer or poor balance that leaves them unable to walk barefoot on a pressure platform.

"Patients with open ulcers are not good candidates (22_ 1 with experience of PP)".

Conversely, there are some patients who can take advantage of PPA. Hence, three participants in our study believed that a specific triage to select appropriate candidate for PPA could decrease the workload for plantar pressure clinic and the time could be manageable.

"I think it would have to be choosing the patients that you use the pressures force or not. Triaging your patients and selecting them so prioritise who you use them on. So, then it's not as time-consuming because you wouldn't be using it on every patient that you see (22_ 5 without experience of PP)".

5.2.6

Theme 6: Cost

It is believed that high cost could be a barrier in clinical use of PPA. The systems are expensive and required space for the system may cause an additional cost. Most clinicians (five) in the current study believed that it would be a barrier for private sectors depending on their circumstances, caseload, and location of practice.

Private clinics need to have a substantial people with diabetes caseload to justify the cost. However, most people with diabetes, especially those considered high-risk, tend to be screened annually in the NHS. Private

clinicians can tailor their practice to particular groups such as those with sports injuries or patients with diabetes.

In addition to the circumstance, the location of the practice can affect cost justification in such a way that practicing in large cities can lead to high caseload and justify the high cost of equipment.

"One of the barriers would probably be cost. Limited customer in the private sector, so it would be depending on where you were delivering the service. Cities probably would be better, but in more rural areas you'd have limited customer (22_5 without experience of PP)".

5.3 **Conclusion**

Clinicians described a range of barriers for clinical implementation of PPA spanning logistical barriers such as time and space and barriers associated with knowledge and understanding. Lack of knowledge in PPA was considered as the main barrier and it was believed that most clinicians don't have enough information about the benefits and limitations of PPA, using this technology, and interpretation of the results.

Clinicians also expressed that through undergraduate modules and continued professional training (CPD) this barrier can be addressed. In undergraduate courses, students can learn about PPA and obtain experience in the field. Additionally, CPD that can be undertaken through

some short courses, reading journals, and self-taught can keep clinicians up to date in the field of PPA and the clinical use of this technology.

Due to the lack of information about PPA, some clinicians don't believe in the accuracy of technology, so demonstrating the clinical benefits of PPA in risk prevention and treatment of diabetic foot problems though practical delivery or via research can convince them to invest on the technology and include it in their practice.

Limited clinic time and lack of space were reported as barriers using this technology in the NHS as set up, measurement and interpretation of data need time and room. Hence, specific triage can exclude the patients who are suitable for PPA and reduce the number of patients in the services of PPA. Then clinicians can better address the time and room barrier by allocating specific clinics and rooms to the triaged patients.

As cost can be a barrier for private clinics in some circumstances, cost analysis according to the location of practice and caseload need to be considered to justify the implementation of PP into services.

6.0 Chapter 6: Discussion

6.1 Introduction

This qualitative study was carried out to explore podiatrists' and orthotists' views and experiences of using plantar pressure measurement in the assessment and treatment of diabetic foot syndrome. The barriers and facilitators of clinical implementation of plantar pressure measurement were the focus during the interviews.

Initial scoping work identified that there is agreement among both technical and clinical outcome focused work [2-9, 120-126] that plantar pressure measurement has positive effects on clinical management of diabetic foot. Plantar pressure measurement can be a clinical tool in risk assessment and prescription of orthoses in diabetic foot patients. However, current orthotic practice does not incorporate the technology, and it indicates that the clinical method used by clinicians to detect high plantar pressure is insufficient [113]. Clinicians see that there is lots of technology being used as research rather than clinical and not necessary for routine practice [99].

While the benefits of plantar pressure measurements for quantitative assessment of orthotic performance were clear for the research team, it

remains to be seen what the barriers to clinical implementation of plantar pressure measurements are and how to implement this technology routinely and easily in practice.

The results provide insights into barriers and facilitators of clinical implementation of plantar pressure measurement. Six themes emerged as (1) The importance of training and education in clinical implementation of plantar pressure, (2) Providing evidence and demonstrating the benefits of PP, (3) Time and space in clinic to undertake assessment, (4) Specific triage, (5) Human resource, (6) Cost.

6.1.1

The importance of training and education in clinical implementation of plantar pressure assessment

Although the clinical benefits of PPA are well known in biomechanical researches [2-5, 7-9, 120-126] and guidelines [27, 163], it is still unclear how they can be incorporated into routine practice. The present study shows that lack of knowledge is one of the barriers in clinical implementation of plantar pressure measurement. All participants believe that most clinicians do not have enough competencies in the use, analysis, and/or interpretation of plantar pressure measurement.

This observation is consistent with the previous studies which found that clinicians were unsure of what to expect from technology in clinical

settings [164]. Either the use of plantar pressure technology appears to be restricted to research settings and is not widely available in clinical settings or the skills to implement them are lacking [99]. Llewellyn et al (2014)found that clinicians, who were not trained or experienced in technology, did not understand the clinical need and utility of the technology in clinical setting [165]. As some of our participants mentioned, clinicians do not believe in the accuracy of the technological advancements in plantar pressure measurement, so they are not willing to alter their treatment protocol. Seifert et al also showed that technology could be used by more therapists if technology availability, therapist training, and evidence-based practice were enhanced [166].

One of our participants believed that in order to use PPA in their clinical practice, they would have to collect the raw data and analyse it which would be quite labour intensive. Martínez Santos et al reported that since the data is generally regarded as being too complex to use and analyse, technology is not typically utilised [99]. That is consistent with a prior study which reported that the detailed information provided by some healthcare devices that typically give therapists access to raw data often needs a level of data processing knowledge that therapists do not routinely require in their role [164]. This is because raw data analysis in itself is a particular skill that cannot be easily performed by clinicians in a clinical setting [164, 167, 168]. In this regard, a multi-disciplinary approach between clinicians, biomedical engineers and data scientists can be used to balance the technical and clinical needs in a clinical setting [164]. Additionally, practitioners believe that they would make use of more user-

friendly technology that is aimed at enhancing patient outcomes [99]. Therefore, PPA companies could design the software to be more clinician user-friendly or offer clinical packages which can prioritise important/clinically relevant or remove the additional data which may be useful in research but not required for clinical outcome necessarily to reduce practitioners' needs to analyse raw data which facilitate clinical use of plantar pressure technology.

All participants in this study believed that training and education regarding the use and interpretation of plantar pressure data are important to improve the clinical use of this technology in clinics. How plantar pressure analysis skills can be acquired was discussed by participants. Most participants believed that the knowledge about plantar pressure measurement in clinical practice should be provided to students during their undergraduate studies. Some also considered continuous professional development (CPD) via postgraduate courses or short courses that aim to update practitioners regarding the latest knowledge and technology in this field. In addition, learning from colleagues and self-study via journals and books were considered as sources of learning by participants. It has been suggested that digital skills such as CAD-CAM have to be integrated in all podiatry curricula which is believed to play a prominent role in practically all facets of professional health life [169].

A previous qualitative study of clinician opinion has shown that currently an individual clinical orthotic practice is mostly based on training which develops over time based on practitioners' clinical experience and

variations amongst clinicians reflect how local factors and education are incorporated [99]. Their findings also indicate that when clinicians make a prescription decision, they consider patient's needs and expectations as well as the biomechanical corrections in insoles and footwear for foot position [99]. Interestingly, research and evidence-based guidelines relating to orthotic practice have a limited impact on clinicians' habits in diagnosis and prescription [99].

Learning via experience, or "experiential learning," is a widely accepted theory of skill acquisition [170]. It is recognised that practical skills are taught through learner participation, but delivering suitable experiential learning can be complicated, perhaps even 'very complicated' [100, 171]. The history-taking process and actively listening to the patient are essential components of the consultation in experience-based clinical practice. The main goal of treatment seems to shift to meeting patient expectations, which often includes biomechanical modifications, so clinicians spend time listening to the patient. This method of diagnosis and prescription departs from the conventional objectives of obtaining biomechanical correction via orthoses. This demonstrates the impact of experience over training as clinicians seek to achieve patient adherence to the treatment in addition to observe the policies of the services, they engage in. This is a recognised trend where practitioners' clinical decision-making is changed according to their experience rather than their training in order to meet clinical outcomes driven by service-led metrics [99, 172, 173].

6.1.2

Providing evidence and demonstrating the benefits of PP

Four participants suggested that the benefits of plantar pressure measurement in clinical management of diabetic foot should be provided to the NHS with strong evidence such as randomised control trial and systematic reviews to encourage them to invest in it. Llewellyn et al. (2014) utilised a series of interviews and surveys of members of staff, practitioners, managers, and commissioners to explore the organisational and policy context for adoption and implementation of clinical technology. They found that for adopting or implementing new clinical technologies, there is no central 'push' from the Department of Health or NICE to the NHS providers [165]. There is a 'bottom-up' adoption culture: any trust could choose to adopt the technologies. In some cases industry producers or clinicians was actively involved to negotiate the uptake of technology [165].

Organisational politics aside, although evidence-based practice (EBP) has received increasing attention in the field of using PPA to guide footwear and insole modifications for people with diabetes in the past few years [2-9, 120-122, 124-126], most practitioners feel more comfortable with the method of risk assessment and orthotic designs that they are familiar with and are not willing to try new ones. Also, current practices of footwear and insole for people with diabetes are mostly empirical and affected by "trial and error" and clinicians prescribe or modify orthoses based on their experience rather than science, so the spread of practice among practitioners is less common [99]. Therefore, some participants in our

study believed that in-person demonstrating the benefits of plantar pressure technology to fellow clinicians can help them to be convinced about the clinical use of PPA technology. Prior studies show that experiences of delivery of care reported by colleagues can often convince clinicians more than forms of scientific evidence via in service training, work shadowing or informal meeting [174, 175]. For example, one area where technology could support practitioners on a daily basis is the examination of insoles before the patient leaves the clinic to implement changes that would typically be made during the review. Unnecessary appointments could be avoided if the effectiveness of treatments would be evaluated and tested on the same day of the consultation. It would enable the practitioner to make any necessary adjustments to the insoles before the patient begins the intervention, ensuring both the efficacy of the procedure and the patient's satisfaction [165].

The other area that needs to be considered in training about PPA or demonstrating the benefits of that to clinicians is approach to use PPA to evaluate risk in diabetic foot management. According to our participants' reports, all three clinicians who are using PPA in their clinical practice are not aware of threshold values and consider colours to interpret the plantar pressure data. That is because this approach reduces data from absolute values to grades or conditions, is simple, understandable, and easy to communicate with patients. Although this type of data reduction can be evidence-based, e.g. red colour indicated plantar pressure more than 200 kPa, it should be highlighted that considering colour instead of actual pressure value could be misleading and dangerous for patient especially in

risk assessment. The use of single colour “red colour" in a plantar pressure device indicates that the pressure is over a specific level which is set in the software e.g., > 200 kPa, but the actual value could be much higher. Assessments which focus on only the colour reduce the ability to distinguish change in pressure or risk. Therefore, it is important to focus on both colours and values of the plantar pressures and not colours.

The ability to "see" what occurs inside the shoe while the patient is wearing the treatment is another issue that is typically taken into account when plantar pressure technology is implemented. With this knowledge, they would have a better understanding of how insoles function and would be better able to identify possible problems [99]. In-shoe pressure analysis via insoles has been developed with sensors provides feedback of the effect of offloading and is playing a growing role in footwear, insole and orthotic design [98]. Feedback on a treatment plan is crucial to understanding whether an intervention will be effective.

6.1.3

Time and space in clinic to undertake assessment

Participants in our study considered time limitation as a barrier to the clinical implementation of PPA. They believed that consultation time in the NHS is limited. In addition to taking too long to set up and operate, plantar pressure devices also produce results that are difficult to interpret and apply during consultations to design or modify insoles.

This finding and interpretation from the clinicians is consistent with previous studies in which time has been considered one of the main barriers in clinical implementation of technology [99-101, 113]. Martinez Santos et al, in a focus group discussion discovered that, although practitioners attempt to integrate plantar pressure technology into their practice, they all had negative experiences which caused them not to use the devices. They reported as they were not trained in PPA, they needed to spend too much time to set up and measure plantar pressure. Finally, they ended up working slowly or collecting wrong information. Also, they believed that plantar pressure data provide too much information however, most of them are not appropriate for clinic [25]. In clinical practice, clinicians have limited time for each patient and technology should be easy to use and set up and provide clear, easy to understand data for both the practitioner and patient to speed up the diagnosis and prescription processes [99]. However, the clinicians believed that technology is time-consuming to set up and calibrate to make the data outcomes worthwhile. The required time to use technology in clinic may be specifically challenging for newly qualified clinicians. Time management is a big concern for new clinicians and implementing a rehab facility and customising the device in addition to other tasks can also be very time consuming [101].

The time it takes for patients to learn how to walk along the designated walkway and land correctly on the pressure plate is also one reason why clinicians have little incentive to use technology solely for the investment of time. If the patient has a significant learning curve to use the device

(e.g., 10 learning trials) the clinician may be less interested in using the device [101].

A feasibility study in New Zealand showed that for using plantar pressure device as a clinical tool, the average duration of the test is 25 min – including the time required to give information about the test to participants and obtain their informed consent [107]. Most participants in our study reported that the consultation time in the NHS is 30 minutes for each patient and it is too limited to use, analyse, and interpret plantar pressure measurement in the routine clinical time.

The feasibility study regarding the clinical use of plantar pressure device also showed that the time required to participate was probably the greatest negative impact for patients. [107]. To avoid this, it would be sensible to do a pedobarography test during a separate appointment as opposed to an optional addition to an existing session. This would also have the added benefit of letting patients know in advance that they need to bring things like their regular shoes and offloading devices [107]. This aligns with the suggestion from some participants in our study, that allocated time and clinic for plantar pressure measurement would improve the clinical implementation of plantar pressure measurement.

6.1.4

Specific triage

The adoption of clinical technology can change the patient pathway and require new ways of working. When new technologies are implemented, organisational processes are redesigned, and employees are accustomed to different working practices [165]. Participants in this study also believed that facilitation in PPA technology can require some changes in triage and patient pathway. As some patients are not suitable for using plantar pressure measurement due to their clinical conditions organisational process can change toward specific triage. For example, patients with open wounds are not able to walk barefoot on platform or they have balance issue and are not able to walk without an assistive device. Previous studies have suggested that the use of a cane or walker has consequences in terms of plantar loading, as the relief gained through the use of these devices is likely to reduce the stress underfoot [93]. Therefore, having specific triage can help clinicians to decrease the number of patients for plantar pressure measurement in their diabetic clinics.

6.1.5

Human resource

Some staff within trusts can be targeted and trained to do plantar pressure measurement for patients; however, it could have the risk of

losing tacit knowledge in cases of leave or retirement of experienced staff. In addition to allocating specific time and space for plantar pressure measurement in selected patients, a few members of staff or newly recruited ones can be trained to cover the specific plantar pressure clinics.

Adopting new devices or procedures in clinical settings will improve by modification in organisational systems, the clinical process, and the staff members' working practices in a trust [165]. Prior research in the private sector suggests that negotiation of necessary changes to staff operations and tailor the implementation to the wider organisation is required to have a successful implementation of new technology [165, 176]. However, little research has been done on how organisational factors influence the adoption of new technologies in the NHS [165, 176].

Previous studies have shown that innovative medical technology may include new care models and forms of organisation for services and staff, such as "nurse-led care, integrated transmural care across the primary–secondary care interface, collaborative or shared care, hospital safety procedures, clinical decision support systems, clinical guidelines, and staff communication and information sharing systems" [177]. Moreover, Llewellyn et al believed that taking up new roles in staff is required to implement some new diagnostic and therapeutic medical devices [165].

6.1.6

Cost

The cost required for device and space were both perceived as a barrier in clinical use of plantar pressure measurement by most practitioners in our study.

As previous studies reported, new clinical technologies are not used routinely in clinical practice as they are expensive, time-consuming to use and complex to interpret [99, 164, 178].

Adoption of these new technologies initially increases provider costs as it requires training, impacts clinical process and patient management, and may lead to fewer patients treated in the short term [99, 165, 166, 179, 180].

Additionally, staff costs can also be included. As noted earlier, more staff should be needed to allocate time and space for plantar pressure measurement to a specific clinic to reduce the workload of clinicians performing the assessment during consultation time. A similar finding was reported by Llewellyn et al that showed, in some trusts, employing additional pathology staff to manage the increased workload resulted in a financial burden for the trust [165].

However, new clinical technologies can have considerable advantages to healthcare systems through improving effectiveness, efficiency and patient safety without raising costs [181]. It has been estimated that a 3% increase in spending on new technologies could lead to a 3% increase in

NHS productivity [182]. Moreover, modern technology can also significantly change the way healthcare is provided, focusing on more affordable "upstream" health promotion and disease preventive measures rather than pricy "downstream" interventions for end-stage disease. [183]. The cost-effectiveness of this approach in preventing foot ulcers and other complications will stimulate its adoption in clinical practice and help develop evidence-based guidelines. Some of the participants mentioned that although implementing this technology in clinical practice of diabetic care can be costly, a cost analysis can show a reduction of the occurrence of ulceration, particularly, which could lead to amputation, with using pedobarography would be very cost-effective. Currently a significant amount of the entire NHS budget goes towards diabetes care.

The DFU is a burden on the NHS and a disabling condition for people. Given the expense, affecting quality of life and risk of foot amputation, it is very important to understand how to more effectively manage diabetic foot syndrome. In the UK, 20 – 40% of healthcare resources which are allocated on diabetes are spent on diabetic foot [184]. Total direct costs to the NHS for complications of DFU have been estimated at £1.61 billion, or around 10% of the total annual direct cost of diabetes mellitus, which is £1 for every £175 spent by the NHS in England. Overall, total healthcare costs related to diabetic foot ulcers and amputations in the UK were estimated at £580.5 million in 2010-2011 [14]. These costs are primarily related to longer hospital stays, increased bed occupancy, and higher outpatient costs [14, 185]. However, ulcers and amputations also create costs for individuals and their families, such as lost work hours, decreased mobility, and commuting to surgery and clinics [14]. As DF ulcers become more

severe, treating the ulcers becomes very expensive. Additionally, patients who had both an infection and peripheral vascular disease reported needing more inpatient and outpatient care, an extended hospital stay, and more antibiotic therapy than those who did not have this complication [185]. The devastating repercussions of this condition and the significant financial burden it places on the NHS highlight the importance of improved management and preventative measures.

6.2 **Conclusion**

Technology has to improve practice without increasing the workload. Therefore, it is essential that technology be developed to satisfy the actual requirements of therapists. To enable the transition from research to clinical practice, technology developers should have a better understanding of the realities of practice earlier in the development processes which can be achieved through exploring clinicians' experiences of the realities of practice and the gaps that need to be filled in via surveys, focus group or interviews.

Undergraduate courses, CPD courses, short courses by manufacturers and self-study are the ways through which students can learn and clinicians can be updated about the plantar pressure measurement in diabetic foot management. The more knowledge the clinicians have, the more willingness they will have to modify their clinical practice.

PPA can be time-consuming to set up, to collect and to interpret within a typical consultation time. Specific triage and using PPA within a specific time and space by trained staff as part of a “plantar pressure clinic” can overcome these barriers.

In addition to the cost of device and maintenance, allocating specific clinic, space and staff to have a “plantar pressure clinic” can cause further financial burden in short time. However, prevention of DFU and amputation can reduce the long-term cost in the NHS.

7.0 Chapter 7: Conclusions to the whole thesis

This research has fulfilled its aim to explore the effectiveness and implementation of PPA in the clinical settings for people with diabetic foot syndrome. In doing so, it has offered the first detailed systematic review of the literature which offers implications to the use of PPA to optimise offloading characteristics of footwear and insole for the prevention of ulcer recurrence, and plantar pressure reduction in the diabetic foot, making a new and unique contribution to the body of knowledge. This fundamental understanding of the field can support clinical decision-making and enhance the future development of evidence based footwear, foot orthotics and insole interventions.

The result of our systematic review revealed that a range of evidence exists, of low to high quality, that the implementation of PPA in the design and modification of footwear and insoles can lead to more effective interventions to offload the diabetic foot. However, PPA as an objective quantitative method to optimise offloading features of footwear and insoles is still not currently a standard technique in diabetic foot management and where clinicians rely on clinical experience and a trial-and-error approach [133].

Next, the qualitative study aimed to explore Podiatrists' and orthotists' views and experiences of using plantar pressure measurement in the assessment and treatment of diabetic foot syndrome. This has highlighted a number of barriers to the use of technology which need to be addressed before it is possible to fully benefit from the use of this technology.

Our qualitative study showed that the barriers to implementation of PPA in clinical practice include lack of knowledge and education about the use and interpret of plantar pressure data, shortage of time and space in routine clinical practice, and high cost of purchase and implementation of this technology. Podiatrists' and Orthotists' views offered several solutions which could facilitate the implementation of PP in clinical practice.

To bridge the knowledge gap, they suggested that Undergraduate students can be taught clinical use of PPA. Also, clinicians can be trained and updated in clinical implementation of PPA through CPD, short courses run by companies or through up skilling from their colleagues or being self-taught. The barriers of a shortage of time and space in clinical settings could be overcome by managers or authorities allocating specific time and space for PPA to be used by one or two members of staff who are trained. Then, the patients to whom PP are appropriate are triaged specifically for PPA, resulting in improvement clinical implementation of PPA in diabetic foot management.

Limitations

Firstly, the primary methodological limitation of the current study is that the findings are not necessarily based on an objective fact but rather on the views and perceptions of the interviewees. However, it should be considered that when new technologies/processes are being implemented, this type of knowledge from evidence standards is required. Therefore, patient / clinician involvement is expected to understand their opinions into real-world problems [135].

Secondly, in a 1:1 interview process research breadth may be less than a large-scale survey due to smaller sample sizes, however, the depth and richness of the data can be enhanced by the use of open ended questions and more discussion in 1:1 interviews [149]. Also, focus group method could be considered for collecting data to gather diversity of opinions with reasonable speed [186]. However, one of its limitations is that some participants may provide more information than others or provide it in such a way that others may feel uncomfortable to express their ideas in front of their peers [186]. Additionally, in this study, having all participants, who would work in different cities, at a specific time and place, was difficult; therefore, we decided to choose 1:1 interview due our clinicians' availability.

Thirdly, the over-riding limitation and challenge to research in this area is the investigation of manageable sample sizes that offer a realistic representation for end-users of plantar pressure technology. Due to time limitations in the study as an MSc project, we had a small sample size.

Also, this study was exploratory to identify different perspectives about clinical implementation of PPA and did not aim to develop a theory. Therefore, saturation was not an aim in sampling of this study. We considered information power concept and purposively aimed to sample from people who were “information rich”.

Although, similar barriers and challenges arose for all participants, with no new themes or subthemes were raised in the final 2 interviews, it is recognised that further purposive sampling from different contexts (locations/education) may have provided more codes around the topic. If time had allowed, larger numbers of clinicians would have been interviewed.

Finally, although various regions in the UK may have different experiences and opinions on PPA in diabetic foot management, geographical information about the participants was not taken into account in this study. However, we have identified barriers and gained appropriate knowledge at this stage. This is the first work in this field and so, initial outcomes were needed before larger studies for further develop.

Recommendation for further studies

This work has established key barriers which exist for implementation of PPA. Further studies are suggested to expand on this to explore a

broader range of factors across wider geographical and clinical scope or settings.

Further work would look to test implementation of PPA where these factors are assessed or managed directly. Therefore, the next piece of work would move it forward to include a broader range of clinical partners to develop solutions to these barriers. Appropriate interventions would be developed and evaluated, according to the findings of the qualitative study, to facilitate the use of PPA in diabetic foot clinics and whether this can assist in provision of a better service.

A specific clinical time and space is advocated to facilitate clinical implementation of PPA. However, how much time and space are required in a diabetic clinic has not been established. It is recommended that in future studies minimum requirements regarding time and space for PPA should be defined.

It is recommended to conduct collaborations between academic, clinical and industry-based partners to establish standardised approaches in order to have training at undergraduate level and/or CPD for clinicians. It is also recommended to undertake further studies to explore how organisational systems and staff operations should be modified to adopt PPA in diabetic foot care clinical settings.

Finally after implementation of PPA, a service evaluation and audit can be recommended to investigate whether patient outcomes are improved by PPA and clinicians are happy with PPA in clinical setting.

8.0 Chapter 8: Appendix

8.1 Appendix A: interview questions

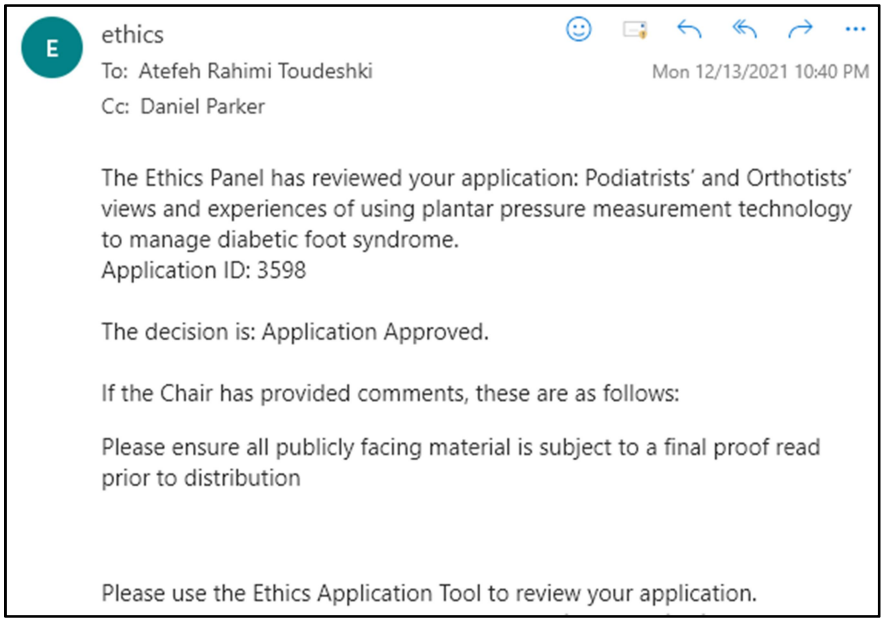
Intro	**Introduction** Thank you for agreeing to be interviewed. We will start with some questions around plantar pressure generally before asking more specific questions around diabetes and plantar pressure use, and specific barriers and facilitators to using plantar pressure in practice.
Section 1: General Questions	Q1: **Can you tell me about your perspective of plantar pressure for clinical use?** **Q2: Over your career, what is your experience of using Plantar Pressure?** **Q3: What have you found to be facilitators for using plantar pressure?** Prompts: Personal (knowledge, confidence), Social (Education, Colleagues, Mentor), Environmental (Equipment, Location, Specialism/patients treated)… (Do you know of anything for clinicians that might be a facilitator)/ rewording Q4**: What have you found to be barriers to using Plantar pressure?**

	Prompts: Personal (knowledge, confidence), Social (Education, Colleagues, Mentor), Environmental (Equipment, Location, Specialism/patients treated)…	
Section 2: Assessing Risk and management of patients with diabetes	**Q5**: **Can you tell me about your experience of using plantar pressure when assessing the risk and management of patients with diabetes?** **Q6: Do you feel there is any value to using plantar pressure for assessing risk and managing patients with diabetes?** **Q7: What have you found to be barriers to using plantar pressure for assessing the risk and managing patients with diabetes?** **Q8: What have you found to facilitate using plantar pressure for assessing the risk and managing patients with diabetes?**	
	IF NO	Q8: Can you tell me why you aren't using plantar pressure? **Q9**: **What made you stop using plantar pressure, or what is stopping you from choosing to use it again?**
	IF YES Facilitators	**Q11**: **What are your reasons and aims of doing this?** **Q**12: Where do you use plantar pressure? In some clinics or all? **Q13:** Do you have access to an in-shoe pressure system or a pressure platform? Or both? **Q14:** How often do you use plantar pressure? **Q15**: **How do you feel using plantar pressure**

		influences your practice?
Method – IF YES ONLY		**Q16**: **When analysing plantar pressure, which method do you use to analyse the data and why?** Q17: Have you heard of the threshold method? **Q18**: **If yes, and you use these – why?**
Section 3: Fitting Orthotics for patients with diabetes	**Q19**: **When fitting orthoses in patients with diabetes, do you use plantar pressure?** **Q20: Do you feel there is any value to using plantar pressure for fitting orthoses for patients with diabetes?** **Q21: What have you found to be barriers to using plantar pressure for fitting orthoses for patients with diabetes?** **Q22: What have you found to facilitate using plantar pressure for fitting orthoses for patients with diabetes?**	
Current situation	IF NO	**Q23**: **Can you explain to me why you don't use plantar pressure for this purpose?** **Q24: What made you stop using plantar pressure, or stopping you from choosing to use it again?**
	IF YES	**Q25**: **What are your reasons and aims of doing this?**

Method	IF YES ONLY	**Q26**: **When analysing plantar pressure, which method do you use to analyse the data and why?** **(How have you analysed any plantar pressure data in the past, or are you aware of how it might be analysed?)/ rewording** **Q27**: Have you heard of the threshold method? **Q28**: If you do not use the method, what are your reasons? **Q29**: If yes, and you use these – why? **Q30**: How do you feel using threshold method influences your practice?

8.2 Appendix B: Ethics approval



E

ethics

To: Atefeh Rahimi Toudeshki

Cc: Daniel Parker

Mon 12/13/2021 10:40 PM

The Ethics Panel has reviewed your application: Podiatrists' and Orthotists' views and experiences of using plantar pressure measurement technology to manage diabetic foot syndrome.
Application ID: 3598

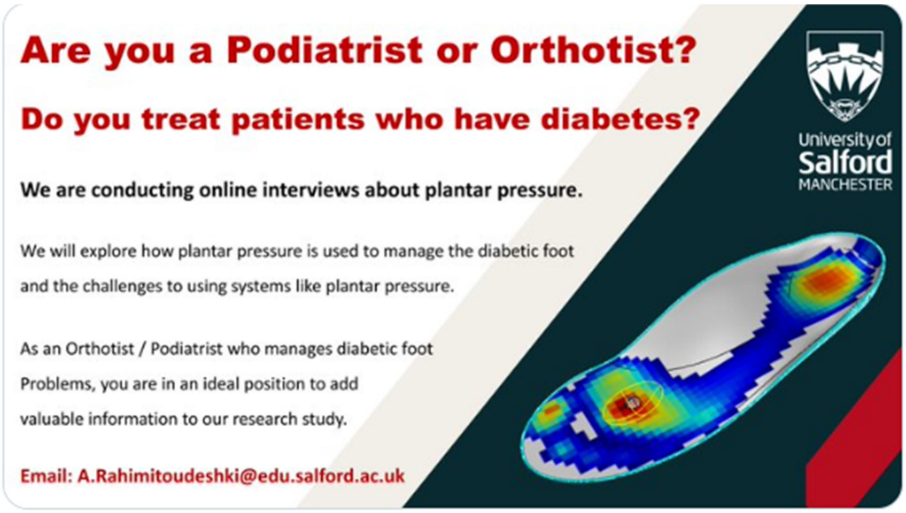
The decision is: Application Approved.

If the Chair has provided comments, these are as follows:

Please ensure all publicly facing material is subject to a final proof read prior to distribution

Please use the Ethics Application Tool to review your application.

8.3 Appendix C: invitation poster on LinkedIn and Twitter



8.4 Appendix D: Participant Information Sheet

"Title of study: Podiatrists' and Orthotists' views and experiences of using plantar pressure measurement technology to manage diabetic foot syndrome.

Name of Researcher: Atefeh Rahimi Toudeshki

1. Invitation paragraph

We would like to invite you to participate in a research project. Before you decide to participate, it is important that you understand the purpose of the research and what it would entail. Please read the following information sheet carefully. The Investigator [Atefeh Rahimi] will be happy to answer any questions you may have about the study before you decide whether to participate or not.

2. What is the purpose of the study?

This study will identify how we can improve the use of plantar pressure and, in particular plantar pressure thresholds in clinical practice in the management of diabetic foot syndromes. So, we will investigate the current barriers and facilitators to the implementation of plantar pressure and threshold method in risk assessment and orthotic prescription/design.

3. Why have I been invited to take part?

We have identified that you:

- An orthotist / podiatrist who is practising in the diabetic field
- An orthotist / podiatrist who has at least 5 years of experiences
- An orthotist / podiatrist who has a qualification in orthoses/podiatry and is HCPC registered
- An orthotist / podiatrist who has access to a computer
- An orthotist / podiatrist who is based in the UK

You will not be suitable to participate in this study if any of the following apply to you:

- You have worked alongside researchers to review pressure use in practice
- You have clinical academic contracts which relate to pressure research
- You have been employed by manufacturers and companies relating to the measurement of pressure

4. Do I have to take part?

No, it's totally up to you whether you want to be part of it. This information sheet describes what will happen in the study, and you will have 24 hours' time to review it before you consent to participate in the study. If you decide to attend an appointment, the study will be explained to you by the investigator and finally investigator will read the consent form for you and your consent will be recorded via Teams. You are free to withdraw at any time without providing a reason.

5. What will happen to me if I take part?

If you choose to participate, you have enough time to take all the information into consideration and ask questions. Then the investigator will explain the study to you and then you have time to ask questions and finally investigator will read the consent form for you and your consent will be recorded via Teams.

Afterwards, a time for an online interview will be set with you. Then, you will be sent an invitation link on Teams for the interview. Before starting the interview, the researcher will ask you some demographic questions. The semi-structured interview will take 20 to 30 minutes during which you will be asked about the current barriers and facilitators to the implementation of plantar pressure and threshold method in risk assessment and orthotic prescription/design and the audio will be recorded for analysis. Following your participation in the interview, you will be given the opportunity to review your transcript and change or rectify anything that you think is necessary.

Then, the interview will be stored on a secure password-protected drive at the University.

The interview will then be written up and analysed. The researcher will look for codes and themes across the data.

The data and outcomes are part of my qualification, once the interview data has been analysed, and may be published in academic journals or presented at Conferences or used as a public health resource. Your interview would remain anonymous, and your name will never be published.

6. What are the possible disadvantages and risks of taking part?

There are not any risks for participating in this study.

8. What are the possible benefits of taking part?

There will be no direct benefit to you from taking part in this study; however, the results of this study aim to improve the implementation of plantar pressure for care in diabetes patients.

9. What if there is a problem?

If you have any concerns about the study, you should ask to speak with the researcher, who will do her best to answer your questions. However, if you remain dissatisfied and wish to complain formally, you can do this through the University of Salford complaints procedure. Details can be obtained from the School of Health and Social Care office (0845 234 0184).

10. Will my taking part in the study be kept confidential?

Yes. All interviews will be anonymous, and all personally identifiable information which is collected about you during the research will be kept strictly confidential, and your name and contact details removed from any information about you which leaves the university so that you cannot be recognised.

We would only share any personally identifiable information if you reveal anything related to criminal activity and/or something that is harmful to yourself or others. In those situations, the researcher will have to share the information with the appropriate authorities.

The handling, processing, and storage of your data are in line with the Data Protection Act 1998 and the General Data Protection Regulations.

The audio recordings will be labelled under a pseudonym to protect your anonymity and stored on a secure password-protected drive at the University, accessed only by the research team.

11. What will happen if I don't carry on with the study?

You can withdraw from the study at any point without having to give a reason. Upon entering the study, you will be given an individual identification number. This will ensure your data is anonymous and stored under this code number. You can withdraw from the study during one week of confirming your transcript. Please contact the investigator using the contact details below and quote your identification number.

12. What will happen to the results of the research study?

The results of this study which is part of my qualification will be published in scientific journals and at professional conferences. You will not be identified in any report of the study results.

13. Who is organising or sponsoring the research?

The study is organised by the School of Health Sciences at the University of Salford.

14. COVID-19 risks control measures

Since the semi-structured interviews will be conducted online, "COVID-19 risks control measures" does not apply to this study."

15. Further information and contact details:

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8.5 **Appendix E: Consent form**

Title of study: Podiatrists' and Orthotists' views and experiences of using plantar pressure measurement technology to manage diabetic foot syndrome.

Name of Researcher: Atefeh Rahimi Toudeshki

1. I confirm that I have read and understand the participant information sheet for the above study. I have had the opportunity to consider the information and to ask questions which have been answered satisfactorily. Yes/No
2. I understand that my participation is voluntary and if I do decide to withdraw, I can withdraw without giving any reason, and without my rights being affected. Yes/No
3. If I do decide to withdraw, the timeframe for withdrawal is 1 week from the date of the interview. Yes/No
4. I agree to participate by completing demographic questions, being interviewed and audio recorded. Yes/No
5. I understand that my personal details will be kept for up to 3 years confidential and and will not be revealed to people outside the research team. I have been assured that no personally identifying details (such as my name) will be included in any reports or publications and the data will be kept confidential. Yes/No
6. I am aware that if I reveal anything related to criminal activity and/or something that is harmful to self or other, the researcher will have to share that information with the appropriate authorities. Yes/No
7. I agree to keep the details of this study confidential. Yes/No

8. I understand that my interview data will be used in a student dissertation, a research report, other academic publications or conferences/presentations. Yes/No

9. I agree to take part in the study. Yes/No

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