An Examination of the Effect of Prescription Footwear on the Kinematics and Kinetics of Gait: With a Focus on Diabetes and Materials

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List of abbreviations

EVA	Ethyl vinyl acetate
TCC	Total contact cast
PU	Polyurethane
RCT	Randomised control trial
RCW	Removable cast walker

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Throughout this thesis where mention is made to any of the above published works the text will be referenced with the publication number e.g. (Published work 10).

Collaboration statement

The published work presented in this thesis are as a result of collaborative research. As the lead author of the published work presented in Chapters 2 – 7 I carried out the main substance of the work. Statements by the collaborating researchers confirming the contribution I made to these published work are provided in Appendix 1.

Abstract

For the prescription of insole/orthoses a vast range of materials are available to clinicians and with the limited scientific evidence available on their effectiveness material choice is often based on the clinician's personal experience. Similarly therapeutic footwear play a major role in the prevention and treatment of diabetic ulcers and recommendations on suitable insole materials and construction are needed. The aim of the work undertaken in this thesis was to extend the current knowledge in the area of orthoses and prescription footwear in order to aid clinicians in patient treatment. Chapter 2 examined literature to date into materials used in footwear orthoses, concluding that at present recommendations for appropriate materials for different patient requirements are not possible. Chapter 3 examined the prescription procedures involved in the provision of foot orthoses by clinicians with an emphasis on material choice and highlighted the diversity in opinion among clinicians with regards to the available materials. Chapter 4 examined the characteristics of orthosis materials and how they affect gait providing information for a clinician to draw an evidence-based orthosis prescription centred on material properties. Two systematic reviews (Chapters 5 and 6) provide a concise review of research to date in the area of diabetic footwear, highlighting the dearth of information in the area, the limitations of the reviewed studies and providing recommendations for future research. The repeatability of a new pressure measurement system was examined in Chapter 7 with favourable results for the new system when compared to an established pressure measurement system. This research has contributed to clinical practice through the provision of valuable information on the performance of footwear materials and has led to the development of recommendations for future research in the area of prescription footwear.

Chapter 1: Introduction and outline of thesis

Orthoses and Prescription footwear

A foot orthosis can be described as a shoe insert that changes foot function (ISO 8549-1, 1989). They are used by clinicians to help relieve lower limb pathologies. Foot orthoses can be grouped into three categories: (1) off the shelf, (2) semi bespoke and (3) bespoke. Off the shelf devices are available in many different specifications which aim to cover a range of applications with limited adaptability for individual requirements. Semi bespoke devices allow clinicians to select a particular base insole and they can then apply patient specific modifications while bespoke devices are generally manufactured based on an accurate positive representation of the patient's foot with fabrication techniques including direct milling, heat moulding and injection moulding.

Prescription footwear is defined as footwear clinically prescribed and/or provided for the purpose of correcting, alleviating or replacing deficiencies or deformities in gait, feet or the lower limbs; where readily available everyday footwear cannot be modified for this purpose (Australian Government Department of Veterans' Affairs, 2009). This type of footwear is sometimes termed therapeutic footwear or medical grade footwear. Prescription footwear can be beneficial to a wide range of clinical conditions including hallux valgus, cerebral palsy, Charcot foot, and the *at risk* foot (rheumatoid arthritis and diabetes). The complexity of the footwear prescription is dependent on the patient's condition; the purpose of the footwear may be to simply fit the patient's foot correctly if they have a foot deformity which prevents them from wearing generic footwear or a more specialised prescription to affect foot function may be required.

Similar to orthoses, prescription footwear is generally grouped into three categories: (1) prefabricated/off the shelf, (2) customised and (3) custom made/bespoke. Prefabricated footwear is manufactured to standard specifications, an example of which is extra depth footwear. These footwear have extra space within the shoe to allow for toe deformities such as hammer toes or the addition of a customised insole or orthosis. As the complexity of the patient's medical condition increases the prefabricated footwear may still be applicable if individualised modifications are made, for example modifications to the sole unit, this footwear is then termed customised. Finally, there is custom footwear for patients with complex conditions and feet with gross deformities. In these patients it is not possible to prescribe prefabricated footwear as they will not fit correctly and in this case custom made footwear using casts of the patient's feet are required. Custom footwear are only prescribed

if absolutely necessary as they require a considerable amount of skill and time to manufacture and are more expensive to produce than prefabricated and customised footwear.

Prescription footwear for people with diabetes

Diabetes Mellitus is a chronic metabolic disease that occurs when the pancreas no longer produces insulin, or when the body cannot make good use of the produced insulin. Diabetes is a growing global issue with 382 million people living with diabetes in 2013, and this figure is expected to rise to 592 million by 2035 (International Diabetes Federation, 2013).

"Every 30 seconds a leg is lost to diabetes somewhere in the world" (The Lancet 2005)

People with diabetes can be affected by a range of complications and foot problems are a common and serious complication among this population. The lifetime incidence of foot ulceration in this population is reported to be as high as 25% (Singh et al., 2005). Neuropathy can lead to insensitivity, deformity (which is known to cause elevated plantar pressures (Bus et al., 2005)) and reduced range of motion in the joints of the lower limb. The presence of neuropathy and/or peripheral vascular disease in combination with ill-fitting footwear or acute trauma can lead to the development of ulcerations (Apelqvist et al., 1990). Inadequate shoe length, width, toe box height and the presence of internal seams are some of the footwear related issues attributed to ulcer development. In addition to ensuring the correct fit of footwear for this population as the presence of deformities can cause elevated plantar pressures the ability of the footwear to offload these areas of high pressures is important to prevent ulcer development. Offloading can be achieved through the combination of insoles/orthoses with the right materials properties to offload and footwear outsoles designed and constructed to offload the required area of the foot.

Material properties

The materials used to construct the outsole, insole and the upper of prescription footwear all require different properties to ensure they are fit for purpose. This thesis will focus on the properties of materials used in the construction of insoles/orthoses for prescription footwear.

The first orthoses were constructed from metal, wood, leather and fabric with modern devices now predominately produced using plastics and polymers (Kogler, 2007). With advances in material science there is now a vast amount of materials available to clinicians for use in insoles and orthoses (e.g. ethyl vinyl acetate (EVA), polyurethane, platazote and polypropylene). It is therefore important that information on the properties and characteristics of these materials are available to clinicians to enable them to make informed decisions on the material(s) to use in their prescriptions. However, generally material suppliers provide limited information on materials to clinicians with materials usually sold using brand names and possibly with information provided on the density of the material. For many clinicians the material choice tends to be based on personal experience, cost and/or availability (Campbell et al., 1982).

The need to quantify the properties of materials used in orthoses has been recognised by many researchers; with studies examining various material properties being carried out since the early 1980's (Campbell et al., 1982). These studies have generally completed a range of tests to assess different materials properties. No one material property can provide sufficient information on how a material will perform as an orthosis so it is essential to assess the material across a range of tests. For example if a material is solely tested on its ability to reduce force then it could wrongly be identified as a suitable orthosis material; some materials when new have a high ability to reduce force but after a short time they lose this ability. Therefore they are not recommended for use in orthoses as they would need to be replaced frequently making their use impractical and not cost effective.

A number of studies have utilised bench testing of materials, using equipment such as universal testing machines and custom designed equipment, to quantify properties such as compression, compression set, density, force distribution, hardness, resilience, shock absorption and stiffness (Campbell et al., 1982; Faulí et al., 2008; Lewis et al., 1991; Paton et al., 2007; Pratt, 1990; Rome, 1991; Sanders et al., 1998). Studies have also examined materials under simulated in shoe conditions (Campbell et al., 1984; Dixon et al., 2003; García et al., 1994) and with advances in technology researchers have utilised in shoe plantar pressure measurement to assess material performance during gait (Birke et al.,

1999; Burns et al., 2008; Lavery et al., 1997; Mohamed et al., 2004; Rogers et al., 2006; Tong & Ng, 2010; Windle et al., 1999).

Many of these studies lacked sufficient information on the specifications of the materials they tested to allow cross study comparisons; with studies using different thicknesses and densities of the same material which would result in significant differences in test results. Another factor which complicates this type of research is that is it not possible to have one list of materials properties which are important for all insoles and orthoses. Whether the orthosis is designed to be accommodative or functional will dictate the materials properties that are most relevant to its purpose.

In an effort to enable research findings on the properties of orthosis materials easy to interpret and applicable to clinical practice a number of researchers have developed their own materials performance index to categorise materials for different purposes (Faulí et al., 2008; Lewis et al., 1991; Lo et al., 2014; Paton et al., 2007). However so far, none of these indexes are without limitations. Three of these articles categorised the materials they tested into three groups based on their required function. However, while the three groupings were similar across studies, there was no consensus among these researchers around the terminology for these groups which causes confusion. Paton et al. (2007) termed their three material groupings as control, dampening and moldable, while Faulí et al. (2008) used adaptation, cushioning and filling and the most recent study by Lo et al. (2014) using accommodation, cushioning and control. The most significant limitation of these studies is the findings are based on bench testing which do not replicate the loading the materials undergo during gait and the in-shoe environment.

Kinetics and kinematics of gait

Kinetics (study of the forces that cause the body to move) and kinematics (study of the geometry of movement) are utilised in footwear research to quantify the effect of material properties of footwear on gait. Three dimensional motion capture using equipment such as cameras, force plates, pressure walkways and in-shoe pressure measurement systems are employed by researchers in this field. In terms of kinematics researchers generally assess the effect of different footwear combinations on the range of motion and the patterns of movement of the joint angles of the foot, ankle, knee, hip and pelvis during gait. While for kinetic analysis, the ground reaction forces, peak pressures and pressure time integrals are examined.

As discussed above, a limitation of much of the research to date on the material properties of footwear is that it involved bench testing. This type of testing does not adequately replicate the loading experienced by the insole/orthosis during gait. However, with the commercial availability of in-shoe plantar pressure system since the late 1980s researchers have had the ability to examine the interaction between the foot and an insole/orthosis (Birke et al., 1999; Burns et al., 2008; Lavery et al., 1997; Mohamed et al., 2004; Rogers et al., 2006; Tong & Ng, 2010; Windle et al., 1999).

Aim and objectives

With the vast range of materials available to clinicians for the prescription of insole/orthoses and the limited scientific evidence available on their effectiveness material choice is often based on the clinician's personal experience. With regards to people with diabetes, therapeutic footwear play a major role in the prevention of ulceration and recommendations on suitable insole materials are needed. Therapeutic footwear can also be used in the treatment of foot ulceration and again more information on suitable materials in their construction is required. Thus, the overall aim of the work undertaken in this thesis was to extend the current knowledge in the area of orthoses and prescription footwear in order to aid clinicians in patient treatment.

The objectives of this work were:

- To conduct a literature review into the materials used for footwear orthoses with a view to identify gaps in testing methodology and material composition and to document the relationship between mechanical testing of materials and testing completed on the insoles/orthoses during gait (Chapter 3).

- To investigate the prescription procedures involved in the provision of foot orthoses by orthotists and podiatrists, evaluating the clinical reasoning behind the prescription procedure with a particular emphasis on material choice (Chapter 4).

- To quantify the effect of insole material on the plantar pressures and lower limb kinematics of walking gait (Chapter 5).

- To examine the effectiveness of currently available diabetic footwear in the prevention (Chapter 6) and treatment (Chapter 7) of foot ulcers in patients with diabetes through structured systematic reviews.

- To assess the repeatability of a new measurement system for the continuous monitoring of plantar pressures and to compare the results of this system to an established pressure measurement system (Chapter 8).

Scope of the Investigation

The scope and boundaries of the reported work were:

- To conduct a narrative literature review into the materials used for footwear orthoses to allow for a comprehensive overview of the review topic; and not a systematic review of research in this area.

- To investigate the prescription procedures involved in the provision of foot orthoses by orthotists and podiatrists. This investigation focuses on gaining an understanding of the clinicians' prescription procedures; and not the exactitude of their clinical practices.

- To quantify the immediate effect of insole material on the plantar pressures and lower limb kinematics of walking gait; and not to assess the long-term effects of the materials or provide recommendations for clinical practice.

- To examine the effectiveness of currently available diabetic footwear in the prevention and treatment of foot ulcers in patients with diabetes through structured systematic reviews; and not to design or develop new footwear.

- To conduct a preliminary assessment of the between day repeatability of a new measurement system for the continuous monitoring of plantar pressures and to compare the results of this system to an established pressure measurement system; and not to fully ascertain the repeatability and reliability of the system.

The body of work which forms the core part of this thesis started five years ago with a collaborative project between Staffordshire University and Salts Techstep, a footwear manufacturer. Research was conducted with an emphasis on diabetic footwear leading to 3 published articles (Chapter 2 - 4). These publications implemented different research methodologies; one of these publications was a review article, one involved a qualitative methodology and the final a laboratory based quantitative approach. Subsequently, as part of the DiaBSmart project two systematic reviews (Chapters 5 and 6) were completed which provide a concise review of research to date in the area of diabetic footwear, highlighting the dearth of information in the area, the limitations of the reviewed studies and providing recommendations for future research. A major limitation of research to date which examined prescription footwear, as identified in the two systematics reviews, is the ability to accurately monitor a patient's adherence to a footwear intervention. Also, the ability to continually monitor plantar pressures as patients complete their activities of daily living would be beneficial to gain a complete understanding of the pressures experienced by the feet on a daily basis. The WalkinSense® (Kinematix, Portugal) is a recently developed commercially available system which allows for both continuous activity and plantar pressure monitoring. The repeatability of this system was examined in a laboratory study and the results were compared to those of an established pressure measurement system (Chapter 7) with favourable results for the new system.

While some of the published work within this thesis is focused on diabetes (Chapters 3-6) the findings from this work are applicable to other patient groups requiring offloading, for example the "at risk" foot in patients with rheumatoid arthritis. Chapters 2-4 examine the materials utilised in orthoses and Chapter 7 presents a pressure measurement device capable of examining the offloading capabilities of orthoses material.

Outline of the thesis

This thesis presents, discusses and evaluates the content and contribution of a group of published papers that the author believes make a substantial contribution to the fields of footwear science and clinical biomechanics. The work represents the development of the author's research interests over a period of 5 years.

The thesis is based on research completed during a Knowledge Transfer Partnership (October 2009 – June 2010) and the DiaBSmart project (a research project funded by the European Commission from November 2011 – present). It is designed to

show that the published work constitute a coherent body of work. The research conducted in the six published articles were primarily designed and completed by Aoife Healy, and who as the lead author of the published work, was responsible for the drafting and final revisions of the published articles.

The main body of the document contains the published work which is presented in a conceptual sequence instead of completely chronologically. Following the presentation of the publications the contribution of the work to the body of knowledge in this area is discussed and finally clinical implications of the research and recommendations for future research are provided.

Chapter 2 (Materials used for Footwear Orthoses: A Review) is a review article which examined literature to date which tested materials used in footwear orthoses. It was concluded that research to date does not allow for a conclusive answer as to what are the most appropriate footwear orthosis materials for different patient requirements.

Chapter 3 (An investigation into the prescription procedures and material choice involved in the provision of bespoke foot orthoses for diabetic patients) aimed to examine the prescription procedures involved in the provision of foot orthoses by orthotists and podiatrists with an emphasis on material choice. This research highlighted the diversity in opinion among clinicians with regards to the available materials. Clinicians' views were divided on whether they believed the materials available to them were fit for purpose and also across the range of materials they chose to use.

As evidenced by the two previous chapters (2 and 3) there is a paucity of research providing recommendations on the orthosis or material used in its construction for different patient requirements. The objective of the study in Chapter 4 (Effect of insole material on lower limb kinematics and plantar pressures during treadmill walking) was to gain a greater understanding of the characteristics of orthosis materials and how they affect gait so to enhance the clinical decision-making process. The materials chosen for testing were based on the findings from the questionnaire study in Chapter 3. Findings from this study provide information for a clinician to draw an evidence-based orthosis prescription centred on material properties.

Chapter 5 (The effectiveness of footwear as an intervention to prevent diabetic foot ulceration or to reduce biomechanical risk factors for ulceration: a systematic review) is a systematic review article which examined the effectiveness of footwear as an intervention for prevention of diabetic foot ulcers. While the reviewed studies showed support for the use of rocker sole footwear and custom orthoses generic recommendations on these

features are not possible as the optimal design will be patient specific. In this article the limitations of the reviewed articles are discussed and recommendations for future research are provided.

Chapter 6 (The Effectiveness of Footwear and Other Removable Off-loading Devices in the Treatment of Diabetic Foot Ulcers: A Systematic Review) is a subsequent systematic review article to that presented in Chapter 5. This review examined the effectiveness of footwear in the treatment of ulceration. While footwear appeared to be the least effective off-loading intervention in ulcer treatment it has a place in certain circumstances, for example in patients for which the use of total contact casts is contraindicated.

Chapter 7 (Repeatability of WalkinSense® in shoe pressure measurement system: A preliminary study) examined the WalkinSense® in shoe pressure measurement system. This system is compact and allows for continual monitoring of a patient's plantar pressures during their daily activities. This study compared the WalkinSense® to the F-Scan system, which is known to be reliable for clinical measurement, with results finding the system as repeatable as the F-Scan.

Chapter 8 (Discussion) integrates the findings of the previous chapters and provides a critical appraisal of the published work.

Chapter 2: Materials used for Footwear Orthoses: A Review

Healy, A., Dunning, D. and Chockalingam, N. (2010)

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Materials used for footwear orthoses: a review

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Footwear orthoses have been used by clinicians for many years to treat lower limb pathologies. Materials traditionally used included wood, leather and fabric with recent advances in material sciences leading to the addition of many materials which have suitable properties and characteristics. Clinicians need an understanding of the properties and characteristics of orthosis materials to make informed decisions on the most appropriate material to meet their patients' needs. The objective of this study was to complete a literature review into materials used for footwear orthoses. Studies were grouped into three categories based on methodology: (1) bench testing, (2) simulated in-shoe conditions testing, and (3) testing of materials when placed in footwear while walking or running. Research to date has used a broad range of testing methodologies to examine an extensive range of materials. The lack of information provided by some researchers on the specifications of the materials they tested compromises the ability to directly compare studies. The age of the material tested was found to affect results. Bench and simulated in-shoe conditions testing, while beneficial in providing general information on the characteristics of the materials, only allow for speculation on how the materials would perform when placed in footwear. Conclusions on the characteristics of materials made by some researchers appear to be dependant on the relative relationships between the materials tested within their own research.

Keywords: foot; orthosis; insole; material properties

1. Introduction

A footwear orthosis can be described as a shoe insert that changes foot function (International Organization for Standardization 1989. ISO 8549-1:1989). They have been used for many years to help relieve lower limb pathologies. The clinician's role in orthosis prescription is not only to assess the biomechanical pathologies of their patients; they should also have an understanding of the properties and characteristics of the orthosis materials available to them (Olson 1988). Shurr and Cook (1990) proposed that the important characteristics of materials used in orthoses are strength, stiffness, durability, density, corrosion resistance and ease of fabrication. While Campbell *et al.* (1982) listed biocompatibility, ease of use, ease of fabrication, availability, durability, simulation of the mechanical properties of soft tissue, subjective comfort, cost and pressure distributing properties as their considerations when selecting a material. To fulfil their defined role footwear orthoses need to have both shock attenuation and movement control characteristics in varying degrees. Early orthoses were constructed from metal, wood, leather and fabric with advances in material sciences in the past 60 years introducing thermoplastic and thermosetting materials, foamed plastics, and viscoelastic polymers that possess suitable properties and characteristics for use in orthoses (Kogler 2007). Custom footwear orthoses are generally manufactured based on an accurate positive representation of the patient's foot with fabrication techniques including direct milling, heat molding and injection moulding. While the ever increasing amount of new materials suitable for use in orthosis prescription allows the clinician to tailor the orthosis material chosen to the individual needs of each patient this will only occur if the clinician is well informed on the properties and characteristics of these new materials.

2. Objective

The main objective of this manuscript is to conduct a thorough literature review into the materials used for footwear orthoses with a view to identify gaps in testing methodology and material composition and to

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document the relationship between *in-vitro* and *in-vivo* testing.

3. Methods

Initial searches were conducted in the electronic databases ScienceDirect and Pubmed using the keywords 'footwear' and 'orthosis' or 'orthotic' or 'insole' and 'material'. These searches were then supplemented by tracking all key references from the appropriate articles identified. A narrative literature review methodology was employed. This was deemed most appropriate as it allows for a comprehensive overview of the review topic to be produced as opposed to other methods, such as systematic reviews, which focus on a specific question.

Research to date that has evaluated the properties of materials used in the manufacture of foot orthoses has tested a extensive range of materials using a wide range of equipment, including different bench testing systems (e.g., UTM and custom designed and fabricated equipment) and in-shoe pressure systems (e.g., FScan (Tekscan Inc., USA) and Pedar (Novel gmBh, Germany)). Direct comparison between studies that have examined the same material is complicated as some researchers use generic names for materials whilst others use trade names without documenting the materials properties and also due to the different thicknesses, densities and hardness (Shore A and O) in which each material is available. For this review the material terminology used replicates that used by the original researchers.

Within research the terms insole and orthosis and often used interchangeably, this review will base its terminology on the definition that an orthosis is designed to change foot function (International Organization for Standardization 1989. ISO 8549-1:1989). Therefore the following definitions are given for the terms used within the review:

- Flat insole: insole which has been cut from a flat sheet of material.
- Custom insole: insole which has been customised to a participant's foot shape.
- Prefabricated insole: insole manufactured to standard specifications.
- Custom fabricated orthosis: device which is custom designed to change the participant's foot function.

The articles were classified into three general categories according to the testing methodology: (1) bench testing, (2) simulated in-shoe conditions testing, and (3) testing of materials when placed in footwear while walking or running. Tables 1 3 provide details on the studies which have tested foot orthosis materials.

4. Results

4.1. *Bench testing of materials*

A limited number of studies were located which bench tested orthosis materials and with only one of these completed in the last 10 years the majority of these studies are outdated. While some of the researchers used modified versions of ASTM standards (Campbell *et al.* 1982, Sanders *et al.* 1998) to test the materials, the remainder used various different pieces of equipment and procedures to measure a wide range of material properties.

Early research by Campbell *et al.* (1982) provided bench testing of 31 materials examining compression in an effort to assess each material's suitability for use in orthoses. This study proposed a possibility of correlating each material's compression characteristics with characteristics that are desirable for clinical interventions, although bench testing cannot simulate the in-shoe environment and therefore cannot predict a materials in-shoe performance. Disc shaped samples (2.85 cm diameter and 6.36 cm^2 cross-sectional area) were cut from each material and placed on an Universal Testing Machine (UTM) for testing. The samples were compressed at a constant rate of 10 mm/min to a maximum load of 23 kg to obtain the stress strain relationship of each material. This resulted in three groups of materials as shown in Table 4 for the authors to conclude that the moderately deformable group were the most appropriate for use as an orthosis. Furthermore, these materials would allow the transfer of high pressure at bony prominences to the surrounding areas of the foot during foot loading. The materials in the highly deformable category were found to reach their limit of deformation at a low stress (about 0.5 kg/m^2) while the very stiff materials deformed very little under compression making both these groups unsuitable materials for redistributing stress during foot loading. However, they stated that selection of a particular material for use as an orthosis material should not solely be based on the compression stress strain curve as many other factors (e.g., compression set) must be considered.

A more recent study by Sanders *et al.* (1998) extended the work of Campbell *et al.* (1982) classifying the materials they tested based on quantitative analysis of the stress strain curves as opposed to the qualitative assessment procedure used by Campbell *et al.* (1982). Two tests (10 and 60 min duration) were performed on samples of each material (11.1 mm diameter) using a

Table 1. Details of studies which completed bench testing of materials.

Author (year)	Materials tested			Testing equipment	Outcome measures
Campbell *et al.* (1982)	Aliplast-4E	Evazote (1.6 mm thick)	Pacer	Instron (model 1125)	Stress–strain curve
	Aliplast-10	Evazote (12.77 mm thick)	Pelite (1.6 mm thick)		
	Aliplast-6A	High Density Neoprene	Pelite (12.7 mm thick)		
	Bonfoam	Kemblo	Plastazote-Low Density (3.2 mm thick)		
	Carpet – Polypropylene (pile weight of 0.74 kg m^{2})	Lynco	Plastazote-Low Density (6.35 mm thick)		
	Carpet – Wool (pile weight of 1.15 kg m^{2})	Neoprene-431 (3.2 mm thick)	Polyurethane Foam		
	Celltite	Neoprene-431 (6.35 mm thick)	Poron-17125		
	'Dr. Scholl's Cushion Insole'	Neoprene-R 425N (3.2 mm thick)	Poron-20125		
	Ensolite (3.2 mm thick)	Neoprene-R 425N (6.35 mm thick)	Poron-Sport		
	Ensolite (6.35 mm thick)	'Odor-Eater Insole'	Spenco		
	Ethafoam				
Fauli *et al.* (2008)	60/40 (12 mm)	Lunalastik (3 mm)	Podialene 160 carne perforado (3 mm)	Hardness meter (Asker C), modified Schob pendulum, UTM, compression set equipment, compression fatigue test machine, permeabilimeter	Density, Hardness, Resilience, Stress–strain characteristics in compression, compression set resistance and compression fatigue resistannce, water vapour permeability and perspiration resistance
	Evamic (5 mm)	Lunasoft SLW (6 mm)	Podialene 200 (5 mm)		
	Herbal Foam Duro (5 mm)	NSL (4 mm)	Podiane I + perforado (1.5 mm)		
	Herbiform Multicolor (2 mm)	Ortheva (4 mm)	Poron (3 mm)		
	Herbiform Plus perforado (1.8 mm)	Orthomic (3 mm)	Poron (5 mm)		
	Herbimed (3 mm)	Orthomic (4 mm)	Porón densidad médica (2 mm)		
	Herbiprex granate (3 mm)	Pelite (3 mm)	Superlátex (4 mm)		
	Herbiprex.Lite (3 mm)	Plastazote (3 mm)	Superlátex (5 mm)		
	Lunairmed (6 mm)	Podialene 160 azul perforado (4 mm)	Superlátex (6 mm)		
	Lunairmed (12 mm)	Podialene 160 blanco (5 mm)	Verde (2.6 mm)		
Lewis *et al.* (1991)	Hygard (3.18 mm)	Poron (high modulus; density 481 kg m^{-3}; 0.79 mm)	TL-61 Standard (1.65 mm)	Resiliometer	Shock absorption capacity and energy return ability
	Hygard (6.36 mm)	Poron (high modulus; density 481 kg m^{-3}; 1.58 mm)	TL-61 Standard (1.91 mm)		

(*continued*)

Table 1. Continued.

Author (year)	Materials tested			Testing equipment	Outcome measures
	Hygard (55 mm)	Poron (high modulus; density 481 kg m^{-3}; 2.37 mm)	TL-61 Standard (3.81 mm)		
	Isoloss LS (1.52 mm)	Sorbothane (hardness 50 durometer; 1.52 mm)	Viscolas (3.96 mm)		
	Isoloss LS (2.29 mm)	Sorbothane (hardness 50 durometer; 2.54 mm)	Viscolas (7.92 mm)		
	Isoloss LS (3.05 mm)	Sorbothane (hardness 50 durometer; 3.18 mm)	Viscolas (11.88 mm)		
Paton *et al.* (2007)	Cleron 3 mm Cleron 6 mm EVA high density 12 mm EVA medium density 12 mm Lunacell Nore EVA 12 mm	MaxaCane 3 mm MaxaCane 6 mm Plastazote low density 6 mm Poron 92 6 mm Poron 94 6 mm	Poron 96 6 mm Poron 4000 3 mm Poron 4000 6 mm PPT 3 mm PPT 6 mm	Custom designed equipment and micrometer	Density, resilience, stiffness, static coefficient of friction, durability and compression set
Pratt *et al.* (1986)	Plastazote medium density (45 kg m^{-3}) 6 mm Poron (PPT) 6 mm	Sorbothane 5–6 mm Spenco 5–6 mm	Viscolas 5–6 mm	Ball bearing and force plate	Height of first peak after contact with material and vertical ground reaction force
Rome (1991)	Closed cell rubber Plastazote	Plexidur O PPT	Vitrathene	Hounsfield type tensometer, shore durometer, Instron 1115 and micrometer	Density, tensile strength, hardness, compression and compression set
Sanders *et al.* (1998)	Nickelplast Nylon reinforced silicone Pelite (soft)	Pelite (firm) Plastazote (firm) Plastazote (regular)	Poron Spenco (thickness of all materials was as near to 4 mm as was available from distributor)	Custom designed equipment	Compressive stiffness and coefficients of stiffness

Table 2. Details of studies which completed simulated in-shoe testing of materials.

Author (year)	Materials tested			Testing equipment	Outcome measures
Brodsky *et al.* (1988)	Pelite (medium) 5 mm Plastazote (soft) 6.6 mm	PPT 6.5 mm Sorbothane 6.55 mm	Spenco 7 mm	Instron (with two custom designed and fabricated jigs)	Compression, combined shear-compression and force distribution
Campbell *et al.* (1984)	Aliplast-4E Aliplast-10 Aliplast-6A Bonfoam Carpet – Polypropylene (pile weight of 0.74 kg m^2) Carpet – Wool (pile weight of 1.15 kg m^2) Celltite 'Dr. Scholl's Cushion Insole' Ensolite (3.2 mm thick) Ensolite (6.35 mm thick) Ethafoam	Evazote (1.6 mm thick) Evazote (12.77 mm thick) High Density Neoprene Kemblo Lynco Neoprene-431 (3.2 mm thick) Neoprene-431 (6.35 mm thick) Neoprene-R 425N (3.2 mm thick) Neoprene-R 425N (6.35 mm thick) 'Odor-Eater Insole'	Pacer Pelite (1.6 mm thick) Pelite (12.7 mm thick) Plastazote-Low Density (3.2 mm thick) Plastazote-Low Density (6.35 mm thick) Polyurethane Foam Poron-17125 Poron-20125 Poron-Sport Spenso	Oven and custom designed and fabricated equipment	Log standardized strain and thickness
Curryer and Lemaire (2000)	Conformagel (gel) Plastazote	PPT Soft shear (gel)	Spenco (all materials approximate thickness 4 mm)	Force plate	Peak force, impulse and resultant shear force
Dixon *et al.* (2003)	Polyurethane elastomer (Shore O 45, 3 mm) Polyurethane foam (Shore O 22, 6 mm) attached to a high density EVA footbed (Shore O 80 with max heel height of 8 mm and forefoot thickness of 4 mm)	Polyurethane foam (Shore O 40, 6 mm in the heel and 3 mm in the forefoot) with polyurethane elastomer (Shore O 45, 1 mm) inserted in the heel and ball of the foot area	Coarse weave plastic (3 mm) base with a top sheet of nylon nonwoven fabric (Shore O 60)	Instron (model 1125)	Stiffness and shock absorption
Foto and Birke (1998)	Plastazote #1 6.4 mm and Plastazote #2 6.4 mm Plastazote #1 6.4 mm and Poron 6.4 mm	Plastazote #1 6.4 mm, Poron 1.6 mm and Microcel Puff 4.8 mm Poron 6.4 mm and Plastazote #2 6.4 mm	Spenco 6.4 mm and Microcel Puff Lite 6.4 mm (1st material in all five samples was the top cover the softest material of each composite)	Customized cyclical compression tester	Stress–strain curve and dynamic compression set

(*continued*)

Table 2. Continued.

Author (year)	Materials tested			Testing equipment	Outcome measures
García *et al.* (1994)	Implus (1.7, 3.4 and 5.5 mm) Noene (2.2 and 4.4 and 8.4 mm)	Poron 1 (2.2, 4.7 and 6.5 mm) Poron 5 (2.2, 4.7 and 6.0 mm)	Sorbothane (2.1, 4.0 and 8.0 mm)	Instron (model 8501) and Rockland cross-channel spectrum analyser (model 5820B)	Rigidity and energy absorption
Gillespie and Dickey (2003)	Microcel-puff	Plastazote	Spenco	Force plate	Initial peak force, force loading rate, filter-bank analysis
House *et al.* (2002)	Polyurethane foam (6 mm) on a high density EVA heel cup Polyurethane foam (6 mm) with visco-elastic polymer inserted in the heel and ball of foot (1 mm)	Saran insole	Viscoelastic polymer (3 mm)	Instron and Parotec in-shoe pressure measurement system	Stiffness, peak deceleration and peak pressure
Kuncir *et al.* (1990)	Aliplast 4E Aliplast 6A Dermaplast (medium density) Dermaplast (firm density)	Evazote Pelite (soft density) Pelite (medium density) Pelite (firm density)	Plastazote (medium density) Plastazote (firm density) (all materials 2.54 cm thickness)	Static load tester	Compression and recovery rates and peak pressure
Leber and Evanski (1986)	Dynafoam Latex foam Molo	Ortho felt Plastazote PPT	Spenco (all materials 3.2 mm thickness)	Harris and Beath foot printing mat	Plantar pressure
McPoil and Cornwall (1992)	PPT	Spenco	Viscolas (all materials 3.2 mm thickness)	EMED-SF pedograph force plate system	Maximum vertical force, vertical force-time integral and maximum plantar pressure
Sanfilippo *et al.* (1992)	Nickelplast Pelite	Plastazote (firm density) PPT	Spenco (all materials 3.2 mm thickness)	EMED-SF pedograph force plate system	Vertical force, force time integral, peak plantar pressure, pressure time integral and contact area

Table 3. Details of studies which completed testing of materials when placed in footwear while walking or running.

Author (year)	Materials tested			Testing equipment	Outcome measures
Birke *et al.* (1999)	Poron (Shore O value 14) Poron (Shore O value 17) Poron (Shore O value 22)	Poron (Shore O value 27) Poron (Shore O value 32) Poron (Shore O value 40)	Poron (Shore O value 55) (all materials 6.35 mm thickness)	EMED Pedar in-shoe system	Mean peak plantar pressure
Burns *et al.* (2008)	Microcel Puff/Poron/ Microcel Puff – 6 mm Poron (extra soft) 6 mm Poron (soft) 6 mm	Poron Performance 6 mm Poron Performance 6 mm/Poron medical 6 mm Spenco 3 mm	Spenco 3 mm/Poron Medical 6 mm Step 2 Evolution (contoured multidensity)	Pedar-X in-shoe system, Foot health status questionnaire (FHSQ), Foot comfort (visual analog scale)	Peak plantar pressure, pressure time integral, foot pain and foot comfort
Dixon *et al.* (2003)	Polyurethane elastomer (Shore O 45, 3 mm) Polyurethane foam (Shore O 22, 6 mm) attached to a high density EVA footbed (Shore O 80 with max heel height of 8 mm and forefoot thickness of 4 mm	Polyurethane foam (Shore O 40, 6 mm in the heel and 3 mm in the forefoot) with polyurethane elastomer (Shore O 45, 1 mm) inserted in the heel and ball of the foot area	Coarse weave plastic (3 mm) base with a top sheet of nylon nonwoven fabric (Shore O 60)	Force plate, video camera and peak motus software	Peak force, ankle and knee flexion angles
Forner *et al.* (1995)	Implus	Noene	Poron 5	Force plate and accelerometers	Vertical force and acceleration parameters
Johnson 1988	Nonshock insole Sorbolite insole Sorbothane heel insert	Sorbothane insole (Walking) Sorbothane insole (Lightweight) Sorbothane insole (Hard blue)	Sorbothane insole (Red) Sorbothane insole (Soft Blue) Viscolas insole	Accelerometer fitted to the leg	Shock Factor
Lavery *et al.* (1997)	Pelite (3.2 mm) and Plastazote (medium density, 3.2 mm)	PPT (3.2 mm) and Plastazote (medium density, 3.2 mm)		Novel Pedar in-shoe system and automated stress–relaxation creep indenter system	Peak plantar pressure, pressure time integral and compressive stiffness
Mohamed *et al.* (2004)	Plastazote (medium density)	Plastazote (medium density) and Aliplast		Novel Pedar in-shoe system	Peak plantar pressure, maximum mean pressure, pressure time integral, mean force and contact area
Pratt *et al.* (1986)	Plastazote medium density (45 kg m^{-3}) 6 mm Poron (PPT) 6 mm	Sorbothane 5–6 mm Spenco 5–6 mm	Viscolas 5–6 mm	Accelerometer mounted between the teeth of a person and a force plate	Acceleration and vertical ground reaction force

(*continued*)

Table 3. Continued.

Author (year)	Materials tested			Testing equipment	Outcome measures
Pratt *et al.* (1990)	Gait Aid (proprietary insole) Plastazote (45 kg m^{-3}; 3 mm)	PPT (3.5 mm)	Viscolas (proprietary insole)	JP Biomechanics Shock Meter	Shock factor
Rogers *et al.* (2006)	Poron (6.4 mm)	Plastazote (top layer; 3.2 mm) and Poron (3.2 mm)		FScan in-shoe system	Peak plantar pressure
Tong and Ng (2010)	Slow recovery Poron (extra soft 4790-92) Poron (soft 4708-blue)	Poron (soft 4708-blue) and Plastazote (firm 30 shore A durometer)	Poron (soft 4708-blue) and Plastazote (soft 15 shore A durometer) (all materials 6.2 mm thick)	FScan in-shoe system	Minimum, maximum and mean peak pressure
Windle *et al.* (1999)	Cambion (Epoflex base varying from 1–5 mm thickness, with top layer (1 mm) Poron) PPT (3 mm)	Saran (Base of polyvinylidene chloride (3 mm) with nylon non-woven fabric top sheet)	Sorbothane (Polyurethane foam footbeds with 1 mm layer of Sorbothane in the heel and ball of the foot and a polyester fabric top sheet)	Paratec in-shoe measurement system	Peak plantar pressure

custom designed and constructed compression testing system to a maximum stress of 220 kPa. The grouping categories proposed by Sanders *et al.* (1998) (Table 5) corresponded generally to those proposed by Campbell *et al.* (1982) (Table 4).

In addition Sanders *et al.* (1998) also assessed the coefficient of friction at the skin-material, and sock-material interfaces in order to gain insight into the slip/stick performance of the materials and interfaces. Results for the skin-material interface, in which they used the medial tibial flare for testing, found in general that stiffer materials (as identified from the compression testing) had higher coefficient of friction values; group 3 values were higher than groups 2 and 1 and group 2 values tended to be higher than group 1. However, the authors believed this result was not completely related to the materials compressive stiffness but more due to their surface characteristics; with Poron® having a very smooth surface and Spenco® covered with a membrane of woven material. Sock-material results showed a trend of higher coefficient of friction values for group 1 than for group 2 materials.

Pratt *et al.* (1986) examined the shock absorption of five materials by measuring the height of the first peak after contact of a ball bearing dropped onto each material (0.056 kg ball dropped from 1.02 m). While the Plastazote®, Spenco® and Sorbothane® materials they examined all had similar results, the Poron® and Viscolas® materials provided the greatest shock absorption. The authors commented on the rapid compression set or bottoming out that is known to occur with Plastazote® and for this reason they carried out the same tests on Plastazote® that had been worn for 72 h with results confirming that the Plastazote®

Table 5. Material groupings from Sanders *et al.* (1998).

Group	Description based on stress strain curve fitting	Material
1	Third-order polynomial fit	Spenco Poron Silicone
2	Second-order polynomial fit	Soft Pelite Medium Pelite Firm Plastazote Regular Plastazote
3	Linear fit	Nickelplast

Table 4. Material groupings from Campbell *et al.* (1982).

Categories		Description of stress–strain curve	Materials	
1	Very stiff	Continuous steep slope	High Density Neoprene Pacer Aliplast-10	Kemblo Pelite (1.6 mm thick)
2A	Moderately deformable	High-moderate initial slope followed by a plateau region that gradually transforms into a steep slope in the final portion of the curve	Poron-20125 Aliplast-6A Poron-'Sport' Plastazote Low Density (3.2 mm, 6.35 mm thick)	Neoprene-R 425N (6.35 mm thick) Neoprene-431 (3.2 mm, 6.35 mm thick)
2B	Moderately deformable	Low-moderate initial slope which gradually transforms into a steep slope in the final portion of the curve	Ensolite (3.2 mm, 6.35 mm thick) Evazote (1.6 mm, 12.7 mm thick) Neoprene-R 425N (3.2 mm thick) Poron-17125 Carpet-Wool (pile weight of 1.15 kg m^{-2}) Carpet-polypropylene (pile weight of 0.74 kg m^{-2}) Aliplast-4E	Ethafoam Celltite Pelite (12.7 mm thick) Spenco Bonfoam Lynco
3	Highly deformable	Low initial slope which quickly transforms into a steep slope with a narrow transition region	"Dr. Scholl's Cushion Insole" "Oder-Eater Insole"	Polyurethane Foam

tested should not be used in footwear orthoses when shock absorption is a requirement. In agreement with Campbell *et al.* (1982), Pratt *et al.* (1986) stated the importance of examining other factors that affect insole materials not just one, in their case shock absorption, in isolation. In contrast to the findings of Pratt *et al.* (1986) with regard to Plastazote®, Rome (1991) assessed a number of material properties (density, hardness, tensile strength, compression and compression set) and concluded that PPT®, Vitrathene® and Plastazote® were suitable for cushioning and shock absorption while Plexidur O® and closed cell rubber were unsuitable.

Whilst, some researchers in an attempt to simplify the process of identifying suitable materials for orthoses have developed performance indexes (Lewis *et al.* 1991, Paton *et al.* 2007, Fauli *et al.* 2008) so far none of these are without substantial limitations. The identification of the most pertinent material properties to be considered in the index and the methods used to quantify these properties are important considerations. Lewis *et al.* (1991) based their index of performance on the materials shock absorption and energy return performance. The testing procedure involved a plunger falling onto the material which was positioned at the base of a resiliometer with the rebound height of the plunger on striking the material and the maximum deceleration and deceleration rate of the material used to calculate the performance index (see Equation 1). The authors proposed that the lower the value the better the performance of the material. Testing was completed on different thicknesses of the same materials with the performance index found to decrease as the thickness of the tested material increased. The differences in the values of the performance index were generally all accounted for by the rebound height and the deceleration rate of the material with no significant differences evident in maximum deceleration between materials. Based on regression analysis for the dependence of the performance index on the thickness of each material the authors calculated the performance index for all materials at a thickness of 4.8 mm and rated the tested materials based on this. Poron® was found to perform best followed by Hygard®, Isoloss LS®, TL-61 Standard®, Viscolas® and Sorbothane®. Interestingly Hygard, Isoloss LS and TL-61 Standard, materials which are not currently used in the construction of foot orthoses, performed better than Viscolas® and Sorbothane®. This finding lead the authors to suggest further evaluation of these materials (Hygard®, Isoloss LS® and TL-61 Standard®) to assess their suitability for use in footwear orthoses construction. The authors discussed their continuing work which aimed to add at least five more relevant parameters (direct compressive insert strain, percentage decrease in plantar pressure under the foot when wearing orthosis, hardness, density and area under the load deformation curve of the orthosis during the loading phase of the normal walking cycle) to the performance index calculation.

$$\mathrm{PI} = d_{\max}^2/(t_{\max} ERA) \quad (1)$$

where PI is the performance index; $d_{\max}$ is the maximum deceleration; $t_{\max}$ is the time to achieve $d_{\max}$; ERA is the energy return ability (rebound height).

A recent bench testing study by Paton *et al.* (2007) focused on materials commonly used in footwear for the prevention of neuropathic diabetic foot ulcers examining their density, resilience, force attenuation, coefficient of friction, compression set and durability, and subsequently developed a performance indicator score and matrix to present their findings. Their matrix (see Table 6) contained three categories (control, dampening and moldability) which the authors believed matched the general functional purpose required in materials used for orthoses design for people with diabetics. For each property tested the materials were divided into two groups, high and low, based on their results (except for density which included a medium group) and each group was given a score (1 or 0) based on their ability to perform the three functions defined in the matrix. Results for all materials in each category can be found in Table 7 with higher values indicating the more suitable the material was for that task (the maximum score possible was 6). Paton *et al.* (2007) acknowledged the limitation of their methodology which does not replicate the in-shoe environment, but believed their research provided clinically relevant information regarding the physical characteristics of the tested materials.

Similar to the methodology used by Paton *et al.* (2007), research by Fauli *et al.* (2008) performed a number of bench tests on orthosis materials testing a total of 30 materials which were divided into four categories based on their polymeric nature (see Table 8).

Table 6. Performance index matrix from Paton *et al.* (2007).

	Control		Dampening		Moldable	
Density	High	1	Medium	1	Low	1
Resilience	High	1	Low	1	Low	1
Force attenuation	Low	1	High	1	Low	1
Coefficient of friction	High	1	Low	1	Low	1
Compression set	High	1	High	1	Low	1
Durability	High	1	High	1	Low	1

Table 7. Performance index results for all materials from Paton *et al.* (2007).

Material	Control	Dampening	Moldability
Plastazote 12 mm	2	2	2
Poron 92 6 mm	1	3	3
Poron 96 6 mm	2	6	2
Poron 4000 6 mm	2	6	2
Poron 94 6 mm	3	5	3
PPT 6 mm	3	3	3
Cleron 6 mm	4	4	1
MaxaCane 3 mm	3	1	2
Poron 4000 3 mm	1	5	3
PPT 3 mm	3	3	3
MaxaCane 3 mm	4	4	1
High Density EVA 12 mm	3	1	2
Medium Density EVA 12 mm	6	2	1
Medium Density EVA 12 mm	5	3	1
Lunacell 12 mm	6	2	1

Table 8. Materials tested by Fauli *et al.* (2008).

Polymer	Material
Polyurethane	Herbiprex.Lite (3 mm)
	Porón densidad médica (2 mm)
	Podiane I + perforado (1.5 mm)
	Poron (3 mm)
	Herbiprex granate (3 mm)
	Poron (5 mm)
Ethylene vinyl acetate	Lunasoft SLW (6 mm)
	Herbiform Plus perforado (1.8 mm)
	Ortheva (4 mm)
	Orthomic (3 mm)
	Herbiform Multicolor (2 mm)
	Lunalastik (3 mm)
	Orthomic (4 mm)
	Lunairmed (12 mm)
	Herbal Foam Duro (5 mm)
	Evamic (5 mm)
	Herbimed (3 mm)
	Lunairmed (6 mm)
Polyethylene	Pelite (3 mm)
	Podialene 160 blanco (5 mm)
	Podialene 200 (5 mm)
	Podialene 160 carne perforado (3 mm)
	Podialene 160 azul perforado (4 mm)
	Plastazote (3 mm)
Latex	60/40 (12 mm)
	Verde (2.6 mm)
	Superlátex (4 mm)
	Superlátex (5 mm)
	Superlátex (6 mm)

From their results the authors grouped the materials based on their suitability for use as an adaptation, cushioning or filling material (see Table 9). With their aim to help practitioners in their material selection the ability to group materials in this manner would be beneficial.

However, as indicated in Table 9 the authors recommended materials from the ethylene vinyl acetate and polyethylene categories as both adaptation and filling materials without defining which variation of the material within these categorises they would class as being suitable for use as adaptation or filling. With the endless combinations of each material available, in terms of material thickness, density and hardness, the actual practicality of the reported method is questionable.

4.2. *Simulated in-shoe conditions testing of materials*

Research to date has used a combination of machine and/or participant testing to examine the effects of simulated in-shoe conditions on orthosis materials. Machine testing has examined the effect of such simulated in-shoe conditions as heat, sustained and repetitive loading, shear force and force distribution. While testing involving participants has compared differences in force and pressure measures while walking on sheets of different materials to walking barefoot. As many foot orthoses are designed with the aim of redistributing and reducing plantar pressures these variables are commonly assessed in orthosis material research.

Campbell and colleagues (1984) followed their initial bench testing study (Campbell *et al.* 1982) with one that examined the same 31 materials under simulated in-shoe conditions. The simulated conditions were heat, sustained loading (compression set) and repetitive loading. To test the effects of heat samples of each material were placed in an oven for 7 days at a temperature of 41°C with temperature selection established from a thermistor which was placed between the foot and shoe of two volunteers for an hour. Following the 7 days the materials were allowed to cool for 24 h before they were placed on an UTM for compression testing. The sustained loading test involved compressing samples of each material to 50% of their original thickness and maintaining this compression for 7 days. After the 7 days the materials were removed the thicknesses were measured (immediately following removal and after 30 min) and then compression testing on the UTM was completed. While the testing procedures described for heat and sustained loading were modified versions of ASTM standards, the

Table 9. Recommendations for suitability of materials for adaptation, cushioning or filling function based on bench testing results by Fauli *et al.* (2008).

	Function of material		
Property	Adaptation	Cushioning	Filling
Hardness	Low–Medium	Low–Medium	High
Stress/strain	Low–Medium	Low–Medium	High
Compression set and compression fatigue	High	Low	Low
Resilience	Not applicable	Low	Not applicable
Perspiration	High	High	Not applicable
Permeability	High	High	Not applicable
Most suitable material	Ethylene vinyl acetate or Polyethylene	Polyurethane or Latex	Ethylene vinyl acetate or polyurethane

repetitive loading procedure was developed by the researchers. Samples of each material were placed on a custom fabricated cyclic loading machine and subjected to loading which approximated the number of steps that would be taken in a 3-month period (samples were loaded to a maximum compression of 3 kg cm^2 (294 MPa) at a rate of 1 Hz with each sample subjected to a minimum 250,000 cycles). The materials thicknesses were then measured and a compression testing was employed. The results from all simulated conditions indicated that the materials identified in their initial study (Campbell *et al.* 1982) as most appropriate for use as an orthosis material, the moderately deformable group (see Table 4), were also shown to be least affected by the simulated in-shoe conditions with repetitive loading found to have the greatest effect on the tested materials. It is important to note that the effect of the three simulated conditions were examined independently, which does not allow for true simulation of the in-shoe environment where all conditions act together.

Similar to Campbell *et al.* (1984) other studies have customised bench testing equipment to examine the effect of simulated in-shoe conditions (Brodsky *et al.* 1988, Kuncir *et al.* 1990, Foto and Birke 1998). Kuncir *et al.* (1990) examined materials used in general footwear orthoses while both Brodsky *et al.* (1988) and Foto and Birke (1998) examined materials used specifically in footwear orthoses for diabetic patients. From their findings on the compression and recovery rates of the materials they tested Kuncir *et al.* (1990) recommended issuing thicker insoles to obese patients and several pairs of insoles for daily rotation to allow a recovery period for the insoles. However, they did not discuss the cost implications of their recommendations with regard to supplying several insoles to a patient and the possibility of the patient having to change their footwear to accommodate a thicker insole. Brodsky (1988) added to the body of orthosis material research by assessing the effects of compression and the previously unexamined effects of shear force and force distribution on the materials when new and after repeated compression using an UTM and custom fabricated jigs. Compression and a combination of shear and compression stress had the greatest effect (loss of material thickness) on Plastazote®, followed by a moderate effect on Pelite® and Spenco®, a minimal effect on Sorbothane®, and no effect on PPT®. In general, small differences between the materials in relation to their ability to distribute force were found, however, Sorbothane® was found to be the most rigid and therefore the least effective in force distribution. Their testing of Plastazote® after repeated compression concurred with the findings of Campbell *et al.* (1982) regarding its bottoming out effect. As Foto and Birke (1998) evaluated combinations of two and three different orthosis materials used together, which had not previously been examined, comparison to other research is not possible. The authors examined the effect of four months of simulated wear (100,000 cycles, 350 kPa of compressive stress at a frequency of 1 Hz) on the tested materials with stress strain and dynamic compression set measured every 500 cycles. Results showed that all materials experienced losses in performance during testing with the greatest losses occurring within the first 10,000 cycles with the authors concluding that their insole combinations of Poron® and Plastazote®, and Spenco® and Microcel Puff Lite® (first material indicates top cover in each combination) were more appropriate insole combinations for patients with diabetes, from a shock attenuation point of view, than the three other combinations tested.

A number of studies have examined different footwear orthosis materials by having participants walk barefoot across sheets of the materials, in an effort to simulate the in-shoe condition

(Leber and Evanski 1986, McPoil and Cornwall 1992, Sanfilippo *et al.* 1992, Curryer and Lemaire 2000, Gillespie and Dickey 2003). Leber and Evanski (1986) placed the materials underneath a pressure mat while the others taped the materials to a force plate. Leber and Evanski (1986) used 26 participants who all complained of forefoot pain on weight bearing and all showed areas of increased pressure under one or more metatarsal heads when tested. While they found that all the materials tested reduced overall plantar pressure when compared to the barefoot condition they ranked the materials as follows: PPT®, Plastazote® and Spenco® were most effective; Dynafoam®, Molo® were somewhat effective; and Ortho felt and Latex foam were least effective.

When compared to the barefoot condition all materials examined by Sanfilippo *et al.* (1992) resulted in a significant reduction in peak pressure, pressure time integral and an increase in contact area. While no significant difference was evident between the materials for peak pressure or pressure time integral in relation to contact area Plastazote®, Spenco® and PPT® were found to be superior to Nickelplast® which was superior to Pelite®. None of the materials tested were found to significantly reduce vertical force or force time integral when compared to the barefoot condition. Furthermore, the contact area results from McPoil and Cornwall (1992) agree with those of Sanfilippo *et al.* (1992), who used the same testing equipment, as they also found the greatest increase in contact area with PPT® and Spenco®.

Additionally, McPoil and Cornwall (1992) divided the foot into three regions (forefoot: 40% of total foot length, midfoot: 30% of total foot length and rearfoot: 30% of total foot length) for analysis with results showing all three materials significantly reduced pressure in the forefoot area when compared to the barefoot condition with no differences evident between the materials. For the rearfoot a significant reduction when compared to barefoot was only evident in PPT® and Spenso® with no difference found between these materials and no significant differences were seen in the mid foot between any of the four test conditions. This analysis, using division of the foot into three regions, showed interesting results for Viscolas®. The rapid movement of the foot at heel strike resulted in a pressure value for Viscolas® similar to that of the barefoot condition in the rearfoot area, whereas in the forefoot area Viscolas® was found to decrease pressure. The authors concluded that Viscolas® is only capable of reducing plantar pressures when the rate of loading is relatively slow and recommended it use for patients with conditions that cause increased plantar pressure in the forefoot. Gillespie and Dickey (2003) developed a filterbank procedure to determine the effective of different foot orthosis materials. The materials were found to reduce initial peak force, loading rate and frequency content of the impact transient in walking with Plastazote® being the most effective material for attenuating the high frequency component of the initial ground reaction force during walking.

Curryer *et al.* (2000) compared the effectiveness of three commonly used foam materials (Plastazote®, Spenco® and PPT®) in reducing plantar shear forces to two gel materials (Soft Shear® and Conformagel®). When compared to the barefoot condition all materials were found to significantly reduce horizontal impulse, F_y (braking) impulses and resultant shear (braking) impulses were significantly reduced by Conformagel®, Soft Shear®, and Spenco® when compared to barefoot and Plastazote, only Conformagel® showed a significant difference from barefoot for Fy (propulsive) impulse and no differences were evident between materials for vertical impulse or resultant shear (propulsive). Peak plantar forces were found to be reduced by all materials with the two gel materials showing the greatest reduction when compared to barefoot. Their findings suggested that the gel materials tested were more effective in reducing shear forces than the other three materials however the authors commented on the likelihood of the gel materials to bottom out quickly, with the lifespan of the gels materials not tested in this study. They speculated on the beneficial use of gel materials in combination with other materials within an orthosis.

García *et al.* (1994) initially measured the impact forces of a single participant walking across a force plate and used their results to simulate the measured forces through machine testing of footwear orthosis materials. They tested three thicknesses of each material with a decrease in rigidity found with decreasing material thickness and an increase in rigidity found with increasing loading frequency. The Poron® materials tested were found to have the lowest rigidity while Noene showed the highest energy absorption. For Sorbothane® careful selection of the thickness was recommended to avoid it bottoming out.

Two studies were indentified which examined the effects of use on footwear orthoses of different materials in the military boots of army recruits (House *et al.* 2002, Dixon *et al.* 2003). While House *et al.* (2002) performed their testing with the prefabricated insoles in the shoes of the participants their study is presented in this section, as opposed to the following section, as the effects of use were simulated using repeated impacts from a machine. They examined the effect of use on the prefabricated insoles,

which involved impacting each insole 40,000 times to represent 100 130 km of running. Each impact applied a 500-kPa load for 100 ms to the heel of the insole at a rate of 1 Hz. No reduction in the ability of any of the insoles to reduce peak pressures was evident following the simulated use on the orthoses with the polyurethane foam with an EVA heel cup found to be the most successful at reducing peak pressures when compared to the no insole condition. Dixon *et al.* (2003) used a combination of mechanical and field testing of four different prefabricated insoles testing each insole new and after real or simulated use. The simulated use involved subjecting each insole to 100,000 impacts with each impact representative of a typical running stride; a 500 kPa pressure reaching a peak value 50 ms after initial contact was applied to the heel of the insoles at a frequency of 1 Hz. Comparison of the stiffness values recorded between 0 and 100,000 impacts showed the greatest changes occurred between 0 and 10,000 impacts, concurring with results of Foto and Birke (1999), with only small changes occurring beyond 40,000 impacts. The polyurethane foam insole with a polyurethane elastomer inserted in the heel and ball of the foot area recorded the lowest initial stiffness and the least increase in stiffness following the impacts. This prefabricated insole also ranked highly in the field tests (stiffness characteristics pre and post 3 weeks wear by recruits) with the authors suggesting it was the most likely insole to influence injury occurrence.

4.3. *Testing of materials when placed in footwear while walking or running*

While some earlier studies used force plates and accelerometers to compare orthosis materials when placed in footwear, advances in technology now permit for the measurement of plantar pressures within the shoe which allow representation of the materials performance during gait.

With regards to running previous research has examined the effect of different materials on plantar pressure, peak forces and joint kinematics (Windle *et al.* 1999, Dixon *et al.* 2003). Windle *et al.* (1999) tested prefabricated insoles worn in the military boots of army recruits and found that all insoles tested were successful in reducing peak plantar pressures when compared to the no insole condition with the Sorbothane® insole found to be the most effective followed by Cambion®, PPT® and Saran®. Sorbothane® was also found to be significantly better than the other insoles in reducing peak pressures during heel strike. Further to their simulated in-shoe research Dixon *et al.* (2003) performed biomechanical testing (force variables and sagittal plane kinematics) of the prefabricated insoles when worn by recruits while running. Results showed that the polyurethane foam insole with the EVA footbed was the only insole found to reduce peak loading during heel impact with a later peak impact force and reduced peak loading rate.

The majority of research which has tested materials used for orthoses while walking has assessed the effects of wear on the materials. Pratt (1990) utilised an accelerometer worn on the ankle while walking to assess the shock attenuating properties of the materials they tested over a one year period. Results showed that Viscolas® (prefabricated insole) and PPT® (flat insole) performed well although deterioration which resulted in an increase in the recorded shock attenuation occurred after 6 9 months use and Plastazote® (flat insole) and Gait Aid (prefabricated insole) had poor shock attenuation properties throughout the time period with Plastazote® (flat insole) showing a large increase in shock attenuation after less than 2 days use.

The remaining research reviewed which assessed the effect of wear examined differences in materials through analysis of in-shoe plantar pressure measurements with a number of them focusing on materials used in footwear orthoses for people with diabetes (Lavery *et al.* 1997, Mohamed *et al.* 2004, Burns *et al.* 2008). Lavery *et al.* (1997) examined differences in plantar pressure when wearing two types of flat insoles, with one type worn in the left shoe and the other in the right shoe, every 3 weeks for a total of 12 weeks. Both the peak plantar pressure and pressure time integral continued to decrease from baseline readings over the 12 weeks. Examination of material stiffness over the 12 weeks found a strong correlation between the pressure time integral and Young's modulus ($r^2 = 0.93$) with the authors proposing this finding to be of benefit to the insole prescription process as it would allow a quick, inexpensive biomechanical test be used to indirectly evaluate plantar pressure measurements. Burns *et al.* (2008) provided a case report on a diabetic participant divided into three parts. Firstly eight insoles (seven flat insoles and one prefabricated insole) were evaluated for patient comfort and plantar pressure distribution with the patient wearing each insole for 1 week each. Secondly, the longer term effects of the most effective pressure reducing (Step 2 Evolution prefabricated insole) and most comfortable foot orthoses (6 mm Poron® Performance/6 mm Poron® flat insole), as determined from part one, were evaluated. Thirdly, the patient nominated his preferred orthosis, from those worn in part two, and a custom fabricated insole in that material was manufactured and assessed. Results showed that all materials tested in part one reduced peak pressure and improved comfort scores when

compared to wearing no insole, with a strong correlations found between both peak pressure and comfort and pressure time integral and comfort ($r = -0.838$ and -0.756, respectively). In part two foot pain improved more in the most effective pressure reducing device than the most comfortable device. For part three the patient choose the prefabricated device which was custom fabricated and after 1 week of wearing the orthosis the final foot pain questionnaire revealed complete resolution of the participants foot pain. Interestingly this study was the only in-shoe test of orthosis materials that evaluated feedback from the participant while wearing the insoles which is very important as it will affect a patient's compliance in wearing the insole. In the diabetic population however it is important to remember that neuropathy leads to a loss of sensation in the foot (Sims *et al.* 1988) which may not allow patient's to give accurate feedback on the comfort of the insole. Mohamed *et al.* (2004) provided two groups of diabetics matched by both body mass index and history of or current foot ulceration with either custom Plastazote® or Aliplast®/Plastazote® flat insoles and measured plantar pressures during walking at the time of fitting and after one and three months of wear. Prior to the one month measurements the orthotist assessed the insoles making any adjustments required due to wear of the orthoses. This resulted in modifications to three of the Plastazote® and six of the Aliplast®/Plastazote® orthoses. When compared to the no insole condition both insoles resulted in significant decreases in plantar pressure and increases in contact area with both insoles equally effective as none of the outcomes measures differed between the groups or with time wearing the insoles. The observation that some of the insoles needed modification following only one month's wear could possibly be attributed to the bottoming out effect of Plastazote® that was reported by Brodsky *et al.* (1988) and Pratt *et al.* (1986, 1990). Rogers *et al.* (2006) assessed the effect of walking 50,000 steps in two different flat insole constructions with results showing both insoles were effective in reducing peak pressure at the forefoot initially. After 50,000 steps however the Poron®/Plastazote® flat insole was found to be more effective as reducing peak pressure and the force time integral under the forefoot. Yet their results must be interpreted with caution as the authors provide no details on how the participants accumulated the 50,000 steps with each insole. Did they alternate the orthoses every day or did they complete the 50,000 with one and then the other. Either way one or both of the insoles could have had considerable recovery time prior to the post 50,000 steps testing which could affect the plantar measurement measurements.

A number of other studies examined the immediate effect of different orthosis materials during walking (Pratt *et al.* 1986, Johnson 1988, Forner *et al.* 1995, Birke *et al.* 1999, Tong and Ng 2010). Whilst some studies used plantar pressure assessment systems, others employed accelerometers to assess shock attenuation.

Birke *et al.* (1999) examined the planter pressures of 19 people with diabetes and a history of foot ulceration while wearing extra depth shoes with flat Poron® insoles of different levels of hardness. Mean peak pressure without insoles were compared to those of the seven flat insoles which results supporting the use of medium hardness Poron® material (Shore O 22-32) to reduce plantar pressures. Additionally Birke *et al.* (1999) examined plantar pressures with participants wearing their own footwear and custom fabricated orthosis. The results showed the lowest pressures values when the participants wore a combination of their own footwear and custom fabricated orthosis when compared to all other treatment conditions. The paucity of details on material composition of custom fabricated orthoses limits the possibility of direct comparison of these results to the flat insoles tested. Tong and Ng (2010) compared plantar pressures while wearing four different flat insole constructions in five participants without any known history of disease or foot abnormalities. While all insoles were found to reduce minimum, maximum and mean peak pressures the authors concluded that the insole combined of Poron® and firm Plastazote® was superior to the other materials tested as it resulted in a 27% reduction in mean peak pressure.

Forner *et al.* (1995) used accelerometers, with one placed on the tibia and one on the forehead to allow measurement of the transmission of the impact wave through the body. Findings showed materials with low rigidity and high shock absorption were recommended to reduce the impact wave, with Noene® found it be the most successful. Previously, supplementary to their bench testing of materials, Pratt *et al.* (1986) measured the effect of each material on skeletal shock during walking using an accelerometer mounted between the teeth of the participant. Whilst, the results were comparable to those found from the bench testing with the old Plastazote® performing worst, new Plastazote®, Spenco® and Sorbothane® had similar values and Poron® and Viscolas® performed the best. Johnson (1988) also examined skeletal shock; however they employed a skin mounting arrangement to place the accelerometer on the leg of the participants. The greatest reductions in Shock Factor were seen with the Sorbothane insoles Lightweight and Soft Blue (30%),

followed by Sorbolite, Nonshock, and Sorbothane walking insole (20%).

5. Discussion

It is clear from examining the research to date that conclusions and recommendations on the most suitable foot orthosis materials proposed by researchers are completely dependent on the methodology (the type of tests they performed; for example: compression, compression set, shear force, etc.) and the material formulation (the same material but of different density/thickness/hardness). Additionally conclusions made by some researchers on material characteristics appear to be dependant on the relative relationships between the materials tested within their own research. Forming conclusions on this basis is not very accurate as a material deemed a good shock attenuator in one study could have easily been seen as a poor shock absorber in another depending on which materials it was compared too. An example of this is the contradicting views of Pratt *et al.* (1986, 1990) and Rome (1991) with regard to the suitability of Plastazote® as a shock absorbing material. Although it is important to note that while making conclusions based on relative relationships can be misleading as no reference values for material characteristics are available (e.g., what should the resilience value of a material used to attenuate shock be?) then this is the only option available to researchers. The age of the material being tested is a key factor when analysing materials, as evidenced by the contrasting conclusions made by Pratt *et al.* (1986, 1990), Leber and Evanski (1986), Rome (1991), and Gillespie and Dickey (2003) with regard to the suitability of using Plastazote® as a cushioning and shock attenuating material.

In addition to material characteristics, the advantages and limitations of the various techniques used to assess these materials need to be explored. Whilst, some studies have discussed the disadvantages to a number of the methodologies employed to examine orthosis materials (Lewis *et al.* 1991, Garcia *et al.* 1994), there is still a paucity of information to support the type of testing equipment/methodology that should be employed in future research. Furthermore, some of the reported tests might not provide a true reflection of results for the material properties that were discussed.

Data obtained from drop tests, can depend on the dropping height, the dropping mass and the area of contact with the surface. If the variables are not controlled or if it does not relate to actual environmental conditions to which the material is being tested, the reported results will not provide any useful information. Similarly when employing UTMs to perform stress strain tests, the loading rate used is sometimes slower than what would occur in the shoe. Because of the visco-elastic nature of material their rigidity increases with frequency. This needs to be considered and the appropriate methodology and equipment should be used to increase the reliability and validity of results.

When using accelerometers and other inertial sensors, there should be careful consideration of placement of these sensors on the subject. For example, the most accurate way of placing an accelerometer is to attach it directly to tibia as opposed to a skin mounted arrangement. In practical terms this might not be achievable; however a reasonable compromise could be made. Pratt *et al.* (1986) employed an accelerometer attached to mouthpiece which according to another study (Lewis *et al.* 1991) will contribute to a 10-ms delay to obtain the signal. Furthermore, the recorded values will be higher when compared to skin mounted accelerometers.

While bench and simulated in-shoe testing provide an understanding of a material's characteristics they cannot determine the actual performance of the material when placed in the shoe. Dixon *et al.* (2003) provided evidence for this with differences in the shock absorption ability of the insoles found when tested in field by participants and when impact was simulated using a machine. Although testing of the orthosis materials over time is necessary to understand the performance limits of the materials it raises issues within study design. Participants are generally given orthoses to wear for a specified time and it is difficult for researchers to accurately assess the amount of time the orthoses were worn and to standardise wear between subjects to allow for accurate statistical analysis.

Many of the studies provided limited details on the formulations and thicknesses of the materials they tested. More detailed information on the materials they used should be provided by researchers in order to allow clinicians to practically apply the recommendations made in footwear orthosis material research.

Many authors have tried to compare bench testing with in shoe performance, but this is very difficult to verify as there are many variables that are difficult to simulate *in vitro*. The difficulties of comparison illustrated in this study highlight the need for more consistency in the presentation of materials used in manufacture of footwear and foot orthoses. Several authors have shown durometer readings of density as an indication of material performance whereas others

have used kinetic information from force platforms or pressure measuring devices.

Due to the range of methodologies and outcome measures used in research to date which has tested a large range materials of various compositions (e.g., different densities and thicknesses) and in different forms (samples cut to required size for bench testing, sheet form, flat insoles, custom insoles, prefabricated insoles and custom fabricated orthosis) a summary on the relative qualities of different materials is not possible. However it is clear from this study, that there is a need to clarify the categories of materials for example the use of generic or trade names and simplify the labelling of the characteristics in an attempt to remove the confused nature of the presentation of these materials, to help inform the clinician.

6. Conclusion

Research to date does not allow for a conclusive answer as to what are the most appropriate footwear orthosis materials for different patient requirements. Bench and simulated in-shoe testing does not allow for all factors that contribute to the effectiveness of a material in its use as a footwear orthosis to be tested. With the development of in-shoe measurement equipment the ability to examine the performance of footwear orthoses during gait is now possible. Over the past 20 years a number of in-shoe studies have tested many different materials however with the endless different formulations and thicknesses of each material and the wide range of materials available clinical recommendations on material choice are not possible.

Acknowledgments

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This review article (Chapter 2) highlighted that much of the research related to orthoses materials was outdated, with the majority of the studies carried out over ten years ago. With the advances in material science over the last ten years there are now a wider range of materials available to clinicians and there was a need to gather information on the materials currently used by clinicians. In order to achieve this a questionnaire was developed to gather information from clinicians on the materials they choose when prescribing orthoses. Findings from this questionnaire are presented in the following chapter (Chapter 3).

Chapter 3: An investigation into the prescription procedures and material choice involved in the provision of bespoke foot orthoses for diabetic patients

Healy, A., Dunning, D., Naemi, R. and Chockalingam, N. (2010)

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An investigation into the **prescription procedures** and **material choice** involved in the provision of **bespoke foot orthoses** for diabetes patients

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David Dunning MSc. FCPodM, MChS, **Roozbeh Naemi** PhD & **Professor Nachiapam Chockalingam**

A study was undertaken to evaluate the clinical reasoning behind the prescription procedure with a particular emphasis on the choice of materials. The aim was to investigate the prescription procedures involved in the provision of bespoke foot orthoses by orthotists and podiatrists.

In 2008 it was estimated that 4.67% (2,440,000 people) of the population in England had diabetes (diagnosed and undiagnosed). This figure is expected to rise to 6.48% (3,605,000 people) by 2025, with this increase due to both the growing prevalence of obesity and the aging population.[1]

There is a significant cost to the NHS on treating diabetes and its complications; it is reported as 5% of the total budget.[2] Foot problems, namely ulcers and amputations, are common and serious complications seen in people with diabetes.[3] This is a global issue with a leg lost due to diabetes every 30 seconds somewhere in the world.[4] However, it is important to note that these foot problems are not an inevitable consequence of having diabetes, as stated by Joslin,[5] 'diabetic gangrene is not heaven-sent, but earth-born'.

Factors such as peripheral neuropathy and arterial disease place the diabetic foot at high risk of ulceration but ulceration will only occur in the presence of some form of trauma. Extrinsic trauma, for example ill-fitting footwear or walking barefoot and stepping on a sharp object, or intrinsic trauma, such as repeated high pressures on parts of the foot during walking in the presence of neuropathy and/or peripheral arterial disease, can result in the development of an ulcer.[3,6]

Therefore, the use of an intervention that decreases foot pressures would make a reduction in the development of ulcers possible. Custom footwear and orthoses are interventions that have been used

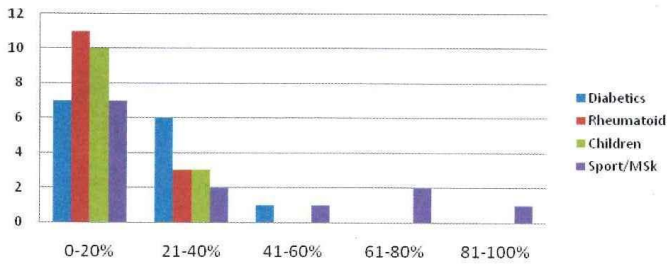

Figure 1. Caseload percentages for respondents.

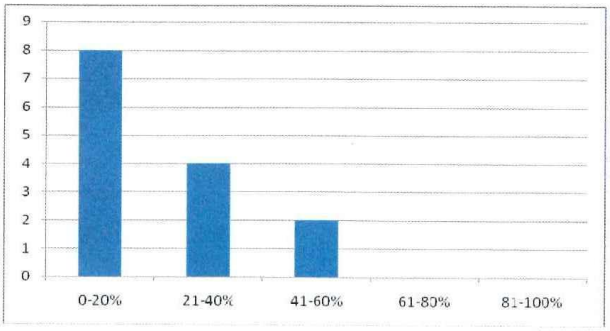

Figure 2. Percentage of respondents' caseload defined as being 'high risk'.

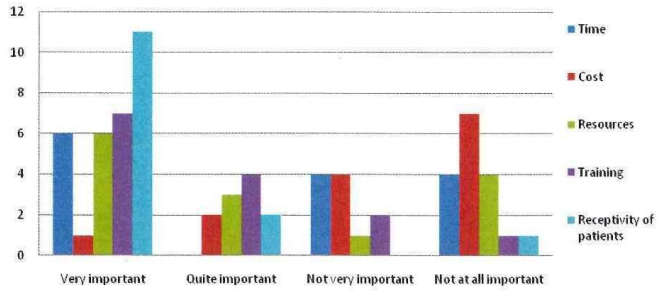

Figure 3. Ratings on importance of a number of factors on choice of casting technique.

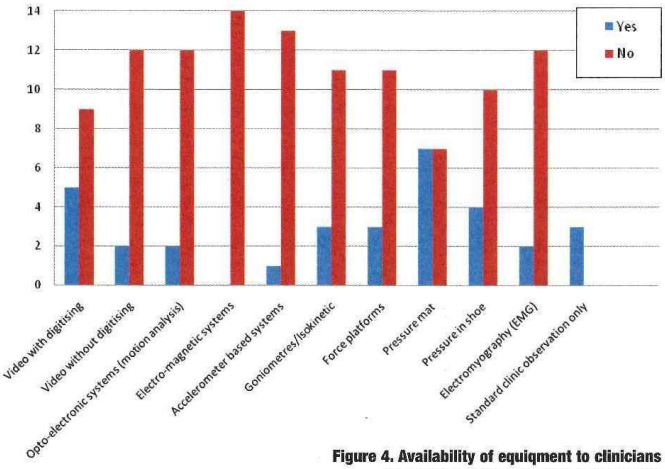

Figure 4. Availability of equiqment to clinicians to assist in biomechanical assessment.

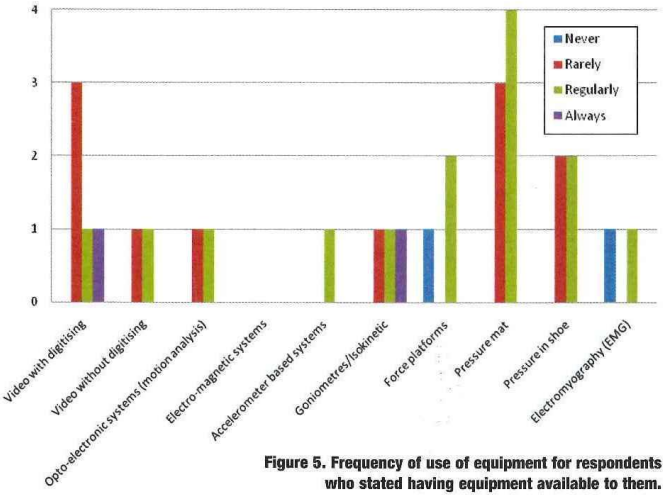

Figure 5. Frequency of use of equipment for respondents who stated having equipment available to them.

extensively by clinicians with diabetic patients considered at high risk of ulceration to reduce plantar pressure. Depending on their desired use, orthoses are constructed to varying levels of shock attenuation and movement control characteristics which are achieved through the selection of an appropriate material/s.

Whilst early orthoses were constructed from metal, wood, leather and fabric, contemporary materials predominantly include thermoplastic and thermosetting materials, foamed plastics and viscoelastic polymers.[7] This is due to advances in both material sciences and fabrication technology. Traditionally materials used for orthoses were heat moulded, and therefore had to be a thermoplastic or thermosetting material, but with the introduction of CAD/CAM (Computer Aided Design/Computer Aided Manufacturing) technology, orthoses can now be directly milled from a block of material.

Due to the vast range of materials now available to clinicians and the current paucity of information available to them on the characteristics of these materials, making a well-informed decision on material selection can prove difficult.

METHODOLOGY

The main objective of this study was to evaluate the clinical reasoning behind the prescription procedure with a particular emphasis on the choice of materials. To achieve this a questionnaire was developed within the biomechanics research group at Staffordshire University with the aim of investigating the prescription procedures involved in the provision of bespoke foot orthoses by orthotists and podiatrists.

This questionnaire is part of a research project that also includes laboratory testing of a selection of materials used in orthoses for diabetic patients. This research project is supported by Salts-Techstep under sKTP project (No: sKTP012).

There were four elements to this questionnaire: the clinicians' profile; the type of devices they routinely prescribed; the material choices for these devices and the factors that affected their choice; and finally whether the materials used were considered the most suitable for their purpose with a focus on diabetes.

In November 2009, 29 questionnaires were distributed to clinical practitioners involved in the prescription and modification of footwear and insoles and who were identified as having experience of both traditional and CAD/CAM methods of manufacturing. Fourteen questionnaires were completed and returned for analysis.

RESULTS

Clinicians' profile

Half the respondents worked in hospital and acute settings, with the remaining half from a combination of community and private clinics. The majority reported prescribing 11 or more bespoke orthoses per month, with a caseload distribution and patient risk percentage as seen in Figures 1 and 2 respectively.

When asked about the casting technique they used, half selected foam box and half selected suspension plaster casting technique. However, 12 of the 14 reported varying their choice of technique according to the patient. In the follow-up comments section, respondents generally stated that the purpose of the orthotic, for example amount of correction required, and the patients tolerance were the main factors in choice of casting technique. For example, one respondant stated 'It depends whether I am prescribing functional or accommodative orthoses. Also, time is a factor ..... sometimes (I) have to make do with a foam impression rather than neutral POP (Plaster of Paris) casts.'

Respondents were also asked to rate the importance of time, cost, resources, training and receptivity of patients on their choice of casting technique. The results are shown in Figure 3.

The next three questions related to the availability of equipment in helping with biomechanical assessment (see Figures 4, 5 & 6). Interestingly, only a few had a variety of equipment available to them, with the pressure mat being the most available to clinicians.

Use and type of orthoses prescribed to people with diabetes

When asked about the type of devices the clinicians predominantly prescribed to people with diabetes, six used functional and accommodative devices in equal amounts, four predominantly used functional orthoses leaving three predominantly using accommodative devices (one respondent did not treat diabetes patients and so did not answer the questions relating specifically to diabetes). This is borne out in Figure 7, which shows that the majority of these experienced clinicians were comfortable in prescribing rigid foot orthoses for people with diabetes.

MATERIAL CHOICES FOR DIABETES AND FACTORS THAT AFFECTED THIS CHOICE

Figure 8 details the materials chosen by the clinicians when prescribing orthoses for people with diabetes, and Figure 9 rates the

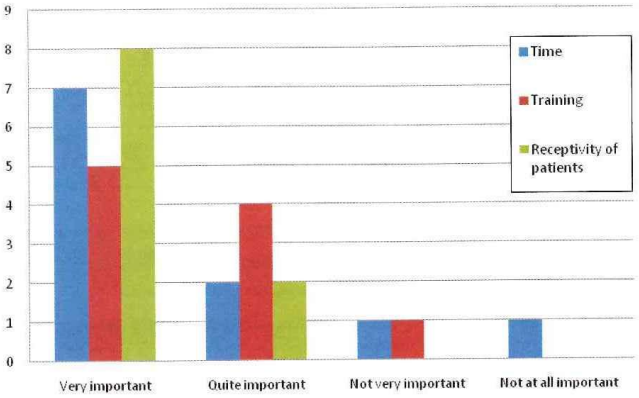

Figure 6. Ratings on importance of a number of factors on choosing to use/not use available equipment.

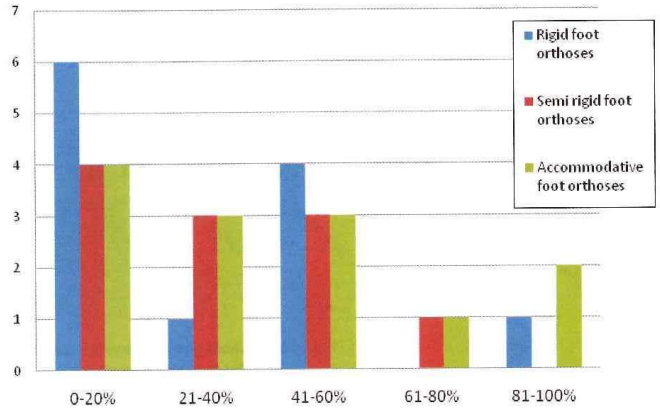

Figure 7. Frequency of type of orthoses prescribed to diabetes patients.

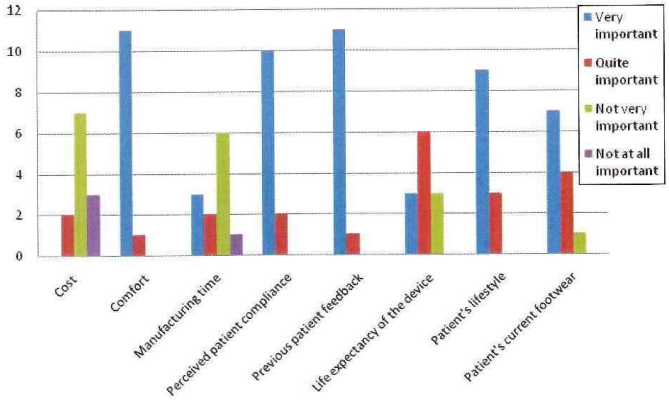

Figure 8. Materials used based on type of orthotic.

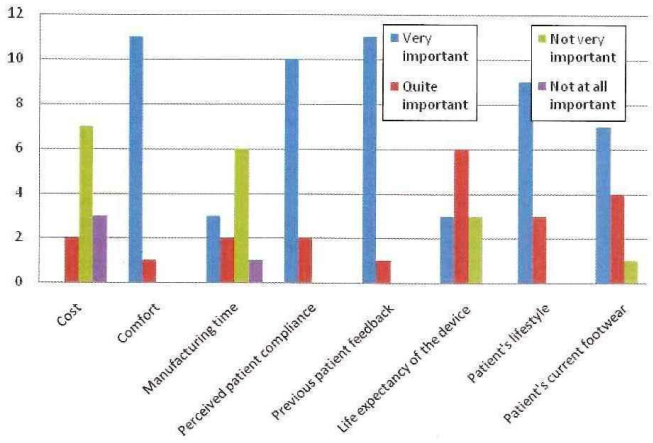

Figure 9. Ratings on importance of a number of factors on material choice.

importance of several factors in material selection. In summary, the respondents used a wide variety of materials, with medium-density EVA being useful in semi-rigid and accommodative devices whilst polypropylene was the material of choice for the majority of rigid devices.

WHETHER MATERIALS ARE SUFFICIENT FOR PURPOSE

The final section related to the materials themselves asking whether the choice of materials has changed significantly in the last five years. Five respondents selected yes and eight chose no.

Some respondents chose to comment that materials have become more functional than cushioning, with two remarking on the introduction of Polyurethane as an option, and one suggesting that the materials are a better quality. When asked if they felt the range of materials available for orthoses provided for diabetes patients was appropriate, the majority replied that it was.

CONCLUSION

This questionnaire had experienced practitioners as respondents who were content to base their casting technique on their patient's needs. Generally respondents showed no reluctance in prescribing functional devices to their diabetes patients.

Traditionally the aim of orthoses/insoles for diabetes patients has been to redistribute weight and provide cushioning.[8] When asked about the materials, respondents were relatively satisfied with the range and quality of the materials available.

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This questionnaire study (Chapter 3) allowed for the identification of materials currently used by clinicians when prescribing orthoses. Findings from the review article (Chapter 2) highlighted the limited amount of in-vivo research that has been carried out into the performance of orthoses materials, with the majority of studies using bench testing or simulated in-shoe testing methodologies. These previous findings informed the methodology for the subsequent laboratory study (Chapter 4) which examined the effect of two commonly used orthoses materials (identified through the questionnaire) on plantar pressures and lower limb kinematics during treadmill walking.

Chapter 4: Effect of insole material on lower limb kinematics and plantar pressures during treadmill walking

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Effect of insole material on lower limb kinematics and plantar pressures during treadmill walking

Aoife Healy, Dave N Dunning and Nachiappan Chockalingam

Abstract

Background: Currently there is a paucity of research providing recommendations on the type of orthotic or material used in its construction for different patient requirements.

Objectives: To gain a greater understanding of the characteristics of orthotic materials and how they affect gait so to enhance the clinical decision-making process.

Study Design: Repeated measures.

Methods: Plantar pressures and kinematics were evaluated for 10 participants while walking on a treadmill under various conditions which included, shoes only and shoes with four different flat insoles and custom devices created in each of two densities of two materials.

Results: For the flat insoles, medium density ethyl vinyl acetate was found to produce greater peak pressures than at least one of the other material conditions and low and medium density polyurethane were most effective at increasing average contact area and at reducing pressure time integral. For the custom devices, while no significant differences were evident, when compared to the shoe only condition, medium density polyurethane increased average contact area by a greater percentage than the other materials.

Conclusions: Results for medium density polyurethane suggest a possible difference in loading characteristics, indicating a potential material suitability for patients with a compromised ability to deal with pressure.

Clinical relevance

Findings from the present study provide information for a clinician to draw an evidence-based orthotic prescription based on material properties.

Keywords

Biomechanics, gait analysis, lower limb orthotics, the diabetic foot

Date received: 7 August 2011; accepted: 24 October 2011

Background

Orthoses are routinely prescribed to people with diabetes to offload pressure in areas of the foot that may cause ulceration. However, there is little scientific evidence on the use of custom foot orthoses in diabetes to improve gait and reduce further deformity. Systematic reviews that have examined the effectiveness of orthoses in preventing ulceration in people with diabetes[1-4] have cautiously supported their use, with the authors considering the limited evidence from which they had made their conclusion. Subsequently these reviews have pointed out a major limitation of research in this area; although orthoses are shown to be of benefit in preventing ulceration, current research does not allow for recommendations regarding the type of orthoses to be prescribed. Furthermore, research to date does not provide a conclusive answer to what the most suitable materials to use in constructing orthoses for different patient requirements are.[5]

In-shoe pressure measurements, namely peak pressure, peak force and pressure time integral[6] are the most common outcome measures used in research to determine the effectiveness of orthoses.[7-10] The widespread use of in-shoe pressure measurements in research studies involving orthotic effectiveness is based on the established link between high foot pressure and ulceration which has

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previously been shown in an early retrospective study by Stokes et al.[11] and a more recent prospective study by Veves et al.[12] The cause of increased foot pressure in people with diabetes has received much discussion with potential contributors including neuropathy[13,14] and limited joint mobility at the ankle and foot.[15-17] Of the limited research available which used in-shoe plantar pressure measurements to compare orthoses materials some have focused on the effect of wear on the materials[9,18,19] while others have compared the immediate effect of different orthoses materials on plantar pressures while walking.[20,21] Both of these studies compared flat insoles with Birke et al.[20] comparing Poron® insoles of different hardness values and Tong and Ng[21] comparing two types of Poron® and two combinations of Poron® and Plastazote®. While this previous research examining Poron was warranted as it is a common prescription choice, other materials which are commonly prescribed, such as ethyl vinyl acetate and polyurethane,[22] have not been examined.

The comparison of plantar pressures when using flat versus custom orthoses have been conducted by a number of researchers.[7,10,20,23-26] While direct comparison between these studies is not possible, due to the wide variety in both participants and interventions used, results from all but one of these studies[23] has supported the use of custom orthoses over flat. Only one of these studies[24] used the same material in the construction of both their flat insoles and custom devices, allowing identification of possible differences in the performance of the materials when used flat and when custom moulded to a participant's foot. Previous research which has examined the effect of orthoses on lower limb kinematics has shown that changes in kinematics are evident when wearing orthoses compared to a shoe only condition.[27]

With the range of material available for the manufacture of custom foot orthoses growing year on year, the aim of this study was to gain a greater understanding of the characteristics of the materials used and how they affect gait with a view to informing the clinical decision-making process in the provision of foot orthoses for people with diabetes. To extend the current knowledge and understanding in this area, it was hypothesized that insole material (ethyl vinyl acetate and polyurethane) and construction (flat and custom) would have an effect on lower limb kinematics and plantar pressures.

Methods

Participants

Ten healthy participants (four males and six females) with an average age of 30.9 (± 12.4) years, weight of 69.3 (± 12.2) kg and height of 172.0 (± 9.4) cm were recruited for the study. While the authors acknowledge the limitations associated with using a small sample size, previous research has reported that sufficient statistical power can be achieved when using a sample size of 10.[28] While the authors acknowledge that differences in gait are evident between gender, the focus of this study was on comparing the orthotic materials and not the participants and therefore we do not consider gender to be an issue in this manuscript.

Ethical approval was received from the university ethics committee and all participants signed the approved consent form before participating in the tests. All participants were free from any musculoskeletal injury at the time of testing and had no known history of foot pathologies or structural abnormalities.

Procedure

This laboratory-based study compared the effects of material choice (used in the manufacture of orthoses) on lower limb kinematics and plantar pressures. Materials chosen to be tested were: low density polyurethane (PU) (Shore A hardness 20–25), medium density PU (Shore A hardness 55 ± 3), low density ethyl vinyl acetate (EVA) (Shore A hardness 25) and medium density EVA (Shore A hardness 50). The materials used were selected based on a previous survey, which found that these are the materials used within orthoses that are commonly prescribed to people with diabetes.[22]

The study consisted of two testing sessions with the first requiring participants to walk on a treadmill while wearing standardised plimsoll shoes (a minimalistic athletic shoe with a canvas upper and rubber sole) under five conditions: (1) shoe only, *and shoe with*; (2) 3-mm flat insole of low density PU; (3) 3-mm flat insole of medium density PU; (4) 3-mm flat insole of low density EVA; and (5) 3-mm flat insole of medium density EVA. As the focus of this study was on comparing the orthotic materials we chose this 'minimalistic' footwear as we wanted to limit the effect of the footwear on gait. Following this baseline assessment, participants had foam box impressions of their feet taken by the same experienced clinician. These impressions were used to create custom devices for each participant in each of the two densities (low and medium) of the two materials (PU and EVA) for the second testing session. These devices were created using CAD/CAM technology with a standard mode of manufacture. A standard prescription form (Salts Techstep, UK) was used with a 4° medial extrinsic rearfoot posting and forefoot balanced to rearfoot vertical on a shell customised to the participant. This type of prescription is common and traditional within the podiatric profession across various countries (modified Root prescription technique). No attempt was made to evaluate the participants using clinical biomechanical paradigms as it was the function of the device, not the participant, that was of interest. A 4° rearfoot posting was used as this was thought to be a very common prescription characteristic across various common orthotic interventions. Prescribed devices were

full length with 3 mm thickness under the forefoot, toes and heel, and a top cover of 1-mm medium density EVA.

The testing procedure for the first session was replicated with the five conditions for this second session being: (1) shoe only, *and shoe with*; (2) custom device of low density PU; (3) custom device of medium density PU; (4) custom device of low density EVA; and (5) custom device of medium density EVA. The order of testing condition for both sessions for each participant was randomly determined using a computer-generated random number list (MS Excel 2007, Microsoft, USA). Forty-two reflective spherical markers (14 mm diameter) were placed on anatomical landmarks on the participant, using double-sided tape on their bases, for use with the Plug-in-Gait and Oxford Foot Models.[29] The shoes used in the present study were modified to allow the reflective markers to be placed on the participants' feet. Shoe modification involved removing sections of the shoes canvas upper to allow the placement of markers on anatomical landmarks. A minimum amount of material was removed to allow the placement and unobstructed movement of markers during gait while aiming to maintain the structural stability of the shoe. As the reflective markers which were placed on the feet had to be removed and reapplied when footwear conditions were changed, markings were made on the skin where the markers were to be placed to aid correct reapplication. An eight-camera motion analysis system (Vicon, OMG, Oxford, UK) was used to record the motion of the individual markers and in-shoe pressures sensors (F-Scan, Tekscan, Boston, USA) with a resolution of 3.9 sensels per cm^2 measured plantar pressure distribution. The F-Scan sensors were trimmed to fit the plimsoll shoes and one pair of sensors was used per shoe size.

Prior to data collection, calibration of equipment was conducted according to manufacturer's guidelines. For the motion analysis system a dynamic calibration was performed and residuals of less than 2 mm from each camera were deemed acceptable. A static standing trial was recorded for each condition and was used to estimate joint centres and other virtual points from the marker locations. Data were collected while the participants walked on the treadmill at a self-selected speed (3.4 ± 0.5 km/h^{-1}). Eight trials of 10 s duration were recorded for each condition. Both motion analysis and in-shoe pressure system employed a sampling frequency of 100 Hz and were synchronised for data collection using a custom-made synchronization box (Tekscan Inc., USA). The heel contact and toe off events during a gait cycle were identified using in-shoe pressure sensors and applied to the motion analysis trials.

Data processing and analysis

Plantar pressure analysis was conducted by dividing the contact area of the foot into six anatomically and functionally relevant regions which are shown in Figure 1. The six regions were hallux, first metatarsal, lateral metatarsals, midfoot, medial heel and lateral heel. Stance duration, peak pressure, peak force, pressure time integral and average contact area for each of the six regions was recorded using the proprietary software (F-Scan Research 6.51, Tekscan Boston, USA). Three-dimensional marker data were filtered with a Woltring filter (MSE=20) which is the method recommended by the manufacturer for optimum results. For lower limb kinematics the range of motion of the following were recorded; femur/tibia flexion, adduction and rotation, forefoot/hindfoot dorsiflexion, adduction and supination, hindfoot/tibia dorsiflexion and inversion and hallux/forefoot dorsiflexion. Additionally the change in angle of these variables (except hallux/forefoot dorsiflexion) early in the loading response[30] (from heel strike to 6% of the gait cycle) was calculated. The first three trials collected for each condition which were deemed acceptable based on the correct data acquisition of both the Vicon and F-Scan systems were used for analysis. Eight trials were collected for each condition to ensure that sufficient data were collected in case of data corruption of trials. The three trials, with six to eight steps per trial (with the first and last steps removed from the analysis), were analyzed and results for these three trials were then averaged to create a representative trial. For statistical analysis a repeated measures ANOVA ($p \leq 0.05$) was used to access differences between conditions. Post hoc pair-wise comparisons with Bonferroni adjustments were conducted for multiple comparisons.

Results

First session – flat material

Mean values for stance duration and F-Scan in-shoe measurements are provided in Table 1 with lower limb kinematic data presented in Table 2. The stance phase duration was significantly less for medium density EVA than low density EVA (0.70 ± 0.03 s vs. 0.71 ± 0.03 s). The shoe only condition produced significantly greater peak pressures than the other conditions at the first and lateral metatarsal regions only. The addition of medium density PU resulted in reduced peak pressure at the first metatarsal region, and all conditions except medium density EVA, resulted in reduced peak pressure at the lateral metatarsal region. Where significant differences were evident between the conditions, medium density EVA always produced greater peak pressures than at least one of the other material conditions. Where significant differences were evident for peak force, medium density EVA was found to produce greater peak forces at the lateral metatarsal region than all the other materials and more than low density EVA and PU at the medial heel. In general, the low and medium density PU were the most effective at increasing average contact area and at reducing pressure time integral. Significant differences for range of motion were evident for femur/tibia adduction with low density EVA significantly greater than medium density EVA and forefoot/hindfoot supination with the shoe only condition significantly less

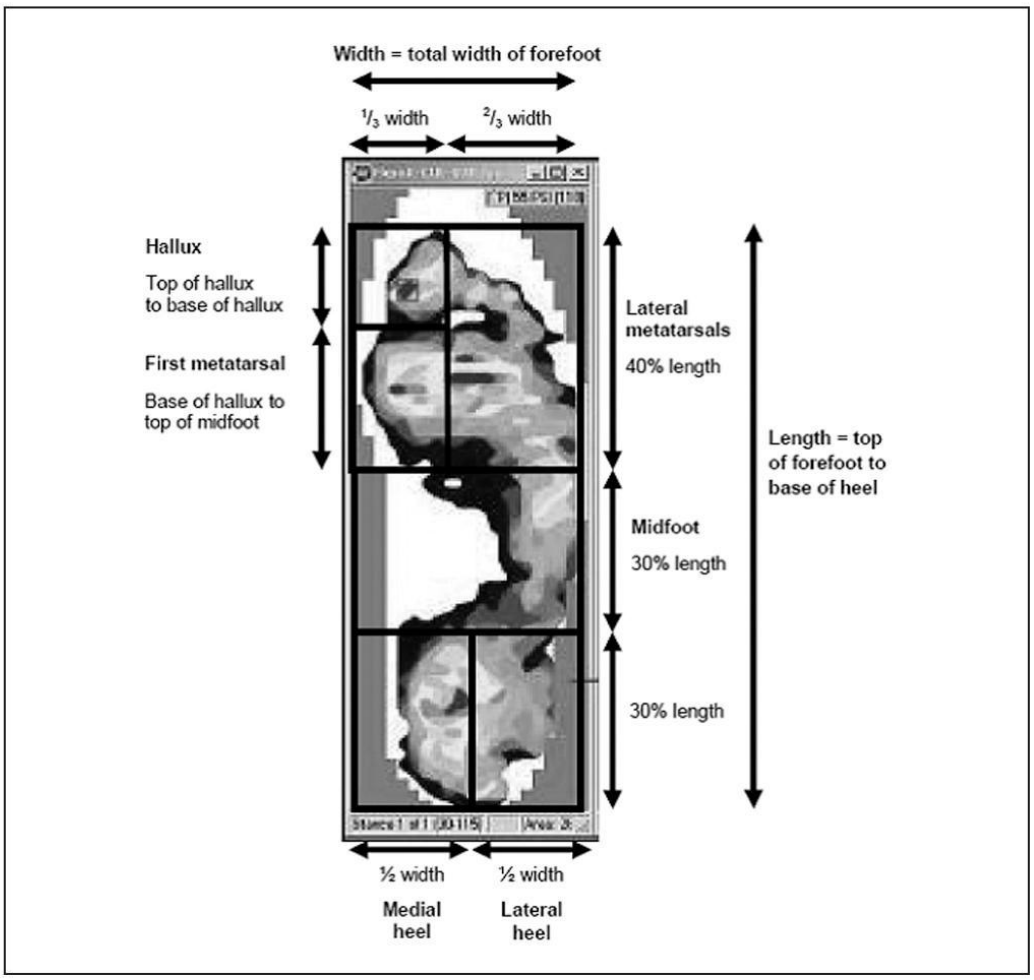

Figure 1. Definition for division of foot into six sections.

than medium density EVA. When going from heel strike to 6% of the gait cycle the change in angle for femur/tibia flexion was significantly greater for medium density EVA than the shoe only condition.

Second session – custom device

Mean values for stance duration and F-Scan in-shoe measurements are provided in Table 3 with lower limb kinematic data presented in Table 4. Medium density EVA and PU were found to significantly increase peak pressure at the hallux when compared to the shoe only condition. Both low density materials (PU and EVA) were found to significantly reduce peak pressure at the first and lateral metatarsals when compared to the shoe only condition. All the materials were effective at significantly reducing peak pressure at the medial and lateral heel when compared to the shoe only condition. Medium density PU and EVA increased peak force at the hallux and midfoot when compared to the shoe only condition. All the materials were effective at significantly reducing peak force at the medial and lateral heel. When compared to the shoe only condition, contact area was significantly increased by all materials at the hallux and midfoot. All materials reduced pressure time integral at the lateral metatarsals and the medial and lateral heel. Significant differences for range of motion were evident for

Table 1. Comparison of F-Scan in-shoe pressure measurements between conditions for flat material session (mean ± standard deviation).

Foot area	Variable	Shoe only	PU medium density	PU low density	EVA medium density	EVA low density	*p* value	Post hoc results
	Stance duration (s)	0.70 ± 0.03	0.70 ± 0.04	0.71 ± 0.04	0.70 ± 0.03	0.71 ± 0.03	0.034*	EVA MD < EVA LD
Hallux	Peak pressure (kPa)	172.34 ± 78.15	151.67 ± 48.82	149.43 ± 58.97	197.64 ± 94.13	171.54 ± 61.12	0.001*	EVA MD > PU LD
	Peak force (N/BW)	0.027 ± 0.014	0.025 ± 0.009	0.024 ± 0.010	0.032 ± 0.017	0.027 ± 0.011	0.021*	NSD in post hoc tests
	Average contact area (cm^2)	3.24 ± 1.37	4.10 ± 1.21	4.38 ± 1.66	3.81 ± 1.40	3.90 ± 1.47	< 0.001*	PU MD, PU LD + EVA LD > SO
	PTI (kPa s)	23.41 ± 14.81	24.23 ± 11.15	22.27 ± 9.39	27.21 ± 15.00	25.08 ± 11.22	0.114	
First met	Peak pressure (kPa)	215.73 ± 69.80	180.04 ± 67.15	191.46 ± 79.32	211.24 ± 62.94	185.35 ± 69.45	< 0.001*	SO + EVA MD > PU MD
	Peak force (N/BW)	0.034 ± 0.012	0.029 ± 0.012	0.031 ± 0.014	0.034 ± 0.012	0.029 ± 0.011	0.007*	NSD in post hoc tests
	Average contact area (cm^2)	8.86 ± 2.67	9.80 ± 2.79	10.57 ± 3.00	9.06 ± 2.04	9.36 ± 2.80	< 0.001*	PU MD > SO; PU LD > SO, EVA MD + EVA LD
	PTI (kPa s)	40.17 ± 14.98	33.37 ± 11.23	34.28 ± 13.11	36.38 ± 9.95	35.38 ± 12.83	0.001*	SO > PU MD + PU LD
Lateral mets	Peak pressure (kPa)	352.45 ± 77.39	288.02 ± 62.90	292.15 ± 51.61	337.26 ± 57.22	295.71 ± 54.79	< 0.001*	SO + EVA MD > PU MD, PU LD + EVA LD
	Peak force (N/BW)	0.057 ± 0.017	0.046 ± 0.011	0.047 ± 0.010	0.054 ± 0.012	0.047 ± 0.011	< 0.001*	SO + EVA MD > PU MD, PU LD + EVA LD
	Average contact area (cm^2)	24.42 ± 3.96	25.98 ± 3.63	28.00 ± 3.74	25.47 ± 3.87	25.38 ± 3.95	< 0.001*	PU MD, PU LD, EVA MD + EVA LD > SO; PU LD > PU MD, EVA MD + EVA LD
	PTI (kPa s)	48.44 ± 11.07	43.93 ± 11.43	39.73 ± 9.37	47.67 ± 10.63	45.52 ± 11.00	< 0.001*	SO, EVA MD + EVA LD > PU LD; SO > PU MD
Midfoot	Peak pressure (kPa)	81.86 ± 57.11	74.55 ± 30.78	76.10 ± 29.37	78.57 ± 35.93	77.35 ± 35.34	0.692	
	Peak force (N/BW)	0.013 ± 0.010	0.012 ± 0.005	0.012 ± 0.005	0.012 ± 0.005	0.012 ± 0.006	0.527	
	Average contact area (cm^2)	10.28 ± 5.06	11.42 ± 4.49	12.74 ± 4.29	10.55 ± 4.94	11.29 ± 4.69	< 0.001*	PU LD > SO, PU MD, EVA MD + EVA LD
	PTI (kPa s)	18.15 ± 6.35	18.96 ± 5.57	18.54 ± 5.92	18.81 ± 5.12	19.20 ± 5.88	0.574	
Medial heel	Peak pressure (kPa)	254.25 ± 69.36	224.40 ± 73.18	228.03 ± 56.81	255.71 ± 63.08	232.65 ± 59.19	0.008*	EVA MD > PU LD + EVA LD
	Peak force (N/BW)	0.041 ± 0.013	0.036 ± 0.012	0.037 ± 0.010	0.041 ± 0.011	0.038 ± 0.010	0.043*	EVA MD > PU LD + EVA LD
	Average contact area (cm^2)	7.77 ± 2.72	8.44 ± 2.38	8.65 ± 2.07	8.31 ± 2.45	8.52 ± 2.54	0.072	
	PTI (kPa s)	41.69 ± 12.71	37.73 ± 13.23	34.84 ± 11.09	41.23 ± 12.90	39.27 ± 12.98	0.001*	SO, EVA MD + EVA LD > PU LD
Lateral heel	Peak pressure (kPa)	262.60 ± 75.93	239.11 ± 70.21	243.65 ± 57.33	267.83 ± 75.53	244.49 ± 64.50	0.003*	EVA MD > EVA LD
	Peak force (N/BW)	0.042 ± 0.014	0.039 ± 0.013	0.039 ± 0.012	0.043 ± 0.014	0.039 ± 0.012	0.075	
	Average contact area (cm^2)	12.60 ± 3.16	13.59 ± 3.53	13.54 ± 3.13	13.28 ± 3.48	13.40 ± 3.25	0.088	
	PTI (kPa s)	38.11 ± 12.36	36.83 ± 12.20	34.26 ± 9.39	39.32 ± 11.69	37.52 ± 10.80	0.007*	EVA MD > PU LD

EVA LD = EVA low density; EVA MD = EVA medium density; met = metatarsal; NSD = no significant difference; PU LD = PU low density; PU MD = PU medium density; SO = shoe only.
*Significant difference ($p \leq 0.05$) between conditions.

Table 2. Comparison of kinematic variables between conditions for flat material session (mean ± standard deviation).

Variable	Angle (°)	Shoe only	PU medium density	PU low density	EVA medium density	EVA low density	*p* value	Post hoc result
Range of motion	Knee – Flexion	62.76 ± 4.56	62.17 ± 4.15	63.40 ± 4.35	62.94 ± 4.71	63.19 ± 4.78	0.405	
	Knee – Adduction	13.51 ± 7.59	13.81 ± 7.37	14.37 ± 7.26	13.71 ± 6.24	14.58 ± 6.79	0.035*	EVA LD > EVA MD
	Knee – Rotation	23.84 ± 7.18	23.73 ± 7.87	23.99 ± 7.84	24.19 ± 8.29	23.79 ± 7.61	0.729	
	Forefoot/Hindfoot – Dorsiflexion	6.07 ± 1.65	5.73 ± 1.82	5.68 ± 2.03	5.57 ± 2.01	5.78 ± 2.14	0.603	
	Forefoot/Hindfoot – Adduction	5.54 ± 1.38	4.89 ± 1.22	5.04 ± 1.55	4.42 ± 1.89	4.65 ± 2.06	0.473	
	Forefoot/Hindfoot – Supination	7.56 ± 2.37	6.74 ± 3.03	6.73 ± 2.90	6.77 ± 2.63	6.07 ± 3.05	0.007*	SO > EVA LD
	Hindfoot/Tibia – Dorsiflexion	27.87 ± 5.72	26.05 ± 5.87	26.93 ± 4.94	27.65 ± 6.65	27.44 ± 5.50	0.247	
	Hindfoot/Tibia – Inversion	15.61 ± 5.47	15.34 ± 5.18	15.88 ± 4.74	15.23 ± 5.78	15.25 ± 5.04	0.655	
	Hallux/Forefoot Dorsiflexion	15.45 ± 4.71	13.62 ± 6.04	15.01 ± 5.85	14.20 ± 4.95	12.94 ± 6.02	0.125	
Change in angle between heel strike and 6% of gait cycle**	Knee – Flexion	3.70 ± 1.68	3.89 ± 1.59	4.39 ± 1.64	4.40 ± 1.74	4.30 ± 2.14	0.037*	SO < EVA MD
	Knee – Adduction	−0.40 ± 0.86	−0.47 ± 1.02	−0.54 ± 0.98	−0.50 ± 1.11	−0.39 ± 1.09	0.246	
	Knee – Rotation	2.21 ± 3.44	0.70 ± 2.51	1.19 ± 2.61	1.68 ± 2.45	1.83 ± 2.81	0.098	
	Forefoot/Hindfoot – Dorsiflexion	0.81 ± 1.01	1.05 ± 0.94	0.92 ± 1.00	0.83 ± 1.02	0.82 ± 0.83	0.682	
	Forefoot/Hindfoot – Adduction	−0.18 ± 0.87	−0.33 ± 0.82	−0.41 ± 0.84	−0.10 ± 0.79	−0.18 ± 0.52	0.492	
	Forefoot/Hindfoot – Supination	−1.20 ± 1.69	−0.49 ± 0.90	−0.81 ± 1.19	−0.89 ± 1.27	−0.74 ± 0.91	0.198	
	Hindfoot/Tibia – Dorsiflexion	−2.91 ± 2.52	−3.81 ± 1.22	−3.74 ± 1.66	−3.44 ± 2.18	−3.76 ± 1.71	0.288	
	Hindfoot/Tibia – Inversion	−1.12 ± 1.45	−1.56 ± 1.07	−1.59 ± 1.29	−1.54 ± 1.08	−1.60 ± 1.41	0.294	

EVA LD = EVA low density; EVA MD = EVA medium density; SO = shoe only. *Significant difference ($p \leq 0.05$) between conditions. **+ = increase in angle from heel strike to 6% gait cycle; – = decrease in angle from heel strike to 6% gait cycle.

forefoot/hindfoot supination with the shoe only condition significantly greater than both PU conditions. When going from heel strike to 6% of the gait cycle the change in angle for femur/tibia flexion was significantly greater for low density PU than low density EVA.

Discussion

As hypothesized, various insole materials and different construction were found to have an effect on plantar pressure, however, in contrast to our hypothesis, there was little effect on lower limb kinematics.

Kinematics

Lower limb kinematics were assessed to examine the effect of the materials on ankle and foot joint mobility. Few significant differences were evident between conditions. Since these differences were small (0.7°–1.49°), they were not considered relevant.[31] Similarly, for the custom devices, some small differences (1.13°–1.92°) in lower limb kinematics were evident between conditions. These small differences may be attributed to extrinsic factors such as marker placement procedures and related skin movement and intrinsic factors such as variability in functional anatomy between the participants. These factors might have had an influence in the changes in actual joint angles and may not contribute to significant modifications in clinical intervention.

Plantar pressure

Results for the flat insoles showed that medium density EVA always produced greater peak pressures than at least one of the other material conditions and that both PU insoles were most effective at increasing contact area and reducing pressure time integral, indicating the possibility

Table 3. Comparison of F-Scan in shoe pressure measurements between conditions for custom device session (mean ± standard deviation).

Foot area	Variable	Shoe only	PU medium density	PU low density	EVA medium density	EVA low density	*p* value	Post hoc results
	Stance duration (s)	0.69 ± 0.04	0.70 ± 0.03	0.69 ± 0.03	0.70 ± 0.03	0.70 ± 0.04	0.21	
Hallux	Peak pressure (kPa)	174.09 ± 77.06	232.54 ± 79.25	203.03 ± 75.16	233.83 ± 93.11	206.31 ± 60.62	< 0.001*	SO < PU MD + EVA MD
	Peak force (N/BW)	0.028 ± 0.01	0.038 ± 0.02	0.033 ± 0.01	0.038 ± 0.02	0.033 ± 0.01	< 0.001*	SO < PU MD + EVA MD
	Average contact area (cm^2)	2.81 ± 1.53	4.84 ± 2.66	3.99 ± 1.61	3.76 ± 1.65	3.81 ± 1.51	0.015*	SO < PU MD, PU LD, EVA MD + EVA LD
	PTI (kPa s)	22.64 ± 11.40	35.71 ± 16.94	33.67 ± 14.42	35.68 ± 18.32	32.34 ± 13.30	< 0.001*	SO < PU MD, PU LD, EVA MD + EVA LD
First met	Peak pressure (kPa)	257.15 ± 85.80	231.69 ± 83.87	217.88 ± 68.92	222.82 ± 67.23	209.45 ± 48.04	0.001*	SO > PU LD, EVA MD + EVA LD
	Peak force (N/BW)	0.042 ± 0.02	0.038 ± 0.02	0.036 ± 0.01	0.036 ± 0.01	0.034 ± 0.01	0.002*	SO > EVA MD
	Average contact area (cm^2)	8.37 ± 2.94	10.37 ± 4.96	9.04 ± 2.69	8.67 ± 3.10	8.95 ± 2.80	0.145	
	PTI (kPa s)	42.83 ± 10.13	39.33 ± 11.51	38.88 ± 9.44	38.92 ± 10.85	38.46 ± 10.56	0.019*	SO > EVA LD
Lateral mets	Peak pressure (kPa)	403.46 ± 102.03	377.06 ± 103.38	343.61 ± 84.37	367.84 ± 65.86	336.85 ± 65.77	0.001*	SO > PU LD + EVA LD; EVA MD > EVA LD
	Peak force (N/BW)	0.066 ± 0.02	0.062 ± 0.02	0.056 ± 0.02	0.060 ± 0.01	0.055 ± 0.01	0.001*	SO > PU LD + EVA LD; EVA MD > EVA LD
	Average contact area (cm^2)	23.00 ± 4.54	26.08 ± 6.83	24.27 ± 5.62	23.55 ± 6.10	23.60 ± 5.54	0.004*	NSD in post hoc tests
	PTI (kPa s)	56.08 ± 8.65	50.99 ± 6.71	47.73 ± 7.89	50.12 ± 6.43	49.14 ± 9.36	< 0.001*	SO > PU MD, PU LD, EVA MD + EVA LD
Midfoot	Peak pressure (kPa)	78.10 ± 31.59	99.51 ± 34.17	92.34 ± 34.45	110.23 ± 38.45	98.38 ± 38.19	0.004*	SO < EVA MD
	Peak force (N/BW)	0.012 ± 0.00	0.016 ± 0.00	0.015 ± 0.01	0.018 ± 0.01	0.016 ± 0.01	0.002*	SO < PU MD + EVA MD
	Average contact area (cm^2)	7.09 ± 4.08	16.96 ± 6.21	15.57 ± 5.66	15.13 ± 7.06	15.23 ± 7.27	< 0.001*	SO < PU MD, PU LD, EVA MD + EVA LD
	PTI (kPa s)	19.76 ± 5.33	24.79 ± 5.02	23.39 ± 6.37	25.34 ± 6.16	24.35 ± 6.82	< 0.001*	SO < PU MD,EVA MD + EVA LD
Medial heel	Peak pressure (kPa)	299.45 ± 120.79	185.67 ± 57.85	185.87 ± 55.76	176.13 ± 58.18	172.67 ± 51.51	< 0.001*	SO > PU MD, PU LD, EVA MD + EVA LD
	Peak force (N/BW)	0.048 ± 0.02	0.030 ± 0.01	0.030 ± 0.01	0.028 ± 0.01	0.028 ± 0.01	< 0.001*	SO > PU MD, PU LD, EVA MD + EVA LD
	Average contact area (cm^2)	6.80 ± 2.34	10.56 ± 4.93	8.37 ± 2.40	8.82 ± 2.74	8.43 ± 1.72	0.017*	NSD in post hoc tests
	PTI (kPa s)	50.31 ± 23.35	31.64 ± 10.87	31.27 ± 11.15	30.73 ± 9.33	29.17 ± 9.44	< 0.001*	SO > PU MD, PU LD, EVA MD + EVA LD
Lateral heel	Peak pressure (kPa)	325.84 ± 100.19	189.66 ± 61.50	194.31 ± 60.10	182.48 ± 49.40	180.99 ± 50.85	< 0.001*	SO > PU MD, PU LD, EVA MD + EVA LD
	Peak force (N/BW)	0.053 ± 0.02	0.031 ± 0.01	0.032 ± 0.01	0.030 ± 0.01	0.030 ± 0.01	< 0.001*	SO > PU MD, PU LD, EVA MD + EVA LD
	Average contact area (cm^2)	11.87 ± 2.81	13.39 ± 4.57	12.21 ± 2.67	12.33 ± 2.67	12.36 ± 2.98	0.287	
	PTI (kPa s)	46.80 ± 16.86	31.87 ± 10.34	32.34 ± 9.85	31.74 ± 7.73	30.31 ± 8.34	< 0.001*	SO > PU MD, PU LD, EVA MD + EVA LD

EVA LD = EVA low density; EVA MD = EVA medium density; met = metatarsal; NSD = no significant difference; PU LD = PU low density; PU MD = PU medium density; SO = shoe only. *Significant difference ($p \leq 0.05$) between conditions.

Table 4. Comparison of kinematic variables between conditions for custom device session (mean ± standard deviation).

Variable	Angle (°)	Shoe only	PU medium density	PU low density	EVA medium density	EVA low density	*p* value	Post hoc result
Range of motion	Knee – Flexion	62.98 ± 3.79	63.28 ± 3.59	63.41 ± 3.62	62.71 ± 3.79	62.91 ± 3.05	0.761	
	Knee – Adduction	12.84 ± 6.49	13.36 ± 5.45	13.91 ± 5.61	12.50 ± 4.05	13.42 ± 5.43	0.533	
	Knee – Rotation	24.98 ± 6.22	26.69 ± 7.58	25.85 ± 6.58	26.10 ± 7.48	26.01 ± 7.62	0.266	
	Forefoot/Hindfoot – Dorsiflexion	7.31 ± 1.77	6.65 ± 1.49	7.00 ± 1.82	7.09 ± 1.62	6.58 ± 2.39	0.292	
	Forefoot/Hindfoot – Adduction	5.48 ± 1.21	4.31 ± 2.45	3.56 ± 1.11	4.40 ± 3.32	3.89 ± 1.44	0.071	
	Forefoot/Hindfoot – Supination	7.10 ± 2.56	5.31 ± 1.86	5.18 ± 1.72	5.66 ± 2.22	6.10 ± 2.74	0.011*	SO > PU MD + PU LD
	Hindfoot/Tibia – Dorsiflexion	26.51 ± 4.66	27.02 ± 4.88	26.71 ± 4.86	26.71 ± 6.04	26.65 ± 5.36	0.974	
	Hindfoot/Tibia – Inversion	15.73 ± 4.43	15.60 ± 5.13	15.43 ± 5.04	15.18 ± 5.73	14.98 ± 3.60	0.789	
	Hallux/Forefoot Dorsiflexion	12.40 ± 8.40	10.81 ± 6.70	11.15 ± 5.92	12.05 ± 5.29	12.29 ± 5.65	0.568	
Change in angle between heel strike and 6% of gait cycle**	Knee – Flexion	4.24 ± 1.64	4.73 ± 1.93	4.86 ± 1.75	4.17 ± 1.90	3.73 ± 1.86	0.004*	PU LD > EVA LD
	Knee – Adduction	−0.89 ± 1.02	−0.66 ± 0.91	−0.97 ± 1.08	−0.73 ± 0.87	−0.83 ± 1.09	0.062	
	Knee – Rotation	1.22 ± 1.72	0.50 ± 3.86	1.40 ± 2.60	0.97 ± 2.46	−0.26 ± 3.48	0.196	
	Forefoot/Hindfoot – Dorsiflexion	0.87 ± 1.08	0.93 ± 1.02	1.33 ± 1.20	1.32 ± 1.50	1.13 ± 1.02	0.022*	NSD in post hoc tests
	Forefoot/Hindfoot – Adduction	−0.26 ± 0.90	0.05 ± 0.62	−0.01 ± 0.65	0.05 ± 0.80	−0.08 ± 0.90	0.675	
	Forefoot/Hindfoot – Supination	−0.99 ± 1.10	−0.59 ± 0.76	−0.77 ± 1.02	−0.66 ± 0.91	−0.83 ± 1.04	0.43	
	Hindfoot/Tibia – Dorsiflexion	−3.76 ± 2.03	−3.95 ± 2.08	−3.71 ± 2.35	−4.22 ± 2.08	−3.89 ± 2.08	0.738	
	Hindfoot/Tibia – Inversion	−1.22 ± 1.42	−1.31 ± 1.37	−1.66 ± 1.79	−0.96 ± 1.50	−1.09 ± 1.25	0.125	

EVA LD = EVA low density; EVA MD = EVA medium density; NSD = no significant difference; PU LD = PU low density; PU MD = PU medium density; SO = shoe only. *Significant difference ($p \leq 0.05$) between conditions. **+ = increase in angle from heel strike to 6% gait cycle; – = decrease in angle from heel strike to 6% gait cycle.

that PU is superior to EVA when pressure reduction is a requirement. When the percentage change in peak pressure of the custom devices were compared to the shoe only condition, findings were similar to previous research[24] whose custom devices were also found to increase peak pressure at the hallux. While it is difficult to identify specific reasons for this increase, the changes could be attributed to the relationship between the participants' plantar surface contour and the construction of the custom devices.

While no significant differences were evident between the materials for average contact area further analysis showed that when compared to the shoe only condition medium density PU increased the average contact area by a greater percentage than the three other materials in all six areas of the foot; hallux (30–38% greater), first metatarsal (16–20%), lateral metatarsals (8–11%), midfoot (20–26%), lateral heel (9–10%) and medial heel (26–32%). This suggests a possible difference in the loading characteristics of the material with medium density PU appearing to conform more with pressure therefore spreading the load over a greater area. This does not affect other measurements such as peak pressure in the zone, but does indicate a contouring around the anatomical structure that is applying the pressure such as the first metatarsal head or the hallux. This could have a clinical significance in the ability of the material to 'off load' areas of the foot by distributing the force over a greater area and therefore changing the shape of the point of contact. Clinicians may consider this useful when choosing a material that needs to be supportive, corrective and have good pressure attenuation characteristics for patients with compromised ability to deal with pressure.

Additionally, while the average contact area for the medial and lateral heel in the custom devices was not significantly different to the shoe only condition, the F-Scan

sensors were cut to fit the shoe without the devices and therefore the sensors did not cover all of the heel contour on the custom devices and subsequently could not measure the entire contact area of the heel contour.

The effect of the manufacturing process on the production of custom devices also needs to be considered, manufacturing techniques may cause material deformation which may influence the material performance characteristics.[32]

Flat insoles versus custom devices

As significant differences were evident when the results for the shoe only condition from both the flat insoles and custom device sessions were tested, subsequent comparisons between the two sessions were not completed.

While the present study examined the effect on plantar pressure and joint mobility of different materials used in orthoses prescribed for people with diabetes, normal population participants were recruited as research to date has not examined orthotic materials in this way before with this study providing baseline data on the performance of the tested materials for the normal population.

Conclusion

Results for the flat insoles suggest the use of PU for patients where a reduction in peak pressures is required. With regard to the custom devices, the results for average contact area for medium density PU suggest a possible difference in the loading characteristics of the material, indicating that it may be a suitable material for patients with a compromised ability to deal with pressure.

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Following on from examining previous research in the area of orthoses materials an examination of previous research into diabetic footwear was conducted. Two systematic reviews were undertaken to examine the effectiveness of diabetic footwear in the prevention (Chapter 5) and treatment (Chapter 6) of foot ulceration.

Chapter 5: The effectiveness of footwear as an intervention to prevent or to reduce biomechanical risk factors for ulceration: a systematic review

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The effectiveness of footwear as an intervention to prevent or to reduce biomechanical risk factors associated with diabetic foot ulceration: A systematic review ☆

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ABSTRACT

Aim: Footwear interventions are used within clinical practice in an effort to reduce ulcerations however the effectiveness of these interventions is unclear. The aim of this paper was to conduct a systematic review which examined the effectiveness of footwear as an intervention for prevention of diabetic foot ulcers or the reduction of biomechanical risk factors for ulceration and to discuss the quality and interpret the findings of research to date.

Methods: The CINAHL, Medline and Cochrane Register of Controlled Trials databases were searched with 12 articles identified for review.

Results: The majority of these studies were cross sectional and examined the effect of different footwear conditions on plantar pressure measurements. Factors which influenced study findings such as participant selection, measurement and analysis techniques, footwear design and compliance are discussed and recommendations for future studies are provided.

Conclusions: No research to date has examined the effectiveness of footwear in preventing ulceration. Conflicting findings are reported on the effective of footwear interventions to prevent reulceration. While the use of rocker sole footwear and custom orthoses in plantar pressure reduction are supported in cross sectional studies, longitudinal studies are required to confirm their benefit.

1. Introduction

The global prevalence of diabetes reported at 336 million in 2011 is expected to rise to 552 million by 2030. This increase is linked to population growth, ageing of populations and lifestyle changes associated with urbanisation (Whiting, Guariguata, Weil, & Shaw, 2011). The annual incidence of foot ulcers in the diabetic population is approximately 2% (Abbott et al., 2002) with an incidence of 7.2% reported for those with neuropathy (Abbott, Vileikyte, Williamson, Carrington, & Boulton, 1998), and the lifetime incidence of foot ulcers is reported to be as high as 25% (Singh, Armstrong, & Lipsky, 2005). The cost of treating diabetes related foot issues places a significant financial burden on healthcare services; in the UK the annual cost of diabetes related foot care and amputation is estimated to be between £639 and £662 million (Kerr, 2012), while in the U.S. at least 33% of the $116 billion cost of treating diabetes is linked to the treatment of foot ulcers (American Diabetes Association, 2008).

1.1. Influence of footwear in ulceration

The most common causal pathway to the development of diabetic foot ulcers is the accumulation of trauma, neuropathy, and deformity. Approximately 80% of ulcers involve some form of trauma (Reiber et al., 1999) and therefore are potentially preventable. The development of many ulcers is related to ill fitting footwear (Apelqvist, Larsson, & Agardh, 1990), with the breakdown of the locations of diabetic ulcers reported to be evenly distributed between the plantar and dorsal surfaces (Cowley, Boyko, Shofer, Ahroni, & Ledoux, 2008). Reiber (Reiber, 1994) examined the causal chain leading to diabetic amputations in eighty patients and found that footwear was a factor in 42% of cases. It has been reported that providing footwear to all patients with diabetes at risk for ulceration would be a cost effective and potentially cost saving measure (Ragnarson Tennvall & Apelqvist, 2001).

1.2. Footwear specifications

Inadequate shoe length, width, and toe box height and the presence of internal seams are some of the footwear related issues that are attributed to ulcer development. However, it is not only the dimensions and overall structure of the footwear that can affect ulcer

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development. Foot deformities such as claw and hammer toes are common in people with diabetes (Smith, Barnes, Sands, Boyko, & Ahroni, 1997) making footwear with adequate space in the toe box to accommodate the deformity an important factor to consider. Additionally, the presence of such deformities is known to cause elevated plantar pressure (Bus, Maas, De Lange, Michels, & Levi, 2005) which is linked to ulcer development (Veves, Murray, Young, & Boulton, 1992) and therefore the ability of the footwear to off load this elevated pressure will also be an important consideration. Elevated plantar pressure in people with diabetes is also linked with the presence of neuropathy (Reiber et al., 1999) and limited joint mobility at the foot and ankle (Fernando, Masson, Veves, & Boulton, 1991). Although at present there is no evidence for a threshold pressure measurement for ulcer development (Armstrong, Peters, Athanasiou, & Lavery, 1998), a reduction of elevated plantar pressures in at risk patients with diabetes is often the quantifiable outcome measure utilized to assess footwear efficacy.

With contradictive findings on the role of footwear in ulcer prevention (Busch & Chantelau, 2003; Reiber et al., 2002) at present a general consensus on which footwear modalities to prescribe to certain patient groups does not exist (Cavanagh et al., 2002; Praet & Louwerens, 2003; Reiber et al., 2002). In general, current footwear recommendations for people with diabetes are dependent on the individual's activity level and the presence of foot deformities and/or elevated plantar pressures. For those considered at low risk of ulceration with no foot deformities wearing running shoes have been shown to be beneficial as they were found to reduce plantar pressures (Kastenbauer, Sokol, Auinger, & Irsigler, 1998; Perry, Ulbrecht, Derr, & Cavanagh, 1995). As risk increases off the shelf therapeutic or extra depth shoes are recommended. In cases where extra depth footwear may not accommodate a foot with significant deformity the manufacture of custom footwear is advised (Bus et al., 2008a).

1.3. Therapeutic footwear

At present there is ongoing speculation regarding what the most beneficial design features are in off the shelf and custom therapeutic footwear for people with diabetes. The properties of the material used in the footwear along with design features such as the inclusion of a rigid rocker and a custom insole are some of the features under discussion. Perry (Perry, Radtke, & Goodwin, 2007) reported that midsole material can affect dynamic balance control and as patients with diabetes and neuropathy are found to have postural instability (Katoulis et al., 1997) the material selected is an important consideration in the manufacture of footwear. Additionally, in relation to footwear materials custom insoles are recommended to achieve maximal pressure reduction (Bus et al., 2008a) however it is unclear what materials are most appropriate (Healy, Dunning, & Chockalingam, 2010). While rocker sole footwear has been shown to reduce plantar pressures in the forefoot area (Praet & Louwerens, 2003) the optimal rocker angle and position vary across individuals (Chapman et al., 2012; Kavros, Van Straaten, Coleman Wood, & Kaufman, 2011) hence the efficacy of off the shelf rocker soled footwear may be questioned. Furthermore patient compliance is an important issue to consider as previous research has found very low rates in patients who are prescribed diabetic footwear (Knowles & Boulton, 1996). While the aesthetics of the footwear are reported as a factor (Williams & Nester, 2006) the patient's perceived value of the footwear (Macfarlane & Jensen, 2003) has also been related to compliance.

A number of review articles are available which assessed the effectiveness of various offloading interventions (e.g. casting, surgical offloading, footwear, hosiery, orthoses and callus removal) on ulcer/reulceration prevention and ulcer treatment (Bus et al., 2008b; Dorresteijn, Kriegsman, & Valk, 2010; Hinchliffe et al., 2008; Maciejewski et al., 2004; Mason, O'Keeffe, McIntosh, et al., 1999; Mason, O'Keeffe, Hutchinson, et al., 1999; Spencer, 2000). Many of these included studies in which a footwear intervention was part of a complex/multidisciplinary approach or those in which provided educational advice on footwear. As the majority of these reviews covered a range of offloading interventions, not exclusively examining footwear, there was limited discussion on methodological issues such as the participants, measurement equipment and outcomes measures used and on the effect of the design features of the footwear on ulcer prevention. Therefore the objective of this paper was to conduct a systematic review which focused solely on the effectiveness of one offloading intervention (footwear) as an intervention for prevention of diabetic foot ulcers or the reduction of biomechanical risk factors for ulceration; assessing the quality and interpreting the findings of published research to date.

2. Methods

The CINAHL, Medline and Cochrane Register of Controlled Trials databases were searched from inception until 31st December 2012. The search term "((Diabet*) AND (Footwear OR Shoe))" was used with results limited to English language and those with adult human participants. Studies which assessed the effect of footwear on a population with diabetes (Type 1 or 2) were considered. All randomised, quasi-experimental and observational studies were considered, and case studies were excluded. The titles and abstracts of the articles identified by the search strategy were screened by one reviewer (AH) to identify potentially eligible articles and retrieve full-text articles. If it was unclear from the title or abstract if an article should be included the full text article was retrieved and reviewed. Full text articles were assessed for the following inclusion criteria: (1) participants had diabetes (Type 1 or 2); (2) ulceration/reulceration rates or biomechanical risk factors for ulceration (i.e. callus and plantar pressure measurement) were outcome measures; (3) study design included a control group or those which employed a repeated measure design with a comparison of a minimum of two types of footwear on the same participants. Articles in which the footwear studied was an intervention for treatment of diabetic foot ulcers were excluded. Additionally, studies in which the footwear intervention was part of a complex/multidisciplinary intervention and studies which provided educational advice on footwear were excluded. The reference lists of studies obtained through the database search were also searched to identify further relevant citations. The systematic search was performed according to the PRISMA Statement (Moher, Liberati, Tetzlaff, & Altman, 2009).

Data were extracted into evidence tables by one reviewer (AH) and a second reviewer (RN) checked the extracted data. The extracted study details focused on PICOS, study duration and the statistical analysis techniques. Quality assessment of the articles was conducted independently by two reviewers (AH and RN) to evaluate the quality of each full-text paper. The quality assessment form used was adapted from McGinley (McGinley, Baker, Wolfe, & Morris, 2009). Quantitative pooled meta-analysis was not performed because of the heterogeneity of study design, intervention methodology and patient population in studies included in qualitative review.

3. Results

The literature search identified 940 articles, with 14 considered eligible for inclusion in the review (supplementary Figure 1). Following data extraction and quality assessment it was identified that the study by Viswanathan and colleagues (Viswanathan et al., 2004) reported plantar pressure values that were significantly lower than those reported in the other included studies. As no explanation was provided in this article for these lower values this study was

excluded. Additionally, an error in presentation of results by Lobmann et al. (Lobmann et al., 2001) was identified with identical pressures values and standard deviations reported for measurements in both standard and therapeutic footwear and therefore this study was excluded, leaving 12 articles remaining for review. A description of the included studies and quality assessment are provided in Table 1. The study design of the twelve included articles consisted of 8 cross sectional repeated measures studies and one cohort, cross over, controlled trial and randomised control trial. All study designs were included for review due to the limited availability of randomised control trials and to allow a comprehensive overview of the available data. Few of the studies reported the sampling method used and the study duration ranged from 1 session to 42 months. Nine of the twelve studies used biomechanical risk factors for ulceration as outcomes measures and four recorded reulceration rates. One study reported both biomechanical risk factors and reulceration rates (Mueller, Strube, & Allen, 1997). All studies bar one included in this review reported on the use of therapeutic footwear, with Soulier et al. (Soulier, Godsey, Asay, & Perrotta, 1987) examining the benefits of running shoes. The majority of studies examined the effect of footwear with the addition of an insole or custom orthotic.

3.1. Quality assessment

3.1.1. Participants

Sample sizes in the included studies ranged from 10 to 400. The majority of the studies provided information on the inclusion and exclusion criteria for their participants. However, less than a third of the studies were rated as providing an adequate description of their participants' characteristics. Details of the participant characteristics reported in the included studies are provided in Table 2. Less than half of the studies reported the type of diabetes (1 or 2) which their participants were diagnosed with. Within the 5 studies which reported on the type of diabetes all reported a greater percentage of participants with Type 2 diabetes. While duration of diabetes, diabetic neuropathy, peripheral vascular disease and a history of ulceration are considered potential risk factors for ulceration (Hokkam, 2009) not all studies reported the prevalence of these factors in their participants. Additionally, many of the studies did not control for these risk factors when selecting/grouping participants. Only one study reported on glucose control (HbA_{1c}) of their participants (Kastenbauer et al., 1998). The gender of the participants is also an important factor as males are at a higher

Table 1
Study description and quality assessment of the reviewed articles.

Study	Study design	Sampling method	Duration	Outcome measure	Participants	Description	Intervention	Compliance	Results	Statistical analysis
					Inclusion and exclusion criteria		Footwear description		Description	
Birke et al., 1999	Cross sectional; Repeated measures	Not stated	1 session	Peak pressure	Limited	Inadequate	Limited	Not applicable	Limited	Adequate
Busch & Chantelau, 2003	Observational	Not stated	Up to 42 months	Ulcer relapse	Stated	Adequate	Adequate	Not stated	Adequate	Adequate
Hsi et al., 2002	Cross sectional; Repeated measures	Not stated	3 sessions	Peak pressure Pressure time integral Contact time	Stated	Limited	Limited	Not applicable	Adequate	Adequate
Hsi et al., 2004	Cross sectional; Repeated measures	Not stated	4 sessions	Peak pressure Pressure time integral Contact time Time to peak pressure	Limited	Adequate	Adequate	Not applicable	Adequate	Adequate
Kastenbauer et al., 1998	Cross sectional; Repeated measures	Not stated	1 session	Peak pressure		Limited	Limited	Not applicable	Limited	Adequate
Kavros et al., 2011	Cross sectional; Repeated measures	Convenience	1 session	Peak pressure	Stated	Inadequate	Adequate	Not applicable	Adequate	Adequate
Mueller et al., 1997	Cross sectional; Repeated measures	Not stated	6 months	Peak pressure Developed skin lesion, blister or ulcer	Stated	Limited	Adequate	Stated	Limited	Adequate
Owings et al., 2008	Cross sectional; Repeated measures	Not stated	1 session	Peak pressure Force time integral	Stated	Inadequate	Limited	Not applicable	Adequate	Adequate
Praet & Louwerens, 2003	Cross sectional; Repeated measures	Not stated	1 session	Peak pressure Total contact area	Stated	Limited	Adequate	Not applicable	Adequate	Adequate
Reiber, Smith, Wallace, Sullivan, et al., 2002	Randomised control trial	Random	2 years	Ulcer relapse	Stated	Adequate	Limited	Stated	Adequate	Adequate
Soulier et al., 1987	Cross over	Not stated	18 months	Callus measurement	Stated	Inadequate	Limited	Not stated	Adequate	Adequate
Uccioli et al., 1995	Controlled trial	Alternate allocation	1 year	Ulcer relapse	Stated	Limited	Limited	Stated	Adequate	Adequate

Table 2
Characteristics of study participants.

Study	Group	Participant characteristics												
		n	Type 1 diabetes no. (%)	Type 2 diabetes no. (%)	Male no. (%)	Female no. (%)	Age (mean years ± SD)	Height (mean cm ± SD)	Weight (mean kg ± SD)	BMI (mean kg/m^2 ± SD)	Diabetes duration (mean years ± SD)	Diabetic neuropathy no. (%)	Peripheral vascular disease no. (%)	History of ulceration / amputation no. (%)
Birke et al., 1999		19	Not reported	Not reported	11 (58)	8 (42)	60.21 ± 10.11	174.99 ± 11.68	95.37 ± 17	Not reported	Not reported	Not reported	Not reported	19 (100) / 0 (0)
Busch & Chantelau, 2003	Intervention	60	5 (8)	55(92)	31 (52)	29 (48)	62 (54, 73)[a]	Not reported	Not reported	Not reported	12 (5, 15)[a]	58 (97)	15 (25)	60 (100) / 0 (0)
	Control	32	3 (9)	29 (91)	18 (56)	14 (44)	67 (50, 74)[a]	Not reported	Not reported	Not reported	15 (6, 23)[a]	29 (91)	8 (25)	32 (100) / 0 (0)
Hsi et al., 2002		14	Not reported	Not reported	6 (43)	8 (57)	61.4 ± 8.3	156 ± 7	61.9 ± 9.4	25.3 ± 3.5	Not reported	14 (100)	Not reported	0 (0) /0 (0)
Hsi et al., 2004		10	Not reported	Not reported	3 (30)	7 (70)	63 ± 9	154 ± 6	59 ± 11	Not reported	13 ± 6	10 (100)	0 (0)	0 (0) /0 (0)
Kastenbauer et al., 1998		13	5 (38)	8 (62)	5 (38)	8 (62)	56 ± 8	Not reported	Not reported	28.6 ± 4.9	20 ± 9	13 (100)	Not reported	4 (31)/0 (0)
Kavros et al., 2011		15 (11 with diabetes)	Not reported	Not reported	12 (80)	3 (20)	69 (55–82)[c]	Not reported	Not reported	Not reported	Not reported	11 (73)	Not reported	13 (87)/4 (27)
Mueller et al., 1997		30	6 (20)	24 (80)	20 (67)	10 (33)	61.7 ± 4	172 ± 13	95.8 ± 19.8	30.3 ± 5.2	19.9 ± 10.1	16 (53)	Not reported	Not reported/ 30 (100)
Owings et al., 2008		22	Not reported	Not reported	11(50)	11 (50)	63.7 ± 10.7	173 ± 7	93.6 ± 20.6	31.6 ± 7.6	Not reported	15 (68)	Not reported	Not reported
Praet & Louwerens, 2003		10	Not reported	Not reported	0 (0)	10 (100)	63	Not reported	Not reported	Not reported	10.2	10 (100)	Not reported	Not reported
Reiber, Smith, Wallace, Sullivan, et al., 2002	Intervention 1	121	8[b] (7)	113[b] (93)	94 (78)	27 (22)	61 ± 10.1	Not reported	Not reported	33 ± 6.8	35% < 6 yrs; 11% 6–24 yrs; 54% ≥ 25 years	71† (59)	1[b] (1)	121 (100)/ 0 (0)
	Intervention 2	119	6[b] (5)	113[b] (95)	92 (77)	27 (23)	62 ± 10.1	Not reported	Not reported	32 ± 6.9	35% < 6 yrs; 8% 6–24 yrs; 57% ≥ 25 years	79† (66)	1[b] (1)	119 (100)/ 0 (0)
	Control	160	13[b] (8)	147[b] (92)	123 (77)	37 (23)	63 ± 10	Not reported	Not reported	33 ± 7.2	30.2% < 6 yrs; 14.4% 6–24 yrs; 55.4% ≥ 25 years	83† (52)	3[b] (2)	160 (100)/ 0 (0)
Soulier et al., 1987		78	Not reported	Not reported	33(42)	45 (58)	55	Not reported	Not reported	Not reported	Not reported	Not reported	Not reported	Not reported
Uccioli et al., 1995	Intervention	33	8 (24)	25 (76)	20 (61)	13 (39)	59.6 ± 11	Not reported	Not reported	Not reported	16.8 ± 12.7	33 (100)	0 (0)	33 (100)/ 0 (0)
	Control	36	9 (25)	27 (75)	23(64)	13 (36)	60.2 ± 8.2	Not reported	Not reported	Not reported	17.5 ± 8	36 (100)	0 (0)	36 (100)/ 0 (0)

[a] Median (interquartile range).
[b] Calculated from percentages provided in the article.
[c] Mean (range).

risk of ulceration than females (Hokkam, 2009). Furthermore, the offloading ability of footwear will be affected by a participant's body weight; however some studies did not provide this information.

3.1.2. Intervention

A limited description of the footwear intervention was provided by the majority of the studies, with many merely providing the name of the manufacturer and/or the style of the footwear. Table 3 highlights the variability across studies with regards to descriptions provided on footwear sole design. Of the 6 studies where compliance with the footwear intervention would have affected the study findings only 4 reported it.

3.1.3. Results and statistical analysis

The majority of the studies were rated as providing adequate information in their results section. The study of Kastenbauer et al. (Kastenbauer et al., 1998) was rated as limited as they reported minimal plantar pressure measurement values, while the reason that the remaining studies were rated as limited (Birke, Foto, & Pfiefer, 1999; Mueller et al., 1997) was that they only examined plantar pressures in one area of foot and therefore didn't provide a full description of how the footwear condition affected the entire plantar surface. The majority of studies reported using repeated measures ANOVA for statistical analysis, with the other reported analysis techniques including paired t-tests, MANOVA, and the χ^2 test.

3.2. Effectiveness of footwear

The articles selected for review were grouped for analysis based on their outcomes measures (Table 4 and 5). The first grouping included studies which used clinical assessments (i.e. ulcer/reulceration rates) and the second grouping included those which used biomechanical measurements (i.e. plantar pressure measurement and callus measurement). There was a wide variety of plantar pressure measurement systems used across the studies. It is not possible to directly compare results across plantar pressure measurement systems (Chevalier, Hodgins, & Chockalingam, 2010), therefore to aid assessment between studies pressure results are presented as percentage change between relative comparisons within studies. Very few studies provided sufficient descriptions of the footwear used in their research thereby limiting the possibility of adequate cross study comparisons.

3.2.1. Studies which used clinical assessment to examine effectiveness of footwear

Mueller et al. (Mueller et al., 1997) examined the effect of 1 month wear of 6 different types of footwear on participants with transmetatarsal amputation, with occurrence of skin lesions, blisters and ulcers ranging from 0% to 28% among their participants. The remaining 3 studies compared a treatment group who wore a therapeutic shoe with a control group who wore their own footwear. Ulcer lapse was reported after between 9 months and 2 years of wear. While two of these studies reported a significantly lower reulceration rate in participants who wore therapeutic footwear (Busch & Chantelau, 2003; Uccioli et al., 1995) compared to those who wore their own footwear, Reiber et al. (Reiber, Smith, Wallace, Sullivan, et al., 2002) found no significant difference between their groups. All the participants in these studies had a history of ulceration. In relation to compliance with the footwear interventions Mueller et al. (Mueller et al., 1997) provided information on the number of participants who completed the 1 month wearing time with each of the interventions. Reieber et al. evaluated compliance based on a physical activity questionnaire and Uccioli et al. (Uccioli et al., 1995) rated compliance as infrequent, occasional, frequent or continuous. Busch and Chantelau (Busch & Chantelau, 2003) did not provide information on footwear compliance.

3.2.2. Studies which used biomechanical measurements to examine effectiveness of footwear

Five studies compared plantar pressure measurements for footwear with and without a rocker bottom, with all studies reporting greater pressure reductions in rocker bottom footwear (Hsi, Chai, & Lai, 2004; Kavros et al., 2011; Mueller et al., 1997; Owings, Woerner, Frampton, Cavanagh, & Botek, 2008; Praet & Louwerens, 2003). For the vast majority of the studies the diabetic footwear was fitted with either an off the shelf or custom orthotic, with three studies assessing the effect of the footwear alone (Birke et al., 1999; Kastenbauer et al., 1998; Kavros et al., 2011) on plantar pressures. All three of these studies reported a greater reduction in peak pressures with the addition of either flat insoles or custom orthotics. Birke et al. (Birke et al., 1999) reported on the beneficial effect of their participants' own

Table 3
Description provided in reviewed studies for therapeutic footwear sole design.

Study	Description provided on footwear sole design
Birke et al., 1999	No details other than brand and model
Busch & Chantelau, 2003	Convex walking sole ('rocker bottom')
Hsi et al., 2002	No details other than brand and model
Hsi et al., 2004	A 249-mm-long sole had a rocker that started to curve up 83 mm from the front end at the medial side and 87 mm from the front end at the lateral side. The thickness of the sole was 29 mm at the heel, 16 mm at the front end, and 24 mm at the maximum of the rocker curve. The rocker sole curved up for 11 mm in height at the front end.
Kastenbauer et al., 1998	No details other than brand
Kavros et al., 2011	The DARCO MedSurg™ shoe has a rocker axis location of 55% of total shoe length measured from the heel. The rocker axis position with respect to the long axis of the shoe (A–P location) is perpendicular. The rocker angle (angle of the front part of the shoe to the ground) is 5°. The height of the shoe (insole of the heel to the ground) is 2.5 cm.
Mueller et al., 1997	The rocker was a traditional rocker sole of about 20°
Owings et al., 2008	The take-off point of the 20° rocker angle was located at 65% of the sole length as measured from the heel
Praet & Louwerens, 2003	Shoe 1 — rocking angle 5°, rocking point at 61.5%; Shoe 2 — rocking angle 10°, rocking point at 67.5%; Shoe 3 — rocking angle 5°, rocking point at 63%; Shoe 4 — rocking angle 8°, rocking point at 60%; Shoe 5 — rocking angle 23°, rocking point at 65%; Shoe 6 — rocking angle 23°, rocking point at 65%
Reiber, Smith, Wallace, Sullivan, et al., 2002	Male footwear semirockered forefoot made rigid with a lightweight extended composite shank; female footwear semirockered with a nonextended steel shank
Uccioli et al., 1995	Semi-rocker sole

Table 4
Studies which used clinical assessment to examine effectiveness of footwear.

Study	Group	Intervention	Outcome measures	Results
Busch & Chantelau, 2003	Intervention Control	1) Diabetic shoe (LucRo®, Schein, Germany) 2) Participants' own footwear	Ulcer relapse	% ulcers after 9 months: 1) 15% 2) 60% P < 0.001
Mueller et al., 1997		1) Full length shoe with toe filler	Developed skin lesion, blister or ulcer	1) 7%
		2) Custom full length shoe, TCI (total contact insert) and an AFO (ankle foot orthosis)		2) 28%
		3) Custom full length shoe, TCI and a rigid rocker-bottom (RRB) sole		3) 4%
		4) Custom full length shoe, TCI, RRB sole and AFO		4) 4%
		5) Short shoe, TCI and RRB sole		5) 0%
		6) Short shoe, TCI, AFO and RRB sole		6) 0%
				No statistical analysis reported
Reiber, Smith, Wallace, Sullivan, et al., 2002	Intervention 1	1) 3 pairs of therapeutic shoes (dress, casual and athletic) and 3 pairs of customized cork insole	Ulceration	% ulcers after 2 years:
	Intervention 2	2) 3 pairs of therapeutic shoes and 3 pairs of prefabricated, tapered polyurethane insole		1) 15%
	Control	3) Participants' own footwear		2) 14% 3) 17%
				No significant difference between groups
Uccioli et al., 1995	Intervention Control	1) Diabetic shoe (Podiabetes, Buratto, Italy) 2) Participants' own footwear	Ulcer relapse	% ulcers after 1 year: 1) 27.7% 2) 58.3 % P = 0.009

non standard footwear with a custom orthotic to reduce plantar pressure when compared to a diabetic shoe alone and the diabetic shoe with various flat Poron insoles. The greatest pressure reduction was found in the participants' own non standard footwear and custom insole, with pressure reductions also evident for the diabetic footwear with medium hardness flat Poron insoles. Kastenbauer et al. (Kastenbauer et al., 1998) compared an extra depth shoe to the shoe with a custom insole, an oxford style shoe and a running shoe. Compared to the oxford style shoe the running shoe and extra depth shoe with custom insole resulted in significantly reduced peak pressures across the foot. While the main aim of the research carried out by Kavros et al. (Kavros et al., 2011) was to compare sole shape (flat vs. rocker bottom) they found that the inclusion of a Plastazote insole had a greater effect on pressure reduction than sole shape. Studies which compared flat insoles to custom insoles reported the superior offloading ability of custom orthoses (Birke et al., 1999; Kastenbauer et al., 1998). Hsi, Chai, and Lai (Hsi, Chai, & Lai, 2002) compared diabetic footwear with an orthotic to their participants' own footwear with decreases in peak pressure and pressure time integral reported for the heel, anterior metatarsal heads and toes and increases found in the midfoot and posterior metatarsal heads for the diabetic footwear. Two studies reported on the effect of running shoes on biomechanical measurements with Kastenbauer et al. (Kastenbauer et al., 1998) reporting a significant reduction in plantar pressure when compared to oxford style shoes, while Soulier et al. (Soulier et al., 1987) reported a reduction in the size of calluses when wearing running shoes compared to their participants' own shoes. The study of Mueller et al. (Mueller et al., 1997) was the only one which reported both biomechanical measurements and clinical assessment.

As peak plantar pressure measurement is known to be affected by walking speed (Burnfield, Few, Mohamed, & Perry, 2004) it is important for researchers to control for speed when comparing footwear conditions. However, of the 8 studies which reported plantar pressure measurements only 3 reported controlling for walking speed (Kastenbauer et al., 1998; Owings et al., 2008; Praet & Louwerens, 2003). Kastenbauer et al. (Kastenbauer et al., 1998) completed their testing on a treadmill with the speed set to 3 km · h^{-1}. The remaining 2 studies reported using self selected walking speed that was monitored and only trials within ± 5% (Praet & Louwerens, 2003) or 10% (Owings et al., 2008) of this speed were included in the analysis. Yet, neither of these studies reported the values for the self selected speed thereby preventing direct comparisons with other studies. Of the remaining 5 studies, 2 reported using self selected walking speeds with no values reported (Birke et al., 1999; Kavros et al., 2011) and 3 reported using self selected walking speeds and provided speed values (Hsi et al., 2002; Hsi et al., 2004; Mueller et al., 1997).

4. Discussion

The majority of the studies in the review were cross sectional, providing information on the effectiveness of footwear conditions in reducing plantar pressures over a short period of time. These results only allow speculation on the effectiveness of their footwear in preventing ulceration as there is no known threshold pressure for the development of ulcers. The literature to date shows huge variability across studies in terms of their design. The large diversity in study participants, footwear interventions, and measurement techniques make comparison and synthesis of findings difficult.

During the quality assessment process the large diversity among studies with regard to the information provided on study participants was identified. To varying degrees researchers have considered the effect of risk factors for ulceration when selecting their participants. In future studies the use of randomisation techniques such as minimisation (Scott et al., 2002) should be considered to control for factors which may affect study results such as duration of diabetes, sex, peripheral neuropathy, peripheral vascular disease and history of ulceration. In addition, future longitudinal studies should reassess baseline characteristics such as neuropathy and peripheral vascular disease at follow up sessions in order to establish if participants' ulceration risk changes over the course of the study.

Conflicting results on the effectiveness of footwear in preventing ulcer relapse are present in the literature. While both Busch and Chantelau (Busch & Chantelau, 2003) and Uccioli (Uccioli et al., 1995) reported a reduction in ulceration rates in participants who wore therapeutic footwear compared to those who wore their own footwear Reiber et al. (Reiber, Smith, Wallace, Sullivan, et al., 2002) reported no significant difference. Methodological issues such as

Table 5
Studies which used biomechanical measurements to examine effectiveness of footwear.

Study	Condition	Outcome measures	Results
Birke et al., 1999	1) Extra-depth shoe (Thermomold, contour last, PW Minor, USA) 2) Extra-depth shoe with Poron® insole (14 Shore "0" durometer) 3) Extra-depth shoe with Poron® insole (17 Shore "0" durometer) 4) Extra-depth shoe with Poron® insole (22 Shore "0" durometer) 5) Extra-depth shoe with Poron® insole (27 Shore "0" durometer) 6) Extra-depth shoe with Poron® insole (32 Shore "0" durometer) 7) Extra-depth shoe with Poron® insole (40 Shore "0" durometer) 8) Extra-depth shoe with Poron® insole (55 Shore "0" durometer) 9) Participants' own footwear and custom orthotic	Peak pressure	Change in peak pressure at location of highest pressure: −6% to −39% (4, 5, 6 vs. 1, 2, 3, 8) −4% to −6% (5 and 6 vs. 7) −39% to −55% (9 vs. 1–8) P < 0.05
Hsi et al., 2002	1) Participants' own footwear 2) Diabetic footwear (ORTHOAKTIV, F.W Kraemer, Germany) with orthotic (Diabetiker SYS 2)	Peak pressure	Change in peak pressure when compared to participants' own footwear (P < 0.05): Heel −14% to −18%; Midfoot +61% to +278%; Posterior MTH +30% to +51%; Anterior MTH −19% to −31%; Toes −20%
		Pressure time integral	Change in pressure time integral when compared to participants' own footwear (P < 0.05): Heel −17% to −28%; Midfoot +30% to +338%; Posterior MTH +38% to +47%; Anterior MTH −21% to −36%; Toes −30% to −45%
		Contact time	Change in contact time when compared to participants' own footwear (P < 0.05): Heel −16% to −19%; Midfoot +35% to +85%; Posterior MTH −6%; Anterior MTH −10%; Toes −15% to −28%
Hsi et al., 2004	1) Diabetic shoe (ORTHOAKTIV, F.W Kraemer, Germany) with rocker sole and insole (Diabetiker SYS 2)	Peak pressure	Change in peak pressure when compared to shoe without rocker sole (P < 0.05): Posterior forefoot −8% to −17%; Anterior forefoot −18% to −24%
	2) Diabetic shoe without rocker sole and with insole	Pressure time integral	Change in pressure time integral when compared to shoe without rocker sole (P < 0.05): Posterior forefoot −9% to −15%; Anterior forefoot −13% to −19%
		Contact time	No significant difference in contact time
		Time to peak pressure (% gait cycle)	Change in time to peak pressure when compared to shoe without rocker sole (P < 0.05): Posterior forefoot +5% to +7%; Anterior forefoot no significant difference
Kastenbauer et al., 1998	1) Participants' own leather soled Oxford style shoe 2) Barefoot 3) Extra depth shoe (Finn Comfort, Germany) with cork insole 4) Running shoe (Adidas Torsion Equipment Cushion, Adidas, Germany) 5) Extra depth shoe (Finn Comfort, Germany) with custom insole	Peak pressure	Change in peak pressure when compared to 1: 2) Hallux −4%; MTH 1 −26%; MTH 2 and 3 −13%; Heel −14% 3) Hallux −16%; MTH 1 −27%; MTH 2 and 3 −19%; Heel −34% 4) Hallux −32%; MTH 1 −29%; MTH 2 and 3 −47%; Heel −39% 5) Hallux −33%; MTH 1 −50%; MTH 2 and 3 −48%; Heel −49% 5 vs. 1: Significant reduction in pressure under hallux, 1st metatarsal head, heel (P < 0.01) and 2nd and 3rd metatarsals (P < 0.05) 4 vs. 1: Significant reduction in pressure under hallux, heel (P <0.01) and 1st, 2nd and 3rd metatarsals (P < 0.05)
Kavros et al., 2011	1) Classis Post-op shoe (Health Design, USA) 2) DARCO MedSurg™ shoe (DARCO International, USA) 3) Classis Post-op shoe with Plastazote insert (1.25 cm thickness) 4) DARCO MedSurg™ shoe with Plastazote insert (1.25 cm thickness)	Peak pressure	Change in peak pressure when compared to 1: 2) Hallux −21%; MTH 1–5 −39%; Midfoot +17%; Heel −14% 3) Hallux −36%; MTH 1–5 −47%; Midfoot −17%; Heel +12% 4) Hallux −35%; MTH 1–5 −50%; Midfoot + 3%; Heel −23% 2 vs. 1: Significant reduction in peak pressure under hallux (P = 0.02), MTH 1–5 (P < 0.001) and heel (P < 0.01)

(continued on next page)

Table 5 *(continued)*

Study	Condition	Outcome measures	Results
			3 and 4 vs. 1: Significant reduction in peak pressure under hallux ($P = 0.01$), MTH 1-5 ($P < 0.001$), midfoot ($P = 0.01$) and heel ($P < 0.01$) 4 vs. 1–3: Significant reduction in peak pressure under hallux ($P < 0.01$), MTH 1-5 ($P < 0.001$) and heel ($P < 0.05$)
Mueller et al., 1997	1) Full length shoe with toe filler 2) Custom full length shoe, TCI (total contact insert) and an AFO (ankle foot orthosis) 3) Custom full length shoe, TCI and a rigid rocker-bottom (RRB) sole 4) Custom full length shoe, TCI, RRB sole and AFO 5) Short shoe, TCI and RRB sole 6) Short shoe, TCI, AFO and RRB sole	Peak pressure	Change in forefoot peak pressure : Residuum −17% to −26% (2–6 vs. 1) Contralateral limb −18% to −21% (2–4 vs. 1) $P < 0.05$
Owings et al., 2008	1) Diabetic shoe (Extra Depth Erika or Canfield Leisure Time, P.W. Minor, USA) + insole 1 2) Diabetic shoe + insole 2 3) Diabetic shoe + insole 3 4) Rigid rocker version of diabetic shoe + insole 1 5) Rigid rocker version of diabetic shoe + insole 2 6) Rigid rocker version of diabetic shoe + insole 3	Peak pressure	Change in peak pressure at regions that had a peak pressure ≥ 450 kPa at baseline: 3 vs. 1: −32% ($P < 0.0001$) 3 vs. 2: −21% ($P < 0.0001$) 2 vs. 1: −14% ($P = 0.003$) 6 vs. 4: −37% ($P < 0.0001$) 6 vs. 5: −29% ($P < 0.0001$) 4 vs. 3: −11% ($P = 0.022$)
		Force-time integral	Change in force time integral: 3 vs. 1: −40% ($P < 0.0001$) 3 vs. 2: −34% ($P < 0.0001$) 2 vs. 1: no significant difference 6 vs. 4: −42% ($P < 0.0001$) 6 vs. 5: −40% ($P < 0.0001$) 4 vs. 3: no significant difference
Praet & Louwerens, 2003	1) Oxford style leather shoe (model 7132-A, Van der Hammen B.V., the Netherlands) 2) Extra depth Oxford style leather shoe (Bimakon Nederland BV, Netherlands) with customised insole 3) Semi orthopaedic shoe (Xsensible Xflex shoe 2700 series, Nimco Orthopaedics, Netherlands) with customised insole 4) Semi orthopaedic shoe (Xsensible Xstretch shoe model 28074, Nimco Orthopaedics, Netherlands) with customised insole 5) Custom rocker sole shoe and insole 6) High shafted custom rocker sole shoe and insole	Peak pressure	Change in peak pressure: 4 vs. 1: Posterior medial heel −34% 4 vs. 3: Posterior medial heel −17% 3 vs. 2: Lateral midfoot −29% $P < 0.05$
		Total contact area	Change in total contact area: 1 vs. 2–6 : −3% to −6% 2-5 vs. 6.: −3% to −4% $P < 0.05$
Soulier et al., 1987	1) Participants' own footwear 2) Running shoe (400 series, New Balance, USA)	Callus measurement	Mean size of calluses tended to reduce relative to the time spent wearing running shoes ($P = 0.001$)

Note: MTH = metatarsal head.

participant selection, ulcer definition and the suitability of the footwear intervention used within the study of Reiber et al. (Reiber, Smith, Wallace, Sullivan, et al., 2002) have been questioned in the literature (Cavanagh et al., 2002; Chantelau, 2002). With regards to the footwear intervention in these longitudinal studies only Uccioli (Uccioli et al., 1995) provided standardised footwear replacement throughout the study with new footwear provided to participants after 6 months, Reiber et al. (Reiber, Smith, Wallace, Sullivan, et al., 2002) did not report changing the footwear but stated that insoles were replaced based on wear patterns and Busch and Chantelau (Busch & Chantelau, 2003) reported providing one or two additional pairs of footwear. The provision of this information is essential to allow appropriate interpretation of the results and recommendations for clinical practice. In addition to providing information on ulceration rates it would be beneficial if future studies provided information on the location of the ulcers. This would allow researchers to assess the relationship between the footwear intervention and the development of the ulcer.

Within the studies which used biomechanical measurements to examine the effectiveness of footwear results were dependant on relative comparisons between footwear conditions within studies. Large reductions in pressure were evident when therapeutic footwear was compared to oxford style shoes (Kastenbauer et al., 1998; Praet & Louwerens, 2003). While standardising the baseline footwear condition provides information on the effects of specific therapeutic and non therapeutic footwear, if the baseline non therapeutic footwear is not footwear typically worn by the participants then its relevance to clinical practice is limited. Many studies reported the inclusion of a rocker sole in their footwear and supported their use, however several provided a limited description of the rocker. Those which supplied information did not all report on the same design features of the rocker and the overall sole design (Table 3). Information should be provided by researchers if the rocker is rigid or non rigid. Further studies should supply more information about the design of footwear interventions to allow cross study comparisons. In addition it is important to note that the placement of the rocker sole for optimal pressure reduction will vary across individuals (van Schie, Ulbrecht, Becker, & Cavanagh, 2000).

Studies which used plantar pressure assessment used a wide variety of methods and foot masks to compare between footwear conditions. Three of the studies only assessed plantar pressure at specific regions of the foot (Birke et al., 1999; Mueller et al., 1997;

Owings et al., 2008) which is insufficient. While the general aim of offloading the foot through the use of footwear is a reduction of pressure in regions at high risk of ulceration it is important to monitor the effect of the footwear over the entire foot to ensure the offloading of one region is not placing an adjacent region at greater risk of ulceration. The included studies reported the use of different step protocols which may have affected the plantar pressure measurements (Bus & Lange, 2005). The addition of measuring plantar pressure during activities of daily living will also aid in understanding the effectiveness of footwear interventions as it has previously been shown that activities such as walking up and down stairs and walking in a circle result in plantar pressure profiles which are significantly different from level walking in a straight line (Rozema, Ulbrecht, Pammer, & Cavanagh, 1996).

The ability to accurately measure footwear compliance remains an issue in longitudinal studies as researchers are dependent on study participants providing this information. Possibly more important is the measurement of activity levels of study participants as Armstrong et al. (Armstrong, Abu-Rumman, Nixon, & Boulton, 2001) demonstrated that their participants took more steps per day inside their homes when they were less likely to be wearing their prescribed footwear.

5. Conclusion

No research to date has examined the effectiveness of footwear in preventing ulceration and the effectiveness of footwear interventions to prevent reulceration is conflicting. Results from cross sectional studies support the use of rocker sole footwear and custom orthoses in plantar pressure reduction, however the effective of these in ulceration prevention needs to be verified through longitudinal studies. Additionally generic recommendations on these features are not possible as the optimal design will be patient specific.

6. Recommendations

Future research examining the effectiveness of footwear interventions in the prevention of diabetic foot ulcers or reduction of biomechanical risk factors for ulceration should provide adequate descriptions of participants' characteristics and consider grouping their participants based on ulceration risk factors. When plantar pressure measurements are used researchers should standardise walking speed, step protocols and access the effect of the footwear over the entire plantar surface. More detailed information on the footwear should be provided; information on the materials used in the construction of the sole, insole and upper, footwear dimensions and sole design should be included. If a rocker bottom is included information on the rocker angle, shoe height, rocker axis position and rocker axis angle with respect to the long axis of the shoe should be included (van Schie et al., 2000). Additionally information on the replacement of footwear and or insoles/orthotics throughout the study should be provided. Where possible in longitudinal studies researchers should measure their participants' compliance with the footwear intervention and their participants' activity levels. Furthermore there is a need for randomised controlled trials in which the groups are homogenously distributed in terms of the ulceration/reulceration risk factors. Only in this circumstance one can adequately evaluate the effectiveness of one type of footwear in preventing or reducing the risk factors of foot ulceration in people with diabetes.

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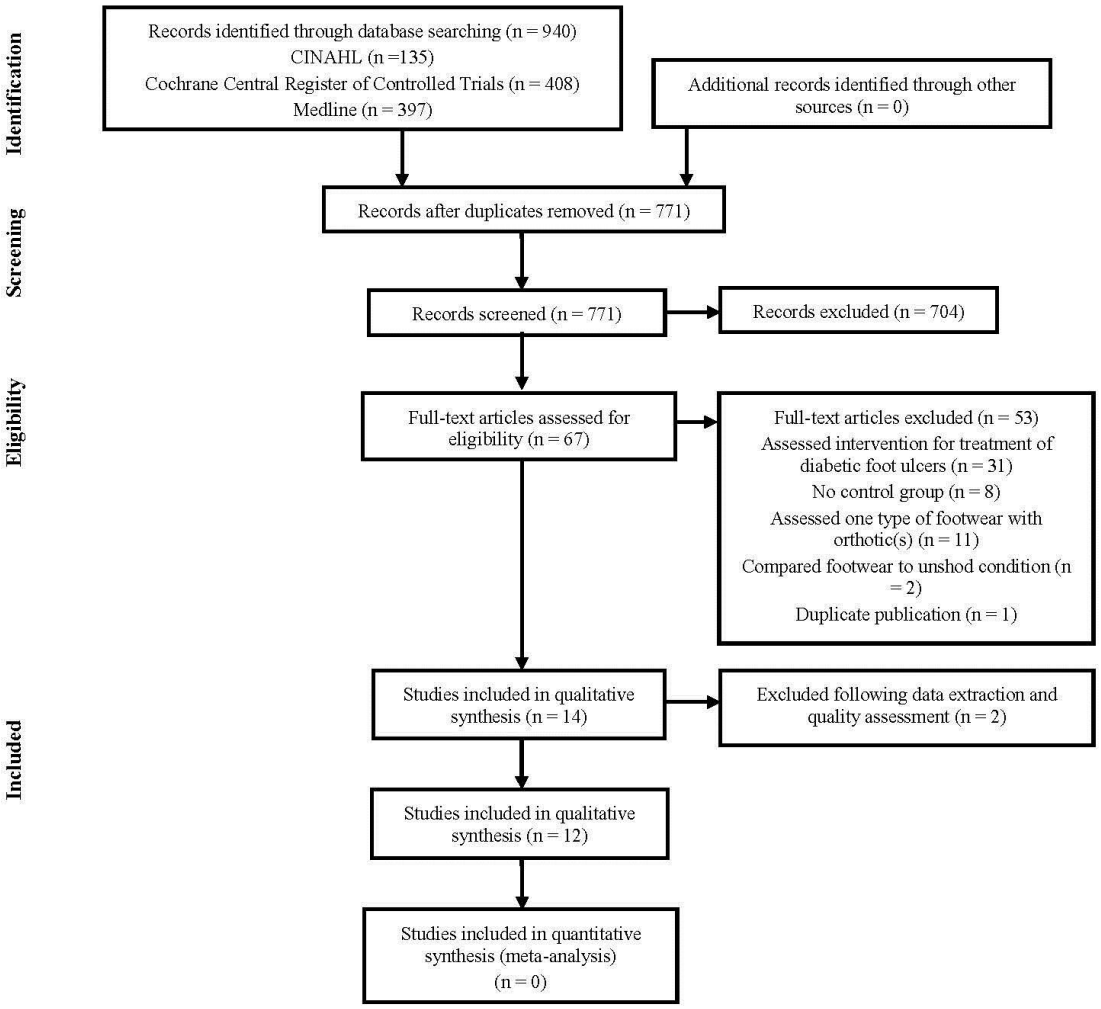

Supplementary Figure 1: Flow diagram for study selection

Chapter 6: The effectiveness of footwear and other removable off-loading devices in the treatment of diabetic foot ulcers: a systematic review

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The Effectiveness of Footwear and Other Removable Off-loading Devices in the Treatment of Diabetic Foot Ulcers: A Systematic Review

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Abstract:

Aim: To conduct a systematic review which examined the effectiveness of footwear and other removable off-loading devices as interventions for the treatment of diabetic foot ulcers or the alteration of biomechanical factors associated with ulcer healing and to discuss the quality and interpret the findings of research to date.

Methods: The CINAHL, Medline and Cochrane Register of Controlled Trials databases were searched with seventeen articles identified for review.

Results: Majority of the identified studies were randomised control trials which compared the ulcer healing rates of different footwear and other removable off-loading device interventions. Three categories of interventions were identified; 1) removable cast walkers (RCWs), 2) half or heel relief shoes and 3) therapeutic shoes. Most studies compared at least one intervention to a total contact cast (TCC). Factors which influenced study findings such as TCC application method, compliance, activity levels, and the footwear worn on the contralateral limb are discussed with recommendations provided for future studies.

Conclusion: Due to the lack of randomised controlled studies conducted in this area it is not currently possible to make strong conclusions on the interventions effectiveness. However, it appears the currently available therapeutic shoes were the least effective intervention followed by half or heel relief shoes. RCWs were found to be the most effective of the removable devices.

Keywords: Biomechanics, diabetes, footwear, plantar pressure, pressure reduction, ulceration.

1. INTRODUCTION

People with diabetes are at a higher risk for ulcerations than those without, with the lifetime risk of developing an ulcer as high as 25% [1]. Neuropathy can lead to insensitivity, deformity (which is known to cause elevated plantar pressures [2]) and reduced range of motion in the joints of the lower limb. The presence of neuropathy and/or peripheral vascular disease in combination with ill-fitting footwear or acute trauma can lead to the development of ulcerations [3]. Once an ulcer develops it is extremely important that it is treated with great urgency and appropriate care as foot ulceration is the precursor to approximately 85% of lower extremity amputations in people with diabetes [4]. Once an ulcer develops early referral to a multidisciplinary team has been shown to significantly reduce amputation rates [5].

1.1. Treatment of Diabetic Ulceration

The principles behind the management of ulcers include: relieving pressure, protection of the ulcer, restoration of skin perfusion, treatment of infection, metabolic control and treatment of comorbidity. Along with local wound care, education for patients and relatives, determining the cause and preventing recurrence form the basis for an effective treatment plan [6].

As elevated plantar pressures are linked to ulcer development [7] the reduction of plantar pressures at the site of ulceration to allow healing is an important aim in the treatment of neuropathic ulcers. Pressure reduction can be achieved by a variety of ways including bed rest, walking aids, total contact casts (TCCs), removable cast walkers (RCWs), therapeutic shoes and dressings.

1.2. Justification for the Review

There are a number of reviews available which have examined the effectiveness of different interventions (surgical off-loading, debridement, antibiotic therapy, dressings, casting and footwear) on the treatment of diabetic foot ulcerations [8–10], including two Cochrane reviews [11,12]. While these reviews examined a variety of treatment interventions there was a limited discussion on methodological issues such as the recruited participants and the information provided on the design features of the off-loading interventions. Detailed information regarding the participants and design features are important parameters that affect the assessment of the efficacy of the footwear and removable off-loading devices in the treatment of ulcers. Therefore the overall aim of this paper was to conduct a systematic review which focuses

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solely on the effectiveness of offloading interventions (footwear and other removable off-loading devices) as interventions for treatment of diabetic foot ulcers or the alteration of biomechanical factors associated with ulcer healing; assessing the quality and interpreting the findings of published research to date. While the effectiveness of these interventions is ultimately determined by longitudinal studies examing ulcer healing rates, studies which examined the immediate effect of these interventions on their ability to offload the foot (assessed through examing biomechanical factors such as peak pressure) were also included as they provide an indication of the potential effectiveness of offloading interventions. This review is a follow up to our previous publication [13] which examined the effectiveness of footwear in the prevention of diabetic foot ulceration.

2. METHODS

The search term "((Diabet*) AND (Footwear OR Shoe))" was used to search the following sources (1) CINAHL, (2) Medline and (3) Cochrane Register of Controlled Trials. The search was restricted to articles published in English and studies involving adult human participants from the start date of the database until 13th January 2014. It was envisaged that the search terms "Footwear" and "Shoe" would encompass all other removable off-loading interventions and all reported studies which assessed the effect of footwear or other removable off-loading devices on participants with diabetes (Type 1 or 2) were considered. All randomised, quasi-experimental and observational studies were considered, and case studies were excluded. One reviewer (AH) assessed the results of the database search to identify possible eligible studies and source full-text articles. For articles where it was not possible to identify eligibility based on their title or abstract a full-text review of the study was completed. Articles were examined for the following inclusion criteria: (1) participants had diabetes (Type 1 or 2); (2) participants had a current foot ulceration; (3) clinical assessment (ulcer healing rates/times or ulcer size) or biomechanical measurement of offloading (plantar pressure measurement) were outcome measures; (4) study design compared footwear or a removable off-loading device to another treatment (dressing) or irremovable device (total contact cast (TCC)/instant total contact cast (iTCC)) or those which employed a repeated measure design with a comparison of a minimum of two types of footwear or removable off-loading devices on the same participants. Papers which employed footwear or removable off-loading devices as part of a complex/multidisciplinary intervention were excluded. In addition manuscripts were also excluded if they only provided educational advice on footwear to participants. The reference lists of studies obtained through the database search were also searched to identify further relevant citations. The systematic search was performed according to the PRISMA Statement [14].

Evidence tables were created for the eligible studies by the first reviewer (AH) and inspected for accuracy by the second reviewer (RN). These tables consisted of information on PICOS, study duration and the statistical analysis techniques used in the eligible studies. A quality assessment form adapted from McGinley, Baker, Wolfe, & Morris [15] was employed to examine the quality of the eligible articles, with the assessment completed by two reviewers (AH and RN) independently. Due to the heterogeneity of the methodologies and participant populations in the eligible studies it was not possible to complete a meta-analysis.

3. RESULTS

Seventeen of the 1091 articles located through the search were considered eligible for inclusion in the review (Supplementary Fig. **1**). Table **1** provides information on the eligible studies the results of the quality assessment. The study design for the seventeen included articles consisted of nine randomised controlled trials (RCTs), one non-randomised control trial, five cross sectional repeated measures studies, a retrospective observational study and a retrospective case-control study. All study designs were included to allow for a comprehensive overview of the available data. With regards to the sampling method employed in the studies, ten studies reported using consecutive eligible patients with the remaining seven studies not stating their sampling method. The duration of the studies ranged from one session for the cross sectional studies to follow up periods between thirty days and sixteen weeks for the prospective studies.

Twelve of the studies used clinical assessment (healing rate/healing time/ulcer size or a combination of these) to examine the effectiveness of the footwear or removable off-loading devices, while six used biomechanical factors associated with ulcer healing (peak pressure/pressure time integral) as outcomes measures. One study reported on both clinical assessment and biomechanical factors [16]. TCC's were the most common intervention compared to footwear or removable off-loading devices in the eligible studies with all but four of the studies investigating them. TCC's were compared to various RCWs or shoes or a combination of these with studies providing comparative data on between two and seven different off-loading interventions. Of the four studies which did not examine TCCs they compared an iTCC to a RCW [17], the addition of footwear to their standard treatment [18], the effect of a felted foam dressing compared to footwear [19] and the effect of a combination of different shoe and insole configurations [20].

The information provided on the ulcer under study within each reviewed manuscript can be found in Supplementary Table **1**. Generally the participants had a grade 1 or 2 (Wagner) ulcer located in the forefoot area. Many of the studies did not report on how long the ulceration had been present, with those who did reporting that the ulcer had been present for between 2 and 13 months.

3.1. Quality Assessment

3.1.1. Participants

Sample sizes in the reviewed studies ranged from 23 to 120 participants, with only 5 of the 17 studies having a sample size greater than 30. Details of the participant characteristics reported in the included studies are provided in Table **2**. Eleven of the seventeen studies provided information on the inclusion and exclusion criteria for their participants, three provided limited information and three provided no criteria for their participants. Seven of the studies were rated as providing sufficient information on their participants'

Table 1. Study description and quality assessment of reviewed articles.

Study	Study Design	Sampling Method	Participants	Description	Intervention	Compliance	Results	Statistical Analysis
			Inclusion and Exclusion Criteria		Description		Description	
Armstrong *et al.* (2005) [17]	Randomised control trial	Not stated	Stated	Limited	Limited	Not stated	Adequate	Adequate
Armstrong *et al.* (2001) [28]	Randomised control trial	Not stated	Stated	Limited	Inadequate	Not stated	Adequate	Adequate
Armstrong and Stacpoole-Shea (1999) [24]	Cross sectional; Repeated measures	Consecutive	Limited	Limited	Limited	Not applicable	Limited	Adequate
Birke *et al.* 2002 [30]	Retrospective; Observational	Consecutive	Stated	Limited	Limited	Not stated	Limited	Adequate
Caravaggi *et al.* (2000) [25]	Randomised control trial	Consecutive	Stated	Adequate	Adequate	Not stated	Adequate	Adequate
Caravaggi *et al.* (2007) [26]	Randomised control trial	Consecutive	Stated	Inadequate	Limited	Not stated	Adequate	Adequate
Chantelau *et al.* (1993) [18]	Retrospective; Case-control	Not stated	Stated	Inadequate	Limited	Not stated	Adequate	Adequate
Faglia *et al.* (2010) [29]	Randomised control trial	Consecutive	Stated	Adequate	Adequate	Not stated	Adequate	Adequate
Fleischili *et al.* (1997) [32]	Cross sectional; Repeated measures	Not stated	Not stated	Limited	Limited	Not applicable	Adequate	Adequate
Gutekunst *et al.* (2011) [16]	Randomised control trial	Not stated	Stated	Adequate	Limited	Not stated	Adequate	Adequate
Ha Van *et al.* (2003) [22]	Non randomised trial	Not stated	Stated	Adequate	Limited	Stated	Adequate	Adequate
Lavery, Vela, Fleischli, Armstrong & Lavery (1997) [20]	Cross sectional; Repeated measures	Consecutive	Not stated	Limited	Adequate	Not applicable	Adequate	Adequate
Lavery, Vela, Lavery & Quebedeaux (1996) [33]	Cross sectional; Repeated measures	Consecutive	Not stated	Limited	Limited	Not applicable	Adequate	Adequate
Lavery, Vela, Lavery & Quebedeaux (1997) [34]	Cross sectional; Repeated measures	Consecutive	Limited	Limited	Inadequate	Not applicable	Adequate	Adequate
Mueller *et al.* (1989) [23]	Randomised control trial	Not stated	Limited	Adequate	Inadequate	Not stated	Adequate	Adequate
Van de Weg *et al.* (2008) [27]	Randomised control trial	Consecutive	Stated	Adequate	Adequate	Not stated	Adequate	Adequate
Zimny *et al.* 2002 [19]	Randomised control trial	Consecutive	Stated	Adequate	Limited	Stated	Adequate	Adequate

characteristics, with eight rated as limited and two as inadequate. Eight of the studies reported on the type of diabetes (1 or 2) which their participants were diagnosed with; those who stated this reported a greater percentage of participants with Type 2 diabetes.

In some of the studies many of the factors which have been identified as risk factors for ulceration [21], the duration of diabetes, presence of diabetic neuropathy and peripheral vascular disease and a history of ulceration, were not stated for participants. The majority of studies which pro-

Table 2. Characteristics of study participants in reviewed articles.

Study	Intervention	Group	Participant Characteristics											
			n	Type 1 diabetes no. (%)	Type 2 diabetes no. (%)	Male no. (%)	Female no. (%)	Age (mean years ± SD)	Height (mean cm ± SD)	Weight (mean kg ± SD)	BMI (mean kg/m² ± SD)	Diabetes duration (mean years ± SD)	Diabetic neuropathy no. (%)	Peripheral vascular disease no. (%)	History of ulceration / amputation no. (%)
Armstrong *et al.* (2005) [17]	1) iTCC		23	Not reported	Not reported	20 (87)	3 (13)	66.9 ± 10.1	Not reported	Not reported	33.3 ± 6.8	Not reported	23 (100)	0 (0)	Not reported/ Not reported
	2) RCW		27	Not reported	Not reported	24 (89)	3 (11)	64.6 ± 9.8	Not reported	Not reported	33.5 ± 6.2	Not reported	27 (100)	0 (0)	Not reported/Not reported
Armstrong *et al.* (2001) [28]	1) TCC + cast boot		19	Not reported	Not reported	14 (74)	5 (26)	Not reported	Not reported	Not reported	Not reported	17.8 ± 8.7	19 (100)	0 (0)	Not reported / Not reported
	2) RCW		20	Not reported	Not reported	18 (90)	2 (10)	Not reported	Not reported	Not reported	Not reported	18.2 ± 10.1	20 (100)	0 (0)	Not reported / Not reported
	3) Half shoe		24	Not reported	Not reported	20 (83)	4 (17)	Not reported	Not reported	Not reported	Not reported	15.3 ± 7.9	24 (100)	0 (0)	Not reported / Not reported
Armstrong and Stacpoole-Shea (1999) [124]			25	Not reported	Not reported	23 (92)	2 (8)	58.0 ± 9.2	Not reported	Not reported	29.6 ± 3.8	14.2 ± 10.2	25 (100)	Not reported	Not reported / Not reported
Birke *et al.* 2002 [30]	1) TCC + rubber walker		13	Not reported	Not reported	7 (57)	6 (43)	47.3 ± 9.1	Not reported	Not reported	Not reported	Not reported	13 (100)	0 (0)	0 (0) / Not reported
	2) Accommodative dressing + Shoe 1		26	Not reported	Not reported	9 (35)	17 (65)	57.5 ± 12	Not reported	Not reported	Not reported	Not reported	26 (100)	0 (0)	0 (0) / Not reported
	3) Shoe 2		57	Not reported	Not reported	26 (46)	31 (54)	58.2 ± 11.5	Not reported	Not reported	Not reported	Not reported	57 (100)	0 (0)	0 (0) / Not reported
	4) Walking splint		18	Not reported	Not reported	14 (78)	4 (22)	56.5 ± 9.6	Not reported	Not reported	Not reported	Not reported	18 (100)	0 (0)	0 (0) / Not reported
	5) Combination of above		6	Not reported	Not reported	2 (33)	4 (67)	56.8 ± 10.5	Not reported	Not reported	Not reported	Not reported	6 (100)	0 (0)	0 (0) / Not reported
Caravaggi *et al.* (2000) [25]	1) TCC + rubber walker/stirrup		26	Not reported	Not reported	18 (69)	8 (31)	60.5 ± 10.7	Not reported	Not reported	27.0 ± 1.6	17.3 ± 10.7	26 (100)	0 (0)	10 (38) / 0 (0)
	2) Shoe		24	Not reported	Not reported	16 (67)	8 (33)	59.2 ± 9.9	Not reported	Not reported	27.3 ± 2.5	16.2 ± 9.1	24 (100)	0 (0)	9 (38) / 0 (0)

Table 2. contd...

Study	Intervention	Group	Participant Characteristics												
			n	Type 1 diabetes no. (%)	Type 2 diabetes no. (%)	Male no. (%)	Female no. (%)	Age (mean years ± SD)	Height (mean cm ± SD)	Weight (mean kg ± SD)	BMI (mean kg/m^2 ± SD)	Diabetes duration (mean years ± SD)	Diabetic neuropathy no. (%)	Peripheral vascular disease no. (%)	History of ulceration / amputation no. (%)
Caravaggi *et al.* (2007) [26]	1) TCC + rubber walker/stirrup		29	Not reported	Not reported	Not reported	Not reported	Not reported	Not reported	Not reported	Not reported	Not reported	29 (100)	0 (0)	Not reported / 0 (0)
	2) RCW		29	Not reported	Not reported	Not reported	Not reported	Not reported	Not reported	Not reported	Not reported	Not reported	29 (100)	0 (0)	Not reported / 0 (0)
Chantelau *et al.* (1993) [18]	1) Standard treatment		22	7 (32)	15 (68)	17 (77)	5 (23)	57 (46-64)[a]	Not reported	Not reported	Not reported	16 (10-23)[a]	22 (100)	0 (0)	Not reported / 5 (23)
	2) Standard treatment + Half shoe		26	7 (27)	19 (73)	18 (69)	8 (31)	56 (52-62)[a]	Not reported	Not reported	Not reported	17 (13-21)[a]	26 (100)	0 (0)	Not reported / 7 (27)
Faglia *et al.* (2010) [29]	1) TCC + stirrup		23	Not reported	Not reported	15 (65)	8 (35)	59.0 ± 8.5	Not reported	Not reported	32.3 ± 4.5	17.7 ± 11.2	23 (100)	0 (0)	15 (65) / 11 (48)
	2) RCW		22	Not reported	Not reported	15 (68)	7 (32)	61.7 ± 10.4	Not reported	Not reported	30.3 ± 1.1	17.2 ± 10.7	22 (100)	0 (0)	15 (68) / 12 (55)
Fleischli *et al.* (1997) [32]		1) Forefoot ulcer	19	Not reported	Not reported	15 (79)	4 (21)	51.6 ± 9.3	Not reported	Not reported	31.5 ± 6.0	Not reported	19 (100)	Not reported	Not reported / Not reported
		2) Great toe ulcer	7	Not reported	Not reported	1 (14)	6 (86)	54.3 ± 8.9	Not reported	Not reported	29.7 ± 2.3	Not reported	7 (100)	Not reported	Not reported / Not reported
Gutekunst *et al.* (2011) [16]	1) TCC + cast boot		11	1 (9)	10 (91)	9 (82)	2 (18)	55 ± 13	183 ± 8	107 ± 27	31.4 ± 6.2	19 ± 14	11 (100)	0 (0)	Not reported / Not reported
	2) RCW		12	2 (17)	10 (83)	10 (83)	2 (17)	53 ± 10	183 ± 10	108 ± 17	32.3 ± 4.5	17 ± 13	12 (100)	0 (0)	Not reported / Not reported
Ha Van *et al.* (2003) [22]	1) TCC + rubber walker		42	6 (14)	36 (86)	38 (90)	4 (10)	58 ± 11	Not reported	Not reported	28.55 ± 3.42	17 ± 11	42 (100)	23 (55)	Not reported / Not reported
	2) Half or Heel relief shoe		51	12 (24)	39 (76)	40 (78)	11 (22)	62 ± 7	Not reported	Not reported	29.06 ± 4.76	15 ± 10	49 (96)	22 (43)	Not reported / Not reported
Lavery, Vela, Fleischli, Armstrong & Lavery (1997) [20]			32	2 (6)	30 (94)	21 (66)	11 (34)	50.5± 9.5	Not reported	Not reported	31.2 ± 5	13.6 ± 9.9	Number not reported[b]	Not reported	Not reported / Not reported

Table 2. contd...

Study	Intervention	Group	Participant characteristics												
			n	Type 1 diabetes no. (%)	Type 2 diabetes no. (%)	Male no. (%)	Female no. (%)	Age (mean years ± SD)	Height (mean cm ± SD)	Weight (mean kg ± SD)	BMI (mean kg/m^2 ± SD)	Diabetes duration (mean years ± SD)	Diabetic neuropathy no. (%)	Peripheral vascular disease no. (%)	History of ulceration / amputation no. (%)
Lavery, Vela, Lavery & Quebedeaux (1996) [33]			25	0 (0)	25 (100)	23 (92)	2 (8)	58 ± 9.2	Not reported	Not reported	29.6 ± 3.8	14.2 ± 10.2	Number not reported[b]	Not reported	Not reported / Not reported
Lavery, Vela, Lavery & Quebedeaux (1997) [34]			25	0 (0)	25 (100)	23 (92)	2 (8)	58.0 ± 9.2	Not reported	Not reported	29.6 ± 3.8	14.2 ± 10.2	Number not reported[b]	Not reported	Not reported / Not reported
Mueller *et al.* (1989) [23]	1) TCC + rubber heel		21	5 (24)	16 (76)	13 (62)	8 (38)	54 ± 10	Not reported	Not reported	Not reported	17 ± 6	21 (100)	3 (14)	Not reported / Not reported
	2) Sandal or Shoe		19	6 (32)	13 (68)	14 (74)	5 (26)	55 ± 12	Not reported	Not reported	Not reported	17 ± 9	19 (100)	4 (21)	Not reported / Not reported
Van de Weg *et al.* (2008) [27]	1) TCC + cast boot		23	Not reported	Not reported	16 (70)	7 (30)	64.8 ± 10.8	Not reported	Not reported	Not reported	12 ± 6.2	23 (100)	0 (0)	Not reported / Not reported
	2) Shoe		20	Not reported	Not reported	18 (90)	2 (10)	58.1 ± 11.1	Not reported	Not reported	Not reported	12 ± 7.17	20 (100)	0 (0)	Not reported / Not reported
Zimny *et al.* (2002) [19]	1) Felted foam dressing + Shoe		27	8 (30)	19 (70)	14 (52)	13 (48)	61.7 ± 13.3	Not reported	Not reported	27.1 ± 4.8	18.4 ± 7.2	27 (100)	0 (0)	Not reported / Not reported
	2) Half shoe		34	14 (41)	20 (59)	19 (56)	15 (44)	61.1 ± 11.6	Not reported	Not reported	27.9 ± 4.4	21.6 ± 11.7	34 (100)	0 (0)	Not reported / Not reported

TCC: Total Contact Cast; iTCC: Instant Total Contact Cast; RCW: Removable Cast Walker; [a] Median (95% Confidence Interval); [b] Study provided mean values for participants' biothesiometer results with some participants' in the range of significant loss of sensation; [c] Median (interquartile range).

vided information on gender reported a higher percentage of male participants, with 550 of the 760 participants (72%) whose gender was reported being male. Some of the studies made no reference to the weight and/or BMI status of their participants; this is valuable information which should be provided as body weight should be a consideration when selecting an appropriate off-loading treatment.

For majority of the studies the participants had diabetic neuropathy diagnosed by the inability to sense a 10 g monofilament and/or a vibration perception threshold >25 V. The presence of peripheral vascular disease was an exclusion criterion for most of the studies, however it was noted that there was a number of different criteria used to define it across studies. One or a combination of the following was used: absence of at least one pedal pulse, measurement of ankle brachial index (ABI) and transcutaneous pressure of oxygen ($TcPo_2$). The studies which used ABI and $TcPo_2$ did not all use the same cut off values to confirm the presence of peripheral vascular disease. It is recommended where possible that measurements of toe pressure or $TcPo_2$ be used to assess the vascular tree as ankle pressure can be falsely evaluated due to calcification of the arteries [6]. Only two studies reported including participants with some level of peripheral vascular disease [22,23].

3.1.2. Intervention

Ten of the seventeen studies were evaluated as providing a limited description of the interventions used in their stud-

Table 3. Description provided in reviewed articles for interventions.

Author	Intervention	Description
Armstrong *et al.* (2005) [17]	1) iTCC	Active Offloading Walker (Royce Medical, Camarillo, CA) wrapped entirely in a cohesive bandage. Technique as described by Armstrong *et al.* [42]
	2) RCW	Active Offloading Walker
Armstrong *et al.* (2001) [28]	1) TCC + cast boot	Technique described by Kominsky [37] except a cast boot replaced the rubber cast walker and plywood platform
	2) RCW	No information provided for RCW
	3) Half shoe	No information provided for Half shoe
Armstrong & Stacpoole-Shea (1999) [24]	1) TCC + rubber walker	Technique described by Kominsky [37], except the plywood sole was not incorporated into the last layer of fiberglass
	2) RCW 1	Aircast pneumatic walker (Aircast, Summit, NJ)
	3) RCW 2	DH pressure relief walker (Centec Orthopaedics, Camarillo, CA)
	4) Baseline shoe	Reebok canvas sneaker (Reebok, Stoughton, MA)
	5) Shoe	Prescription depth inlay shoe with PW Minor stock inlays (PW Minor and Son, Batavia, NY)
Birke *et al.* 2002 [30]	1) TCC + rubber walker	Technique described by Birke *et al.* [38]
	2) Accommodative dressing + Shoe 1	6 inch long piece of ¼ inch adhesive felt attached to the forefoot with a cut-out over the ulcer area and surgical shoe (Darco International Inc., Huntington, WV) modified with a ½ inch wedged sole
	3) Shoe 2	Surgical shoe modified with a ¼ inch nonpolyethylene foam inlay, a relief cut-out under the ulcer area and a ½ inch wedged sole
	4) Walking splint	Technique described by Birke *et al.* [38]
	5) Combination of above	
Caravaggi *et al.* (2000) [25]	1)TCC + rubber walker/stirrup	Extensive description of technique provided within article
	2) Shoe	Cloth therapeutic shoe with a rocker-bottom sole and a rolling point that is situated beside the metatarsal arch during walking. The shoe is predisposed (extra depth) for lodging an 8-mm–thick cushioned elastic insole made of plastazote (alkaform) on which an area of unloading is prepared in the area of the plantar ulcer. The unloading area must be 5–8 mm larger than the perimeter of the ulcer. The shoe is opened dorsally with velcro straps that permit the dressing to stay in place. All patients used the same type of shoe, with a plantar insole but no area of unloading, for the unaffected foot
Caravaggi *et al.* (2007) [26]	1) TCC + rubber walker/stirrup	Technique described by Caravaggi *et al.* [25] with short description provided within article
	2) RCW	Aircast Pneumatic Walker (XP Diabetic Walker) with short description provided within article
Chantelau *et al.* (1993) [18]	1) Standard treatment	Oral antibiotic (Cephalexin or Clindamycin), daily wound care with debridement (either mechanically or with necrolytic ointments), local antiseptic treatment (e.g. povidone iodine) and sterile cotton gauze dressing until healing
	2) Standard treatment + Half shoe	As above with the addition of the provision of a half shoe (IPOS, Lüneburg, Germany)
Faglia *et al.* (2010) [29]	1) TCC + stirrup	Technique described by Caravaggi *et al.* [25] with extensive description provided within article
	2) RCW	Stabil-D (Podartis, Montebelluna, Treviso, Italy) with extensive description provided within article
Fleischili *et al.* (1997) [32]	1) TCC + cast boot	Technique described by Coleman, Brand & Birke [39], except the plywood sole was not used and an outer layer of fibreglass cast material was applied over the total contact layer and splints
	2) RCW	DH Pressure relief walker (Royes Medical Co., Camerillo, CA)
	3) Baseline shoe	Rubber soled canvas Oxford shoe
	4) Half shoe	Darco OrthoWedge (Darco International, Inc., Huntington, WV)
	5) Shoe	Darco rigid-soled (Darco International, Inc., Huntington, WV)
	6) Dressing + shoe	Elastic cloth tape was applied around the forefoot with the adhesive side away from the skin. Next, a 1/4-inch piece of felt cut to accommodate the lesion was applied to the adhesive surface of the tape. An identically shaped piece of ¼-inch polyethylene foam was applied directly to the top of the felt and the entire area was covered with a second piece of elastic cloth tape. The patient was then placed in a postoperative shoe for testing.

Table 3. contd...

Author	Intervention	Description
Gutekunst *et al.* (2011) [16]	1) TCC + cast boot	No description provided
	2) RCW	DH Pressure Relief Walker (Össur, Foothill Ranch, CA, USA)
Ha Van *et al.* (2003) [32]	1) TCC + rubber walker	Extensive description provided within article
	2) Half or Heel relief shoe	For ulcers under the forefoot or toes, Barouk half shoe was used, which has a heel 6 cmin height extending from the posterior edge of the foot to the midfoot and stretches under the forefoot by means of a platform that remains a distance from the ground and supports a shaft. The Sanital heel-relief shoe was used in patients with ulcers under the hindfoot. This shoe places the foot in 20° equinus and has a Sanital plastazote insole with a posterior opening that leaves the posterior and plantar aspects of the heel unsupported
Lavery, Vela, Fleischli, Armstrong & Lavery (1997) [20]	1) Baseline shoe	Canvas oxford
	2) Shoe 1	Therapeutic shoe (PW Minor & Son, Batavia, NY: Sir Super Depth for males; Duchess for females)
	3) Shoe 1 with insole	Therapeutic shoe with insole (4mm plastazote/urethane)
	4) Shoe 2	Cross trainer (New Balance, Boston, MA: MX750WB)
	5) Shoe 2 with insole	Cross trainer with insole
	6) Shoe 3	Comfort shoe (SAS Shoemakers, San Antonio, TX: Timeout for males; Freetime for females)
	7) Shoe 3 with insole	Comfort shoe with insole
Lavery, Vela, Lavery & Quebedeaux (1996) [33]	1) TCC + cast boot	Technique described by Burnett [40] except the plywood sole was not incorporated into the last layer of plaster and an outer layer of fibreglass material was applied after the total contact layer posterior splint had been applied
	2) Baseline shoe	Thin rubber sole canvas oxford shoe
	3) Shoe	Xtra Depth shoes (PW Minor and Son, Batavia, NY)
	4) RCW 1	DH Pressure Relief Walker (Royce Medical/Centec Orthopaedics, Camarillo, CA)
	5) RCW 2	Aircast Pneumatic Walker (Aircast, Summit, NJ)
	6) RCW 3	Three D Dura Stepper (DeRoyal Orthopedic, Powell, TN)
	7) RCW 4	CAM walker (Zinco, Pasadena, CA)
Lavery, Vela, Lavery & Quebedeaux (1997) [34]	1) TCC + rubber heel	Technique described by Burnett [40] except the plywood sole was not incorporated into the last layer of plaster and an outer layer of fibreglass material was applied after the total contact layer posterior splint had been applied. The centre of the walking cast heel was placed at 40% of the heel-to-toe distance
	2) TCC + cast boot	No information provided for the cast shoe
	3) Baseline shoe	Thin rubber soled canvas oxford shoe
	4) Shoe	Xtra Depth therapeutic shoes (PW Minor & Son, Batavia, NY)
Mueller *et al.* (1989) [23]	1) TCC	Technique described by Sinacore [41] and Coleman, Brand and Birke [39] with extensive description provided within article
	2) Sandal or Shoe	Prescription footwear as described by Coleman [48]
Van de Weg *et al.* (2008) [27]	1) TCC + cast boot	Technique described by Kominsky [37]
	2) Shoe	Custom-made of felt and supplied with a rigid leather socket stiffened with Rhenoflex, a composite of rubber and plastic with thermoplastic properties. The height of the shoes is twice the distance from the foot base to the lateral malleolus. The custom full-length insoles were made from cork and a plastazote and PPT (polyethylene foam and polyurethane) covering. Extra depth was provided in the inlay for the ulcer. The pivot point of the rocker bar was placed proximal to the MTPs and the outsole stiffened. A plastic trial cast was always made for a test fitting to check the last measurements, innersole accommodation and balance before the shoe was completed
Zimny *et al.* (2002) [19]	1)) Felted foam dressing + Shoe	Combination of 0.635 cm thick rubber foam with a 0.158 cm layer of felt adhered rubber glue (Mastic-Verbandskleber, ASID Bonz and Sohn GmbH, Boeblingen, Germany) with extensive description provided within article. No information provided on the shoe other than it was a postoperative shoe
	2) Half shoe	Pressure relief half shoe (Thanner, Hoechstaedt, Germany)

TCC: Total Contact Cast; iTCC: Instant Total Contact Cast; RCW: Removable Cast Walker; RCC: Removable Contact Cast.

Table 4. Studies which used clinical assessment to examine the effectiveness of footwear or removable off-loading devices as the treatment intervention.

Author	Intervention	Outcome Measure(s)	Follow Up Period	Results
Armstrong *et al.* (2005) [17]	1) iTCC	Healing rate %	12 weeks or until would healing	1) 86.4; 2) 58.3 (1 vs. 2*)
	2) RCW	Healing time (days) [mean ± SD]		1) 41.6 ± 18.7; 2) 58.0 ± 15.2 (1 vs. 2*)
Armstrong *et al.* (2001) [28]	1) TCC + cast boot	Healing rate %	12 weeks or until would healing	1) 89.5; 2) 65; 3) 58.3 (1 vs. 2 and 3*)
	2) RCW	Healing time (days) [mean ± SD]		1) 33.5 ± 5.9; 2) 50.4 ± 7.2; 3) 61.0 ± 6.5 (1 vs. 3*)
	3) Half shoe	Activity (daily steps) [mean ± SD]		1) 600.1 ± 320.0; 2) 767.6 ± 563.3; 3) 1461.8 ± 1452.3 (1 vs. 3*)
Birke *et al.* 2002 [30]	1) TCC + rubber walker	Healing rate %	12 weeks	1) 92; 2) 93; 3) 81; 4) 83 (Statistical analysis not performed)
	2) Accommodative dressing + Shoe 1	Healing time (days) [mean ± SD]		1) 47.7 ± 41.4; 2) 36.1 ± 36.3; 3) 41.4 ± 41.9; 4) 50.5 ± 29 (Statistical analysis not performed)
	3) Shoe 2	Adjusted healing time[a] (days) [mean]		:1) 31.7; 2) 20.9; 3) 32.7; 4) 38.2 (2 vs. 3 and 4**)
	4) Walking splint			
	5) Combination of above			
Caravaggi *et al.* (2000) [25]	1)TCC + rubber walker/stirrup	Healing rate %	30 days	1) 50; 2) 21 (1 vs. 2*)
	2) Shoe	Ulcer size		Faster reduction in 1 than 2*
		Patient acceptance (visual analog scale) [mean ± SD]		1) 88.33 ± 17.3; 2) 91.15 ± 9.9 (NSD)
Caravaggi *et al.* (2007) [26]	1) TCC + rubber walker/stirrup	Healing rate %	90 days	1) 82.7; 2) 79.3(NSD)
	2) RCW	Healing time (days)		1) 48; 2) 71 (1 vs. 2*)
Chantelau *et al.* (1993) [18]	1) Standard treatment	Healing rate % (by outpatient treatment only)	Until healed	1) 59; 2) 96 (Statistical analysis not performed)
	2) Standard treatment + Half shoe	Healing time (days) [median (95% CI)]		1) 118 (55-165); 2) 70 (45-143) (NSD)
		Rate of transient hospitalisation (%)		1) 41; 2) 4 (1 v 2**)
		Duration of hospitalisation (days) [median (95% CI)]		1) 22 (18-40); 2) 15 (Statistical analysis not performed)
Faglia *et al.* (2010) [29]	1) TCC + stirrup	Healing rate %	90 days	1) 73.9; 2) 72.7 (NSD)
	2) RCW	Healing time (days) [mean ± SD]		1) 35.3 ± 3.1; 2) 39.7 ± 4.2 (NSD)
		Ulcer size decrease (cm^2)		1) 1.41 to 0.21; 2) 2.18 to 0.45 (NSD)
Gutekunst *et al.* (2011) [16]	1) TCC + cast boot	Healing rate %	Not reported	1) 82; 2) 42 (1 vs. 2*)
	2) RCW	Healing time (days) [mean ± SD]		1) 95 ± 61; 2) 94 ± 64 (NSD)
Ha Van *et al.* (2003) [22]	1) TCC + rubber walker	Healing rate %	Until healed or when treatment failed (complications or absence of healing at study end)	1) 81; 2) 70 (1 vs. 2*)
	2) Half or Heel relief shoe	Healing time (days) [mean ± SD]		1) 68.6 ± 35.1; 2) 134.2 ± 133.0 (Statistical analysis not performed)

Table 4. contd...

Author	Intervention	Outcome Measure(s)	Follow Up Period	Results
		Compliance		Compliance: Significantly better in 1 than 2*
				Complete compliance %: 1) 98; 2) 10 (1 vs. 2*)
Mueller *et al.* (1989) [23]	1) TCC + rubber heel	Healing rate %	Until healed	1) 90%; 2) 32% (1 vs. 2*)
	2) Sandal or Shoe	Healing time (days) [mean ± SD]		1) 42 ± 29; 2) 65 ± 29 (Statistical analysis not performed)
		Incidence of infection		Incidence of infection: Significantly greater in 2 than 1*
Van de Weg *et al.* (2008) [27]	1) TCC + cast boot	Healing rate %	16 weeks	1) 26; 2) 30 (Statistical analysis not performed)
	2) Shoe	Healing time (days) [mean ± SD]		1) 59 ± 39; 2) 90 ± 12 (NSD)
		Ulcer size decrease (cm2)		1) from 3.6 to 0.4; 2) from 1.9 to 0.4 (NSD between groups)
Zimny *et al.* (2002) [19]	1) Felted foam dressing + Shoe	Healing time (days) [mean (95% CI)]	10 weeks	1) 79.6 (75-84); 2) 83.2 (77-90) (NSD)
	2) Half shoe	Ulcer size decrease (cm^2)		1) 1.1 to 0.02; 2) 1.2 to 0.03 (NSD between groups)

RCW: Removable Cast Walker; TCC: Total Contact Cast; iTCC: Instant Total Contact Cast; *significant difference $p \leq 0.05$; **significant difference $p < 0.01$; ᵃHealing time adjusted by width and ulcer grade using a lognormal regression model; NSD: No significant difference.

ies, with 4 considered adequate and 3 inadequate. Those evaluated as limited provided information on the manufacturer and/or the style of the footwear or removable off-loading device. Only two of the ten studies in which compliance with the interventions would have affected the results reported on it.

3.1.3. Results and Statistical Analysis

One study [24] was evaluated as providing limited information within the results as it only reported plantar pressures in one region of foot thereby not providing a complete account of the effect of the intervention on the foot as a whole. The area they assessed was the heel while the ulcerated area was the forefoot. The majority of the cross sectional studies reported using repeated measures ANOVA with Tukey's post hoc test for statistical analysis, while the RCTs predominately used a Mann-Whitney U test, χ^2 test and/or Kaplan-Meier curves.

3.2. Effectiveness of Footwear or Removable Off-loading Devices

The articles selected for review were grouped and analysed based on their outcomes measures (Tables **4** and **5**). The first group included studies which used clinical assessments (healing rate/healing time/ulcer size or a combination of these) and the second group included those which used biomechanical measurements (peak pressure and/or pressure time integral). In the clinical assessment group, nine of the twelve studies were RCTs, while in the biomechanical measurements group only one of the six studies was a RCT. Of the studies which used biomechanical measurements some used a canvas oxford shoe as a baseline comparison but this was not carried out in all studies. In an attempt to allow cross study comparisons, as the majority of the studies examined TCCs, the TCC will be used as the baseline comparison for plantar pressure measurements. As all the studies which measured plantar pressures used the same measurement system (Pedar in-shoe system, Novel, Munich, Germany) it is possible to directly compare the pressure values (Supplementary Table **2**).

3.2.1. Studies Which Used Clinical Assessment to Examine Effectiveness of Footwear or Removable Off-Loading Devices

3.2.1.1. Irremovable Offloading Devices

The studies which examined healing rates in irremovable offloading devices (TCC or iTCC) reported, for the majority, similarly high rates of ulcer healing in their participants (approximately 70-90%). Caravaggi, Faglia, Giglio, Mantero, Quarantiello, *et al.* [25] reported a lower rate of 50% for their participants, however, this was over a short follow up period of 1 month and in a later study by the same group using the same TCC technique in which participants were followed up for three months the reported rate was 83% [26]. Van De Weg, Van Der Windt, & Vahl [27] reported a lower healing rate of 26% which they reported may be due to the inclusion of Grade 2 ulcers compared to studies which only included Grade 1. The mean values reported for healing time ranged from 33.5-95 days, with a relatively large standard deviation (ranging from ± 3.1 to ± 61 days) reported for most of the studies.

3.2.1.2. Removable Cast Walkers

Of the five studies which examined RCWs none of them examined the same model. Three studies reported significantly lower healing rates for their RCWs when compared to

Table 5. Studies which used biomechanical measurements to examine the effectiveness of footwear or removable off-loading devices as the treatment intervention.

Author	Condition	Outcome Measures	Results
Armstrong and Stacpoole-Shea (1999) [24]	1) TCC + rubber walker	Peak Pressure	1 < 2, 3, 4 and 5*; 1, 2, 3 < 5* 3 < 1, 2, 4 and 5*; 1, 2, 3 and 4 < 5*)
	2) RCW 1	Pressure Time Integral	
	3) RCW 2		
	4) Baseline shoe		
	5) Shoe		
Fleischili *et al.* (1997) [32]	1) TCC + cast boot	Peak Pressure	% difference in peak pressure when compared to TCC: Group 1 (Forefoot ulcer): 2) -38; 4) 44; 5) 172; 6) 119 (2 < 1 < 4 < 6 < 5*) Group 2 (Hallux ulcer): 2) 40; 4) 149; 5) 537; 6) 351 (2 and 1 < 4 < 6 < 5*)
	2) RCW		
	3) Baseline shoe		
	4) Half shoe		
	5) Shoe		
	6) Dressing + shoe		
Gutekunst *et al.* (2011) [16]	1) TCC + cast boot	Peak pressure	Significant % difference when compared to TCC*: Peak pressure: Midfoot -38; Forefoot -51; Ulcer area -55
	2) RCW	Pressure Time Integral	Pressure Time Integral: Forefoot - 63; Ulcer area -63
		Maximum Force	Max Force: Forefoot -46; Ulcer area -46
		Force Time Integral	Force time integral: Forefoot -56
		Contact time	NSD
		Contact area	NSD
Lavery, Vela, Fleischli, Armstrong & Lavery (1997) [20]	1) Baseline shoe	Peak pressure	Comparing 1 to shoe only (2, 4 and 6):
	2) Shoe 1		Participants with ulcers under the first MTH: 6 < 4 and 2*
	3) Shoe 1 with insole		Participants with ulcers under the lesser MTHs: 6 < 4 and 2*
	4) Shoe 2		Participants with ulcers under the Hallux: 2 and 6 < 4 *
	5) Shoe 2 with insole		Comparing 1 to shoe and insole only (3, 5 and 7):
	6) Shoe 3		Participants with ulcers under the first MTH: 7 = 3 = 5*
	7) Shoe 3 with insole		Participants with ulcers under the lesser MTHs: 7 = 3 = 5*
			Participants with ulcers under the Hallux: 3 and 7 < 5*
			In the unulcerated foot area: 3, 5 and 7 < 1*
			Comparing shoe to shoe with insole (Conditions 2-7):
			In all forefoot regions: 3 < 2*; 5 < 4*; 7 < 6*
Lavery, Vela, Lavery & Quebedeaux (1996) [33]	1) TCC + cast boot	Peak pressure	% difference for ulcers under 1st MTH when compared to TCC: 2) 539; 3) 464; 4) 14; 5) 76; 6) 101; 7) 184 (1 = 4 < 5 < 6 < 7 < 3 < 2*)
	2) Baseline shoe		% difference for ulcers under 2nd - 5th MTH when compared to TCC: 2) 507; 3) 349; 4) -2; 5) 76; 6) 125; 7) 155 (1 = 4 < 5 < 6 < 7 < 3 < 2*)

Table 5. contd...

Author	Condition	Outcome Measures	Results
	3) Shoe		% difference for ulcers under hallux when compared to TCC: 2) 423; 3) 260; 4) 21; 5) 109; 6) 57; 7) 130 (1 = 4 < 6 < 7 < 3 < 2*)
	4) RCW 1		
	5) RCW 2		
	6) RCW 3		
	7) RCW 4		
Lavery, Vela, Lavery & Quebedeaux (1997) [34]	1) TCC + rubber heel	Peak pressure	% difference in peak pressure for ulcers under 1st MTH when compared to TCC: 2) 16: 3) 642; 4) 557 (1 = 2 < 4 < 3†)
	2) TCC + cast boot		% difference in peak pressure for ulcers under 2nd - 5th MTH when compared to TCC: 2) 113; 3) 1200; 4) 864 (1 < 2 < 4 < 3†)
	3) Baseline shoe		% difference in peak pressure for ulcers under hallux when compared to TCC: 2) 5: 3) 452; 4) 280 (1 = 2 < 4 < 3†)
	4) Shoe		

RCW: Removable Cast Walker; TCC: Total Contact Cast; iTCC: Instant Total Contact Cast; *significant difference $p \leq 0.05$; **significant difference $p < 0.01$; †Healing time adjusted by width and ulcer grade using a lognormal regression model.

irremovable devices [16,17,28], while two reported no significant difference in healing rates [26,29]. Two of the five studies reported significantly greater healing times for RCWs [17,26].

3.2.1.3. Half or Heel Relief Shoes

Four studies examined the use of half or heel relief shoes in the treatment of ulcers with varying results; Armstrong, Nguyen, Lavery, van Schie, Boulton, *et al.* [28] reported a healing rate of 58.3% while Ha Van, Siney, Hartmann-Heurtier, Jacqueminet, Greau, *et al.* [22] reported 70%, and Chantelau, Breuer, Leisch, Tanudjaja, & Reuter [18] reported 96%. The participants were followed up for a longer period by Chantelau, Breuer, Leisch, Tanudjaja, & Reuter [18] and Ha Van, Siney, Hartmann-Heurtier, Jacqueminet, Greau, *et al.* [22] which may have contributed to their higher healing rates. Two of these studies compared their footwear to a TCC with the results showing significantly lower healing rates for the footwear [22,28]. Zimny, Meyer, Schatz, & Pfohl [19] found that the use of felted foam dressing was as effective as the half shoe.

3.2.1.4. Therapeutic Shoes

Four of the studies examined various off the shelf and custom shoes in the treatment of ulcerations. Findings of these studies were conflicting as two of them reported similar healing rates when compared to TCCs [27,30] while the other two reported significantly lower healing rates for their footwear when compared to TCCs [23,25].

3.2.2. Studies Which Used Biomechanical Measurements to Examine Effectiveness of Footwear or Removable Offloading Devices

Of the six studies in this group only one was an RCT. Peak plantar pressure data was the most commonly reported biomechanical measurement. As all the studies used the same measurement equipment it is possible to cross compare between studies; the pressure data reported within the studies is available in Supplementary Table **2**. However it should be noted that while all the studies were consistent in eliminating steps associated with initiation and termination of gait from their pressure analysis and only used data collected mid gait, they reported asking their participants to self-select their walking pace and did not report these walking speeds. Plantar pressure measurements are known to be affected by walking speed [31] and therefore if the walking speeds were different across treatment interventions, which we cannot determine, then the measurements would not be fully comparable. The majority of the studies reported data for the forefoot with peak pressure values ranging from approximately 30-130 kPa for TCCs, 60–200 kPa for RCWs, 180 kPa for a half shoe, 150-350 kPa for therapeutic shoes, 150-320 kPa for comfort/athletic shoes and 200-500 kPa for canvas oxford shoes. For the few studies which reported peak pressures in the heel values for TCCs were 160-180 kPa, 190-208 kPa for RCWs, 250kPa for a therapeutic shoe and 270 kPa for an athletic shoe.

3.2.2.1. Irremovable Offloading Devices

Five studies compared plantar pressures in TCCs to therapeutic shoes and/or RCWs. Consistently all the studies which examined TCCs and therapeutic shoes reported significantly lower peak plantar pressures for the TCCs [24,32–34]. When TCCs were compared to various RCWs there were mixed results among the studies. Armstrong & Stacpoole-Shea and [24] reported that their TCC was superior to the RCW in pressure reduction while Gutekunst, Hastings, Bohnert, Strube, & Sinacore [16] reported superior offloading in the mid and forefoot for the RCW. Fleischli, Lavery, Vela, Ashry, & Lavery [32] reported that their TCC was superior to the RCW for offloading forefoot ulcers but both devices were as effective for offloading hallux ulcers. Furthermore, Lavery, Vela, Lavery, & Quebedeaux [33] tested four different RCWs to a TCC and found only one of

the four to be as effective in peak pressure reduction as the TCC. Lavery, Vela, Lavery, & Quebedeaux [34] was the only study to compare two types of TCCs, one with a rubber heel and the other a cast boot, reporting that both TCCs were as effective for 1st MTH and hallux ulcers but that the TCC with rubber heel was superior in offloading ulcers at the 2nd – 5th MTHs.

3.2.2.2. Removable Cast Walkers

The DH Pressure Relief Walker was the most tested RCW with four studies reporting on it. This RCW showed the most positive results of the tested RCWs with two studies showing it to be as effective as a TCC [32,33], one reporting on its superior forefoot offloading when compared to a TCC [16] and one which while showing a reduced effectiveness in peak pressure reduction found the RCW superior to a TCC in reducing pressure time integral [24]. None of the other RCWs tested were more effective than TCCs, but all RCWs were more effective at offloading when compared to half or therapeutic shoes.

3.2.2.3. Half or Heel Relief Shoes

One studies measured peak pressures while wearing a half shoe, with results finding it less effective than a TCC or RCW but more effective than a postoperative shoe [32].

3.2.2.4. Therapeutic Shoes

Across all studies therapeutic shoes did not reduce peak plantar pressures as much as TCCs, RCWs or half shoes. Lavery, Vela, Fleischli, Armstrong, & Lavery [20] was the only study to compare a range of shoes; examining the pressure reduction abilities of an extra depth therapeutic shoe to a comfort and athletic shoe. In addition they assessed if there was a further benefit in pressure reduction with the addition of a viscoelastic insole to the shoes. Results showed that the comfort shoe reduced peak pressures significantly more than both the athletic and therapeutic shoe. The addition of the insole reduced pressure significantly more for all shoes then when no insole was used.

4. DISCUSSION

The majority of the studies had a low sample size with less than one third having greater than 30 participants and. In terms of the ulcerations in the studies most studies excluded participants with more than more ulcer and the grade of the ulcers was generally Wagner Grade 1 or 2. While the studies which employed biomechanical measurements consistently found therapeutic shoes the least effective in pressure reduction none of these were RCTs. One of the three RCTs which examined therapeutic shoes in the clinical assessment studies group reported footwear to provide similar healing rates when compared to TCCs [27]. The positive results for therapeutic shoes in this study could possibly be attributed to the fact that the footwear was custom made as opposed to off the shelf and also that the participants were asked to limit their ambulation to 33% of usual activity. The other two RCTs reported TCCs to be superior to therapeutic shoes for ulcer healing rates [23,25].

It is difficult to establish a consensus based on findings from the longitudinal studies for TCCs and RCWs as there are a wide range of factors that hinder the synthesis of the findings. The two studies which reported similar healing rates for TCCs and RCWs utilised the same new TCC method which differs significantly from the traditional method and resulted in some of the lowest healing rates among the studies which tested TCCs [26,29]. It is possible that the same positive result for the RCW may not have been seen if tested against a more traditional TCC.

RCWs were not as effective in clinical assessment trials but demonstrated to be equal or better than TCCs in some cases for pressure reduction. This finding implies that it is may be an issue with compliance to the RCW, which is supported by the study by Armstrong and colleagues [17]. Their results exhibited superior healing rates for a RCW converted to an iTCC with the addition of a cohesive bandage compared to the same RCW without the forced compliance. Additionally this is supported by research, which did not meet the inclusion criteria for this review, which reported that when RCWs are made irremovable they can be as effective as TCCs [35,36]. The DH pressure relief walker was the most tested RCW in the reviewed studies which examined biomechanical measurements. While promising results for this RCW were reported in the studies which examined biomechanical measurements; the one RCT within the clinical assessment group which tested this device reported significantly lower healing rates for this RCW when compared to a TCC indicating that further research into the effectiveness of this device in the treatment of ulcers is warranted.

As detailed above compliance is a major factor in the effectiveness of a treatment intervention. However, in the reviewed articles it was only monitored in two of the ten studies where it would have been a factor in the treatment outcome [19,22]. While Ha Van and colleagues monitored compliance, Zimny *et al.* attempted to ensure compliance in wearing the prescribed footwear by visiting participants at least every third day. The reported compliance rates of Ha Van and colleagues highlighted the poor compliance to the footwear intervention compared to the TCC (10% vs. 98%). The researchers reported this as disappointing considering that they provided extensive education to their participants highlighting the importance of offloading in an attempt to reinforce compliance. While one of the limitations to the use of TCCs and the favoured use of RCWs by some clinicians is a reduction in treatment costs it should be considered that the literature to date shows significantly longer ulcer healing times when RCWs are used compared to TCCs, but this again could be related to treatment compliance [17,26]. Clinicians consistently report significant difficulties in patient acceptance of off-loading devices and in many cases are faced with the challenge of balancing their treatment goal of achieving ulcer healing as quickly as possible with what their patients will accept using. This is often a reason for prescribing a half, heel relief or therapeutic footwear for their patient who refuses to wear a TCC.

Through the quality assessment many of the reviewed articles were considered as having provided a limited description of the interventions used within their studies. The authors of the current review acknowledge that with restricted word limits for publications it is not always possible to report as much information in their articles as researchers might like. However, with the increasing availability of the

option within journals to supply online supplementary information future research should aim to provide as much detailed information about their treatment interventions as possible.

The following subsections discuss some additional important issues which may have affected the results of the reviewed studies and could explain some of the diversity in research findings.

4.1. Factors Related to TCC Effectiveness

TCCs are widely considered the gold standard for offloading neuropathic ulcers. While in general the findings of the reviewed studies support this there are a number of factors related to TCCs which need to be considered and require further investigation. Within the thirteen studies which reported examining a TCC eight different methods of TCC application were referenced [22,25,37–42] and one study provided no information on the application of their TCC [16]. Two studies which examined plantar pressures for a number of off-loading devices and footwear in the same participants reported modifying the referenced TCC technique to allow the participants to walk immediately following the application of the TCC [32,33]. As the methods of applying the TCC were different their effectiveness in offloading may not be uniform across the reviewed studies.

In addition there were various methods used by the studies to enable ambulation while wearing a TCC. Five studies used a cast boot for all their participants [16,27,28,32,33], four used rubber heels [22–24,30], one used a stirrup [29], and two studies used a rubber heel or a stirrup depending on the ulcer location [25,26]. One study compared the effectiveness of casts with rubber heels to those with cast boots [34] with results highlighting that differences were evident between the devices. While both types of TCC were equally effective in offloading ulcers located at the hallux or 1^{st} MTH, the TCC with a rubber heel were more effective in offloading ulcers under the 2^{nd}-5^{th} MTHs. However subsequent research by this group of researchers found that a TCC with a rubber heel significantly increased sway when compared to a TCC with a cast boot, RCW, half shoe or canvas oxford shoe. They therefore recommended the use of TCCs with cast boots over rubber heels to improve stability as this is a common complication for people with diabetes is postural instability, with postural sway found to be greater in people with diabetes [43].

The frequency of TCC replacement and the regularity and level of wound care for the study patients are also factors that would have affected wound healing. For the majority the studies the TCC were changed every 1-3 weeks however Caravaggi and colleagues developed a TCC which did require replacement [25,26]. This method was designed to reduce the side effects associated with traditional TCCs, utilising fibreglass bandages to reduce the weight of the cast and make ambulation easier, reduce friction with the skin and the occurrence of skin lesions. This type of cast also allowed for a window cut out of the cast at the site of the ulcer to all wound care and dressing changes without the requirement of removing and replacing the device. The majority of studies reported using weekly wound cleaning and debridement however some studies either provided daily wound care or instructed their participants in performing regular wound care. With regards to the longitudinal studies the diversity in healing rates across studies may possibly be attributed to the large variability in follow up periods for ulcer healing used by the reviewed studies.

A major challenge to health care professionals is to convince their patients about the importance of offloading to ulcer healing. As many of these patients have no pain sensation it is difficult for them to understand the negative impact that walking with an active ulcer can have on healing. As TCCs enforce compliance this is thought to be one of the main reasons that they are considered the "gold standard" in the treatment of plantar ulcers [44]. This is corroborated by research which has found that patients with ulcerations only wear their removable offloading devices for a minority of their daily steps [45] and it has also been reported that if RCWs are made irremovable they can be as effective as TCCs in ulcer treatment [35,36].

There are limitations to the use of TCCs such as their high cost, they don't allow easy access for wound inspection, they require a skilled person for application and they may be rejected by patients as they can cause difficulties in sleeping. They are also not suitable for all patients with alternative strategies recommended for patients with severe ischemia, infection or osteomyelitis [46].

4.2. Walking Aids and Ambulation/Daily Activity Levels

When accessing study conclusions it is important to take into account if walking aids were used to further offload the affected limb in addition to the offloading device or if the participants were given any recommendations with regards to walking and their daily activities. Approximately half of the studies made no comments regarding if their participants used walkers or crutches; three reported that none of their participants used crutches [25,29,32], two reported all their participants used crutches or walkers [18,22,30] and two studies reported providing walkers or crutches to those requiring them [23,27]. Another important issue to consider is that the use of crutches while offloading the affected foot may increase pressures on the contralateral foot thereby increasing the risk of developing complications in that foot [47].

The majority of the studies either did not instruct their participants to limit their ambulation/daily activities or if they did the provided instructions were not reported. Only four studies reported on this with one asking employed people to stop work [22], two asking participants to limit their ambulation to 33% of usual activity [23,27] and one asking participants to refrain from walking as much as possible [19].

4.3. Contralateral Limb

Only five of the seventeen studies reported on the footwear worn on the contralateral limb. Three of these were cross sectional studies which used extra depth shoes [33,34] or canvas oxford shoes [32] on the contralateral limb. The remaining two studies were RCTs; Caravaggi, Faglia, Giglio, Mantero, Quarantiello, *et al.* [25] reported that participants in the shoe group wore the same shoe on the contralateral leg and did not report on the contralateral footwear of the TCC

group while Gutekunst, Hastings, Bohnert, Strube, & Sinacore [16] stated their participants wore their own footwear the majority of which were an extra depth shoe with a total contact insole. Only one of the reviewed studies measured pressure values for the contralateral limb reporting that a TCC with rubber heel or cast boot did not increase pressures on the contralateral limb with an extra depth shoe. Providing recommendations to patients on footwear to be worn on the contralateral limb is very important as it may not only have an impact on the healing of the ulcer on the affected foot but could also lead to the development of ulcers on the contralateral foot if inappropriate footwear is worn. It is recommended to closely monitor the unaffected limb as much as the affected limb to prevent the development of further foot complications.

The authors would also like to make the reader aware of our previous review article which discusses issues around providing sufficient descriptions of interventions, plantar pressure measurement and participant randomisation techniques, and provides recommendations for future research which also apply to this review [13].

5. CONCLUSION

From research to date in this area it is not possible to make strong conclusions on which footwear or removable off-loading device is most effective for ulcer treatment; this is due to the lack of RCT studies conducted in this area. While further structured research with appropriately designed RCT is needed, it appears that with regards to the use of footwear alone in the treatment of diabetic neuropathic ulcerations, currently available therapeutic shoes are the least effective intervention. This was followed by half or heel relief shoes with RCWs found to be the most effective of the removable off-loading devices.

6. RECOMMENDATIONS

Future research in this area should take into consideration the issues raised within this review. While it is no doubt difficult to monitor and enforce compliance with removable treatment interventions this is something that must be addressed in future research. Activity levels of study participants is also an important factor that can be difficult to measure accurately but is vital in determining the effectiveness of interventions. Detailed information on the structure and material composition of treatment interventions should be adequately reported within articles. With regards to the contralateral limb it is important that future studies assess the effect of the intervention on the contralateral limb and also provide suitable footwear or footwear recommendations to participants to limit the development of complications on the unaffected foot.

CONFLICT OF INTEREST

The authors confirm that this article content has no conflict of interest.

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SUPPLEMENTARY MATERIAL

Supplementary material is available on the publishers Web site along with the published article.

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Supplementary Table 1: Ulcer information provided in reviewed articles

Author	Participants	Ulcer information								
		Number	Stage	Grade	Site	Duration (months)	Size			
							Area (cm^2)	Length (cm)	Width (cm)	Depth (cm)
Armstrong et al. (2005)	1) iTCC	At least one[a]	Active	Grade 1A (University of Texas)	Plantar forefoot/midfoot	Not reported	2.7 ± 1.3	Not reported	Not reported	Not reported
	2) RCW	At least one[a]	Active	Grade 1A (University of Texas)	Plantar forefoot/midfoot	Not reported	2.0 ± 1.1	Not reported	Not reported	Not reported
Armstrong et al. (2001)	1) TCC	At least one[a]	Active	Grade 1A (University of Texas)	Plantar forefoot/midfoot	4.3 ± 5.7	1.3 ± 0.8	Not reported	Not reported	Not reported
	2) RCW	At least one[a]	Active	Grade 1A (University of Texas)	Plantar forefoot/midfoot	5.6 ± 6.2	1.4 ± 1.4	Not reported	Not reported	Not reported
	3) Half shoe	At least one[a]	Active	Grade 1A (University of Texas)	Plantar forefoot/midfoot	5.5 ± 7.1	1.3 ± 1.2	Not reported	Not reported	Not reported
Armstrong and Stacpoole-Shea (1999)	All	One	Active or recently healed (less than 4 weeks)	Grade 1A (University of Texas)	1st MTH: 10; Hallux: 5; Lesser MTHs: 10[b]	Not reported	Not reported	Not reported	Not reported	Not reported
Birke et al. 2002	1) TCC	One	Active	2.2 ± 0.8 (Wagner)	1st MTH: 8; Lesser MTHs: 5[b]	6.0 ± 4.7	Not reported	1.4 ± 0.9	0.9 ± 0.5	0.6 ± 0.5
	2) Accommodative dressing + Shoe 1	One	Active	1.8 ± 0.8	Hallux: 1; 1st MTH: 11; Lesser MTHs: 14[b]	4.9 ± 5.0	Not reported	1.3 ± 1.2	0.9 ± 0.7	0.4 ± 0.4
	3) Shoe 2	One	Active	1.7 ± 0.8	Hallux: 30; Lesser toes: 16; 1st MTH: 6; Lesser MTHs: 5[b]	2.2 ± 3.3	Not reported	1.2 ± 0.9	0.7 ± 0.5	0.3 ± 0.6
	4) Walking splint	One	Active	1.8 ± 0.8	Hallux: 2; 1st MTH: 7; Lesser MTHs: 9[b]	3.2 ± 3.8	Not reported	1.6 ± 1.3	1.1 ± 0.9	0.5 ± 0.6
	5) Combination of above	One	Active	1.8 ± 1.0	Hallux: 2; 1st MTH: 2; Lesser MTHs: 2[b]	5.0 ± 5.5	Not reported	1.6 ± 0.7	1.0 ± 0.5	0.6 ± 0.8
Caravaggi et a. (2000)	1)TCC	One	Active	Not reported	Plantar surface	Not reported	5.87	Not reported	Not reported	Not reported
	2) Shoe	One	Active	Not reported	Plantar surface	Not reported	4.31	Not reported	Not reported	Not reported
Caravaggi et al. (2007)	1) TCC	One	Active	Not reported	Plantar surface	Not reported	3.9 ± 3.4	Not reported	Not reported	Not reported
	2) RCW	One	Active	Not reported	Plantar surface	Not reported	3.4 ± 3.0	Not reported	Not reported	Not reported
Chantelau et al. (1993)	1) Standard treatment	At least one	Active	Grade 1 : 3; Grade 2 : 11; Grade 3: 8 (Wagner)[b]	Toes 1-5 (dorsal/plantar): 8; MTHs 1-5: 14[b]	Not reported	Not reported	Not reported	Not reported	Not reported
	2) Standard treatment + Half shoe	At least one	Active	Grade 1 : 7; Grade 2 : 11; Grade 3: 7; Grade 4: 1 (Wagner)[b]	Toes 1-5 (dorsal/plantar): 5; MTHs 1-5: 21[b]	Not reported	Not reported	Not reported	Not reported	Not reported
Faglia et al. (2010)	1) TCC	One	Active	Grade 1A (University of Texas)	Plantar forefoot /midfoot	Not reported	1.4 ± 1.2	Not reported	Not reported	Not reported
	2) RCW	One	Active	Grade 1A (University of Texas)	Plantar forefoot /midfoot	Not reported	2.2 ± 2.2	Not reported	Not reported	Not reported

MTH: metatarsal head; [a]If more than one plantar ulcer then the largest wound was used as the index ulcer for inclusion in the study; [b] Represents number of participants; [c] Time in weeks: median (IQR).

Supplementary Table 1: Continued

Author	Participants	Ulcer information								
		Number	Stage	Grade	Site	Duration (months)	Size			
							Area (cm^2)	Length (cm)	Width (cm)	Depth (cm)
Fleischili et al. (1997)	1) Forefoot ulcer	One	Active or recently healed	Not reported	1st MTH: 9; Lesser MTHs: 10; Hallux: 7[b]	Not reported	Not reported	Not reported	Not reported	Not reported
	2) Great toe ulcer					Not reported	Not reported	Not reported	Not reported	Not reported
Gutekunst et al. (2011)	1) TCC	At least one	Active	Grade 1 or 2 (Wagner) / Grades 1-3 (University of Texas)	Forefoot: 8; Midfoot: 3[b]	Not reported	Not reported	Not reported	Not reported	Not reported
	2) RCW	At least one	Active	Grade 1 or 2 (Wagner) / Grades 1-3 (University of Texas)	Forefoot: 11; Midfoot: 1[b]	Not reported	Not reported	Not reported	Not reported	Not reported
Ha Van et al. (2003)	1) TCC	One	Active	Grade 1A (San Antonio)	Forefoot: 35; Midfoot (Charcot): 4; Hindfoot: 3[b]	13 ± 18.4	Not reported	2.0 ± 1.2	1.4 ± 0.8	0.5 ± 0.5
	2) Half or Heel relief shoe	One	Active	Grade 1A (San Antonio)	Forefoot: 49; Rearfoot: 2[b]	4.4 ± 8.9	Not reported	1.6 ± 1.2	1.0 ± 0.9	0.3 ± 0.3
Lavery, Vela, Fleischli, Armstrong & Lavery (1997)	All	One	Active or recently healed	Not reported	Hallux: 10; 1st MTH: 10; Lesser MTHs: 12[b]	Not reported	Not reported	Not reported	Not reported	Not reported
Lavery, Vela, Lavery & Quebedeaux (1996)	All	One	Active or recently healed	Not reported	Hallux: 5; 1st MTH: 10; Lesser MTHs: 10[b]	Not reported	Not reported	Not reported	Not reported	Not reported
Lavery, Vela, Lavery & Quebedeaux (1997)	All	One	Active or recently healed	Not reported	Hallux: 5; 1st MTH: 10; Lesser MTHs: 10[b]	Not reported	Not reported	Not reported	Not reported	Not reported
Mueller et al. (1989)	All	One	Active		Hallux: 2; lesser toes: 1; 1st MTH: 12; lesser MTHs; 17; Midfoot: 5; Rearfoot: 3[b]					
	1) TCC			Grade 1: 15; Grade 2: 6 (Wagner)[b]		5.1 ± 6.4	1.8 ± 2.5	Not reported	Not reported	0.4 ± 0.3
	2) Sandal or Shoe			Grade 1: 13; Grade 2: 6[b]		5.7 ± 6.6	2.8 ± 3.4	Not reported	Not reported	0.2 ± 0.1
Van de Weg et al. (2008)	1) TCC	One	Active	Grade 1: 2; Grade 2: 21 (Wagner)[b]	Forefoot: 20; Mid/Rearfoot: 3[b]	4 (3, 8)[c]	4.2 ± 3.1	Not reported	Not reported	Not reported
	2) Shoe			Grade 1: 2; Grade 2: 18[b]	Forefoot: 18; Mid/Rearfoot: 2[b]	5 (4, 8)[c]	3.0 ± 3.1	Not reported	Not reported	Not reported
Zimny et al. (2002)	1) Felted foam dressing + Shoe	One	Active	Grade 1: 6; Grade 2: 21 (Wagner)	Forefoot	Not reported	1.1 ± 0.14	Not reported	Not reported	Not reported
	2) Shoe			Grade 1: 8; Grade 2: 26[b]	Forefoot	Not reported	1.2 ± 0.14	Not reported	Not reported	Not reported

MTH: metatarsal head; [a]If more than one plantar ulcer then the largest wound was used as the index ulcer for inclusion in the study; [b] Represents number of participants; [c] Time in weeks: median (IQR).

Supplementary Table 2: Peak pressure (kPa) data from reviewed articles.

Peak Pressure (kPa)			Sub group		Foot region						
					Heel	Midfoot	Forefoot	1st MTH	MTHs 2-5	Hallux	Ulcer area
TCC		Armstrong and Stacpoole-Shea (1999)			180*						
		Fleischili et al. (1997)					124 ± 79			35 ± 41	
		Gutekunst et al. (2011)			160	180	134				166
		Lavery, Vela , Lavery & Quebedeaux (1996)									
		Lavery, Vela , Lavery & Quebedeaux (1997)	Participants with 1st MTH ulcer	with rubber heel				59 ± 26	45.8 ± 16.5	39.8 ± 44.1	
			Participants with MTHs 2-5 ulcer					34 ± 26.4	38.9 ± 16.8	40.4 ± 51.7	
			Participants with Hallux ulcer					52.6 ± 54.8	62.9 ± 46.3	49.2 ± 47.9	
			Participants with 1st MTH ulcer	with cast shoe				68.4 ± 52.9	52.7 ± 23	34.9 ± 42.9	
			Participants with MTHs 2-5 ulcer					60 ± 46.2	83 ± 50	36.2 ± 46.5	
			Participants with Hallux ulcer					73.2 ± 97	84.6 ± 68.4	51.8 ± 42.4	
RCW	**DH Pressure Relief walker**	Armstrong and Stacpoole-Shea (1999)			190*						
		Fleischili et al. (1997)					77 ± 33			49 ± 33	
		Gutekunst et al. (2011)			208	111	66				74
		Lavery, Vela , Lavery & Quebedeaux (1996)						80	83	64	
	Aircast Pneumatic Walker	Armstrong and Stacpoole-Shea (1999)			200*						
		Lavery, Vela , Lavery & Quebedeaux (1996)						123	150	111	
	Three D Dura Stepper	Lavery, Vela , Lavery & Quebedeaux (1996)						141	191	83	
	CAM walker	Lavery, Vela , Lavery & Quebedeaux (1996)						199	217	122	

TCC: Total Contact Cast; RCW: Removable Cast Walker; MTH: metatarsal head; *estimated from Figure in article; **calculated from provided data in article

Supplementary Table 2: Continued

Peak Pressure (kPa)			Sub group		Foot region						
					Heel	Midfoot	Forefoot	1st MTH	MTHs 2-5	Hallux	Ulcer area
Half shoe	**Darco OrthoWedge**	Fleischili et al. (1997)					178 ± 76			87 ± 99	
Therapeutic shoe	**Darco rigid-soled**	Fleischili et al. (1997)					337 ± 126			223 ± 99	
	PW Minor therapeutic	Armstrong and Stacpoole-Shea (1999)			250*						
		Lavery, Vela, Fleischli, Armstrong & Lavery (1997)	Participants with 1st MTH ulcer	without insole				355 ± 162	276 ± 92	190 ± 91	
				with insole				284 ± 102	223 ± 61	157 ± 73	
			Participants with MTHs 2-5 ulcer	without insole				255 ± 79	277 ± 71	181 ± 84	
				with insole				222 ± 54	238 ± 45	164 ± 73	
			Participants with Hallux ulcer	without insole				238 ± 63	243 ± 54	192 ± 82	
				with insole				227 ± 70	218 ± 52	172 ± 65	
		Lavery, Vela , Lavery & Quebedeaux (1996)						395	382	191	
		Lavery, Vela , Lavery & Quebedeaux (1997)	Participants with 1st MTH ulcer					387.6 ± 146.6	214.1 ± 57	166 ± 140.1	
			Participants with MTHs 2-5 ulcer					252.6 ± 88.4	375.07 ± 147.9	116.3 ± 107.3	
			Participants with Hallux ulcer					297.2 ± 99.6	301.8 76.3	187.2 ± 66	
	Dressing and post op shoe	Fleischili et al. (1997)					271 ± 85			158 ± 97	
Shoe	**SAS Comfort shoe**	Lavery, Vela, Fleischli, Armstrong & Lavery (1997)	Participants with 1st MTH ulcer	without insole				292 ± 129	246 ± 66	185 ± 92	
				with insole				274 ± 103	240 ± 76	178 ± 69	
			Participants with MTHs 2-5 ulcer	without insole				216 ± 41	247 ± 53	161 ± 71	
				with insole				221 ± 46	233 ± 40	148 ± 71	
			Participants with Hallux ulcer	without insole				218 ± 66	222 ± 54	198 ± 110	
				with insole				227 ± 78	201 ± 48	176 ± 90	

TCC: Total Contact Cast; RCW: Removable Cast Walker; MTH: metatarsal head; *estimated from Figure in article; **calculated from provided data in article

Supplementary Table 2: Continued

Peak Pressure (kPa)			Sub group		Foot region						
					Heel	Midfoot	Forefoot	1st MTH	MTHs 2-5	Hallux	Ulcer area
	Canvas Oxford shoe	Fleischili et al. (1997)					513**			233**	
		Lavery, Vela, Fleischli, Armstrong & Lavery (1997)	Participants with 1st MTH ulcer					497 ± 169	396 ± 109	221 ± 137	
			Participants with MTHs 2-5 ulcer					385 ± 138	452 ± 118	205 ± 107	
			Participants with Hallux ulcer					252 ± 87	361 ± 114	211 ± 110	
		Lavery, Vela , Lavery & Quebedeaux (1996)						447	516	277	
		Lavery, Vela , Lavery & Quebedeaux (1997)	Participants with 1st MTH ulcer					437.9			
			Participants with MTHs 2-5 ulcer						505.8		
			Participants with Hallux ulcer							271.4	
	Reebok canvas sneaker	Armstrong and Stacpoole-Shea (1999)			270*						
	New Balance cross trainer	Lavery, Vela, Fleischli, Armstrong & Lavery (1997)	Participants with 1st MTH ulcer	without insole				324 ± 125	260 ± 65	180 ± 67	
				with insole				285 ± 105	234 ± 63	169 ± 68	
			Participants with MTHs 2-5 ulcer	without insole				230 ± 4.9	265 ± 51	182 ± 84	
				with insole				208 ± 47	246 ± 49	179 ± 88	
			Participants with Hallux ulcer	without insole				215 ± 5.4	245 ± 56	237 ± 109	
				with insole				203 ± 63	226 ± 47	204 ± 82	

TCC: Total Contact Cast; RCW: Removable Cast Walker; MTH: metatarsal head; *estimated from Figure in article; **calculated from provided data in article

The previous chapters highlighted some limitations to previous research methodologies, such as the inability to monitor compliance to treatment interventions and the activity levels of the participants. Another limitation of current clinical and research plantar pressure measurement is that it is typically measured for a short period during infrequent visits, providing only limited information on the types of pressures the person's feet is experiencing on a daily basis. The following chapter (Chapter 7) presents a new plantar pressure measurement system which is capable of addressing these limitations as it allows for continuous plantar pressure measurement along with monitoring the activity of the participant and their compliance to an intervention.

Chapter 7: Repeatability of WalkinSense® in shoe pressure measurement system: A preliminary study

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Repeatability of WalkinSense® in shoe pressure measurement system: A preliminary study

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ABSTRACT

Plantar pressure measurements are regularly utilised while assessing patients with in-shoe systems allowing for discrete assessment. In the present study a new portable system capable of continuous monitoring of plantar pressure is assessed for its repeatability when compared to another commercially available and widely used system.

1. Introduction

Measurement of plantar pressure is a valuable resource to healthcare professionals when assessing various foot pathologies [1]. It is widely used when assessing diabetic patients where high plantar pressure has been shown to be a major risk factor for the development of ulcers [2,3]. In clinical settings plantar pressure is usually monitored by clinicians during infrequent visits in a lab environment that can only provide a brief window into the loading of that foot over the course of a day. This information is then used to prescribe shoes/orthoses to address the issues relating to abnormal pressure which causes ulceration. This raises the need for plantar pressure measuring devices that can continually monitor the patient's pressure. Recently a new portable in shoe measurement device which allows for daily, continuous monitoring of plantar pressure has become available. This system named "WalkinSense" (Tomorrow Options Microelectronics, S.A., Sheffield, UK) consists of a data acquisition and processing unit and eight individual sensors for plantar pressure measurement (Fig. 1) which can be attached to either an insole or the patient's sock. Similar to the F-Scan (Tekscan Inc., Boston, USA) system these sensors are piezoresistive force sensors. Recent research [4] has shown the F-Scan system to be reliable for clinical measurement and hence it is considered capable of relative comparisons for use within this study. The overall aim of this preliminary study is to assess the repeatability of *WalkinSense* system and to compare the pressure values to the values reported by the F-Scan System and not to examine the clinical suitability or ease of use in patient assessment.

2. Methodology

2.1. Participants

3 healthy male participants with an average age of 36.3 (±8.1 years), weight of 85.0 (±8.2 kg) and height of 177.0 (±3.6 cm) were recruited for the study. Ethical approval was sought and received from the University Ethics Committee. All participants signed an informed consent before any laboratory testing.

2.2. Procedure

The study consisted of two testing sessions with the 1st session requiring participants to walk across the laboratory at a self selected pace while wearing their own footwear with both the F-Scan and WalkinSense systems in their right shoe. The 8 WalkinSense sensors were located as follows: 1 each on the hallux, midfoot, medial heel and lateral heel and 4 on the forefoot (Fig. 2). The F-Scan sensor was calibrated to the manufacturer's guidelines and both systems used a sampling rate of 100 Hz. Both systems are capable of continuous plantar pressure recording and each participant completed 3 trials consisting of between 5 and 6 steps. This procedure was replicated after 24 h on Day 2.

2.2.1. Data processing and analysis

Plantar pressure profiles for the 8 WalkinSense sensors for each trial were exported from the proprietary software (WalkinSense version 0.96, Tomorrow Options Microelectronics, S.A.). The

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Fig. 1. WalkinSense system.

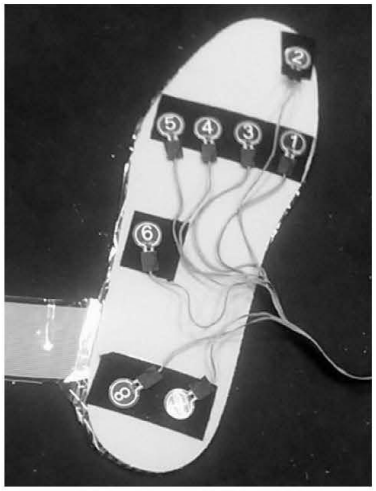

Fig. 2. Placement of WalkinSense sensors and F-Scan sensor beneath the flat insole.

positions of the 8 sensors in relation to the F-Scan sensor were located and 8 polygons (approximately the same surface area as the WalkinSense sensors) were created using the F-Scan software (F-Scan Research 6.33, Tekscan, Boston, USA). Plantar pressure profiles for these 8 polygons were then exported for each trial using the F-Scan software. Subsequently representative stance phase trials (with the first and last steps removed from the analysis) for both systems for each foot region on Day 1 and Day 2 were created by averaging all trials on each day for the 3 participants. Additionally the peak pressure value for the 8 regions for both the WalkinSense and F-Scan systems were identified.

Table 1
Peak pressure values (kg/cm^2) for WalkinSense and F-Scan on Day 1 and 2.

Foot region	Peak pressure (kg/cm^2)			
	WalkinSense		F-Scan	
	Day 1	Day 2	Day 1	Day 2
Hallux	1.05	1.29	1.17	1.22
Metatarsal 1	1.81	1.94	1.59	1.63
Metatarsal 2	2.36	2.48	1.47	1.62
Metatarsal 3	2.94	2.86	2.03	1.91
Metatarsal 4	2.05	2.16	1.76	1.25
Midfoot	0.71	0.71	0.47	0.42
Medial heel	2.30	2.13	2.01	1.62
Lateral heel	3.16	2.74	2.45	2.04

3. Results

Figs. 3–10 provide representative plantar pressure profiles for Day 1 and Day 2 across the 8 foot regions. Table 1 presents peak pressure values for the 8 foot regions measured using both systems on Day 1 and Day 2.

4. Discussion

With regards to the repeatability of WalkinSense, differences in peak pressure values at the 8 foot regions between Day 1 and 2 ranged from a reduction of 0.24 kg/cm^2 to an increase of 0.42 kg/cm^2. Similar differences in peak pressure values were seen in F-Scan with values ranging from a reduction of 0.15 kg/cm^2 to an increase of 0.51 kg/cm^2. These ranges in peak pressure values across days are comparable to other pressure measurement systems [5].

When compared to F-Scan, WalkinSense consistently reported higher peak values, except for the hallux on Day 1. Differences in peak pressure values between systems ranged from a reduction of 0.12 kg/cm^2 to an increase of 0.91 kg/cm^2 on day 1 and increased between 0.07 and 0.95 kg/cm^2 on Day 2. There are some possible reasons that may explain the differences seen between the systems. Firstly, the polygons created using the F-Scan software were based on the entire surface area of the WalkinSense sensor which may not be equal to the active sensing area of the WalkinSense sensor.

Secondly, the location of the polygons in the F-Scan software may not have been in exactly the same position as the WalkinSense sensors. While these issues will not have affected the between day comparisons they may have affected the overall pressure value comparisons between the two systems.

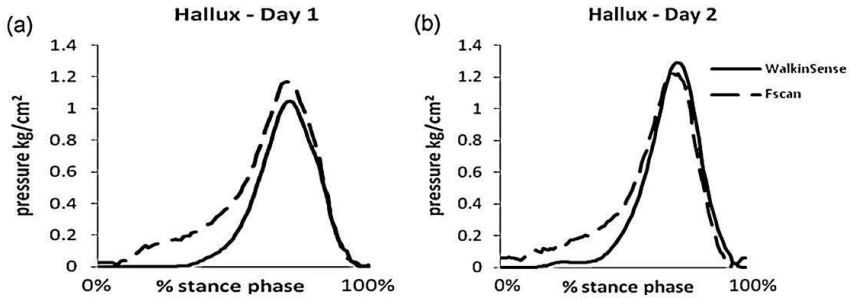

Fig. 3. Contact pressure profile of the hallux for WalkinSense and F-Scan during the stance phase of walking on Day 1 (a) and 2 (b).

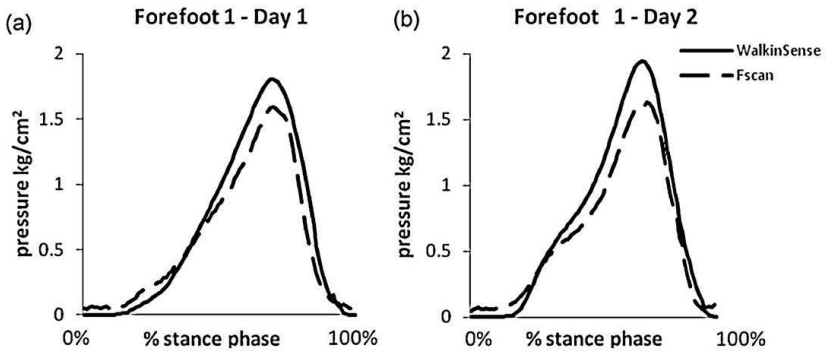

Fig. 4. Contact pressure profile of forefoot 1 for WalkinSense and F-Scan during the stance phase of walking on Day 1 (a) and 2 (b).

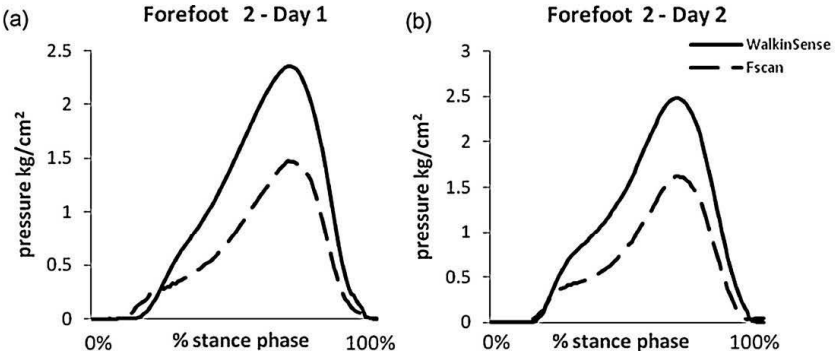

Fig. 5. Contact pressure profile of forefoot 2 for WalkinSense and F-Scan during the stance phase of walking on Day 1 (a) and 2 (b).

In addition to the benefit of continuous daily plantar pressure monitoring that WalkinSense has over other measurement systems it may also potentially reduce the amount of time the clinician has to spend analysing the pressure data. It is common practice with other pressure measurement systems for the clinician to divide the foot into a number of regions (apply masks) that they deem to be most important in their analysis of the pressure data. However recent research had identified issues in the reliability of masking [6]. As WalkinSense consists of 8 individual sensors the clinician can directly apply the sensors to the areas they want to assess with no need for post processing of the data.

In conclusion this preliminary study found WalkinSense system to be as repeatable as another currently available pressure measurement system. When compared to F-Scan WalkinSense appears to consistently report higher pressure values than F-Scan. This warrants further investigation with a larger sample

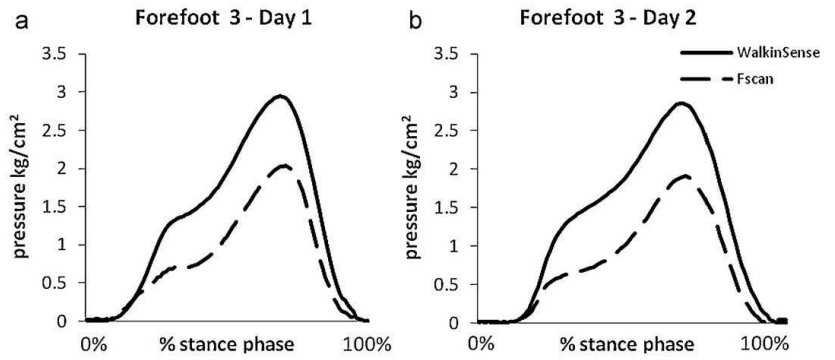

Fig. 6. Contact pressure profile of forefoot 3 for WalkinSense and F-Scan during the stance phase of walking on Day 1 (a) and 2 (b).

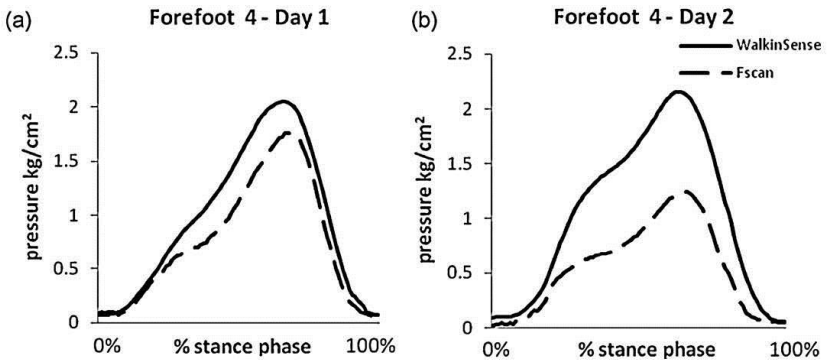

Fig. 7. Contact pressure profile of forefoot 4 for WalkinSense and F-Scan during the stance phase of walking on Day 1 (a) and 2 (b).

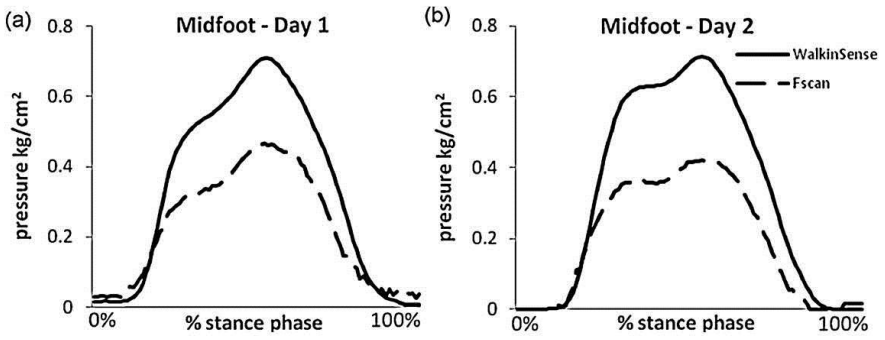

Fig. 8. Contact pressure profile of the midfoot for WalkinSense and F-Scan during the stance phase of walking on Day 1 (a) and 2 (b).

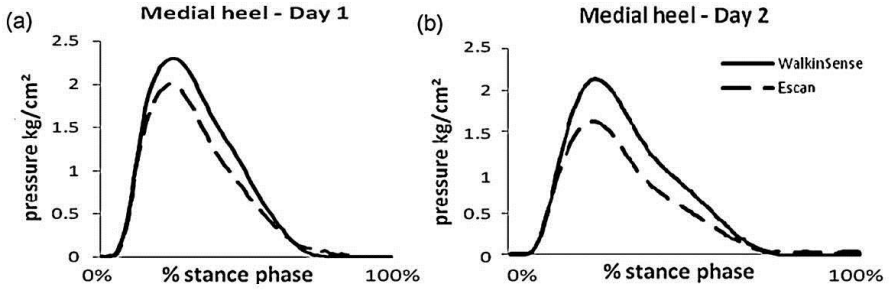

Fig. 9. Contact pressure profile of the medial heel for WalkinSense and F-Scan during the stance phase of walking on Day 1 (a) and 2 (b).

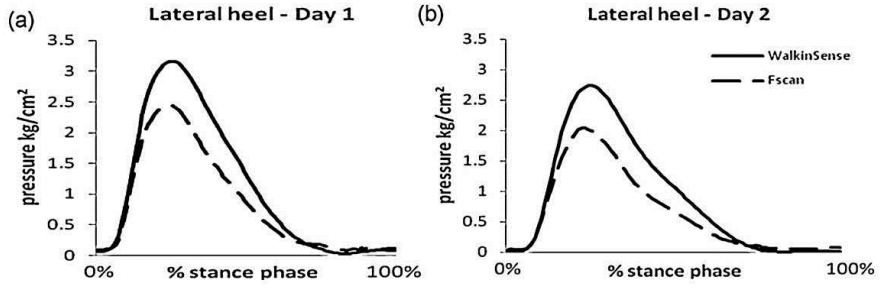

Fig. 10. Contact pressure profile of the lateral heel for WalkinSense and F-Scan during the stance phase of walking on Day 1 (a) and 2 (b).

size to fully ascertain the repeatability and reliability of the system.

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Chapter 8: Discussion

Introduction

This research has contributed to clinical practice through the provision of valuable information on the performance of footwear materials and has led to the development of recommendations for future research in the area of prescription footwear which have been published within the systematic reviews (Chapters 5 and 6). While this work focused on diabetic footwear its findings extend to other “at risk” populations, for example rheumatoid arthritis.

Knowledge dissemination of this work is demonstrated through the contribution to various other research projects related to clinical footwear and gait analysis within the biomechanics research team at Staffordshire University which have resulted in peer reviewed publications (Published work 1-15), a chapter in a clinical footwear book (Published work 16), published conference papers (Published work 17-31), presentations at numerous conferences (Published work 32-59), and demonstrations provided at several workshops (Published work 60-63).

Main findings and discussion

Materials used in footwear insoles/orthoses

Clinicians need an understanding of the properties and characteristics of materials used to manufacture orthoses to make informed decisions on the most appropriate material to meet their patients’ needs. The study in Chapter 2 examined literature to date which examined materials used in footwear orthoses. It was concluded from this study that research to date does not allow for a conclusive answer as to what are the most appropriate footwear orthosis materials for different patient requirements.

This review highlighted that much of the research around insole materials was outdated; of the 31 studies identified only 6 of them (19% of the identified studies) were completed in the last 10 years. With the changes that have occurred in material science in this time many of the materials tested may no longer be in use or are now produced in a

different specification; for example Campbell et al. (1982) tested two different types of carpet material. As there are currently no standardised methods for testing insole materials the testing methodology and equipment used varied widely across studies making comparisons difficult and many researchers based their conclusions around the relative comparisons of the range of materials they tested. There is a need for absolute results in the form of quantitative assessment of material properties as opposed to focusing on relative comparisons.

If standardised testing methods were available which resulted in an absolute result for the materials performance this would allow for cross study comparisons and would result in the generation of practical information to allow categorisation of materials for different treatment purposes. Furthermore, it is not adequately helpful to clinicians for researchers to simply recommend a material by name, e.g. Poron, some indication on the specifications of the material are needed as materials are generally available in a wide range of thicknesses and densities and these will affect the materials performance.

As discussed in the literature review above some research groups have developed their own materials performance index to categorise materials based on their performance characteristics (e.g. accommodation, cushioning and control). However, at present none of these are without significant limitations; most notably their results are based on bench testing of materials. There was no examination of how the performance of the material in a bench testing relates to its performance within the shoe as an orthosis. Supporting work has been completed which shows that differences may exist between bench testing and in-shoe testing (Published work 20). This work examined the effect of temperature on the rebound characteristics of materials commonly used in diabetic footwear. Results showed that the rebound behaviour of the material when tested at room temperature, which is the standard material testing procedure, were different to when the same material was tested at higher temperatures (37, 45 and 55°C), which the material experiences within a shoe environment. This finding has implications for developing material performance indexes and for the selection of materials for use in therapeutic footwear.

As recognised through the review (Chapter 2) most of the identified studies were more than 10 years old and therefore information on the materials currently being utilised by clinicians was limited. To address this a questionnaire was developed (see Appendix 2) to examine the prescription procedures involved in the provision of foot orthoses by orthotists and podiatrists with an emphasis on material choice. This questionnaire focused on materials the clinicians' chose to use when treating patients with diabetes. Foot problems such as ulcerations and amputations are common and serious complications seen in people

with diabetics and custom footwear and orthoses are interventions used by clinicians to reduce the risk of ulceration. There were four elements to this questionnaire; the clinicians' profile, the type of devices they routinely prescribed, the material choices for these devices and the factors which affected their choice and finally whether the materials used were considered the most suitable for their purpose with a focus on diabetes.

In November 2009, 29 questionnaires were distributed to clinical practitioners with 14 questionnaires completed and returned for analysis. The questionnaires were distributed to clinicians who were known to have experience of using both traditional and CAD/CAM manufacturing and would therefore have access to a wide range of materials. Closed questions were utilised to gather information on clinical practice and material selection while minimising the effort and time on part of the respondent. A limited number of open ended questions were also included to gain insight into the opinions and attitudes of the respondents.

This study highlighted the diversity in opinion among clinicians with regards to the available materials. The clinicians' views were divided on whether they believed the materials available to them were fit for purpose and also across the range of materials they chose to use. When asked about using guidelines for prescribing orthoses the response was divided; half the respondents said they didn't use any with the ones who used guidelines stating that they used their own. The respondent's comments on their use of guidelines are provided below:

"After in excess of 35 years in practice I utilise aspects from all the training courses I have attended from various manufacturers and incorporated them into my own clinical experience."

"All prescriptions are based on clinical grounds, as I'm legally responsible for the prescription. Follow research/clinical guidelines I see as appropriate."

"I use my own past experience."

"Cost is a major factor e.g. we tend to use a polyprop sheet with no top cover and place it under the liner of the existing shoe, we reserve top covers for at risk clients only. We use chairside devices 90% of the time."

"I rely entirely on past experience, training and discussing with other orthotist/technicans. Although guidelines would be helpful, are there too many exceptions to rule as every patient is unique. Neuropathy, ischaemia, necrosis, ulceration, activity, life style, arthritis, mental health status, and all the combinations of these."

"Developed guidelines for use in football and rugby union."

"I utilise my own guidelines to allow me to provide consistently good results to patients with occasional design compromises to limit lifestyle effect for clients unless its not achievable."

"I use all my years of experience in prescribing orthoses. Each and every patient must be assessed individually then a decision is made as to which orthotic is prescribed."

These comments show the diverse opinion among even this small group of respondent clinicians about guidelines. Some have developed their own while others didn't think the use of guidelines was suitable. In terms of research there is a need to examine the development of guidelines and assess their usefulness and practical application to clinical practice. This issue will be discussed further in the section on diabetic footwear below.

The clinicians were then asked about the material choices for the devices (rigid, semi rigid and accommodative) they prescribe to patients with diabetes. Conflicting opinions with regards to the selection of materials for different functions i.e. accommodative, semi rigid and rigid devices were evident among the respondents (see Figure 1 and comments below).

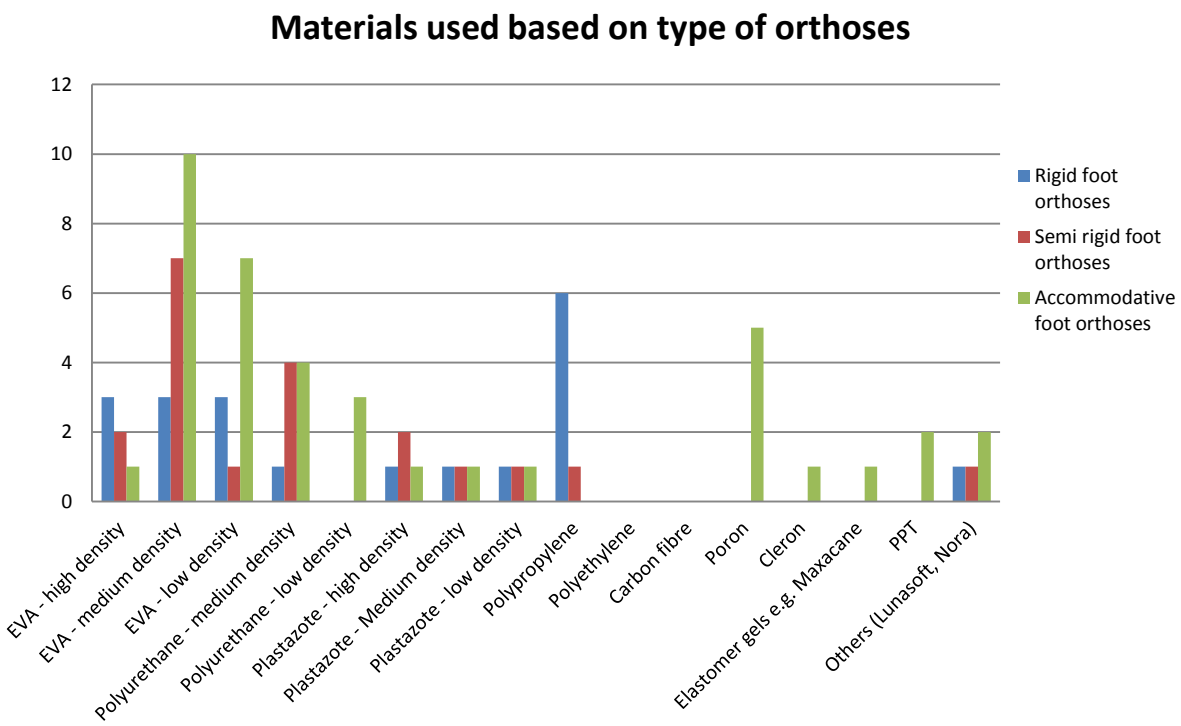

Figure 1: Materials used based on type of orthosis

<u>Rigid foot orthoses</u>

"Generally use a mixture of materials."

"I tend to provide dual density FFOs/TCIs. Rear in medium density, forefoot in low density (soft - Lunasoft). Very dependant on patient's weight, gait and degree of control required."

"Inexpensive, long lasting, strong (polypropylene)."

"Usually as base layer (high density EVA), rarely I use shock absorption for diabetics. Comfortable to wear, flexible at late stance, easily adaptable/molded to footwear."

"Price/quality of finish/well tolerated (low density EVA and polypropylene)."

Semi rigid foot orthoses

"All very dependant on patient's weight, gait, stance etc. Very difficult to generalise. Once again dual density approach is used."

"I use material combinations to offer support and cushioning to the diabetic foot, usually incorporating sinks and pillows, and adaptation of footwear."

"Easy to adjust, good compliance, easy to produce (high density EVA)."

"As base layer (medium density EVA)."

Accommodative foot orthoses

"Easy to adjust, good compliance, easy to produce (medium density EVA). Poron as top cover only."

"EVA medium and low density and polyurethane medium density as base layers; EVA low density also as top cover and Poron as top cover."

"I rarely treat diabetics but if I do they tend to have total contact EVA type devices."

While materials such as Poron, Cleron, Elastomer gels and PPT were selected solely for use in accommodative devices and polypropylene for rigid devices the remaining materials were selected by different respondents for use in all three types of devices. While there are numerous materials which can be used by clinicians to achieve the same treatment outcome, it was an unexpected result from the questionnaire to see some clinicians select a material for use in accommodative devices and others select the same material for use in a rigid device. This finding further supports the need for research into material performance which would lead into guidelines for clinicians. However, there was a limitation to the structure of the question that may have affected the results. Within the section for each type of device (rigid, semi rigid and accommodative) there was no space to differentiate between materials used a base material and those as top covers. Therefore some clinicians may have selected a material usually used in accommodative devices in the rigid device section as they may use it as a top cover for the rigid device.

The following question asked if the clinicians felt that material choice had changed significantly in the last 5 years. Again there was division in the respondents with five selecting yes and eight selecting no. The comments made by the clinicians are supplied below:

Comments from people who said yes:

"Less cushioning and more functional/corrective"

"Polyurethane has become an option"

"I always look at function but if I can get a device that can provide function and comfort that helps so polyurethane for example"

"There has been numerous new materials introduced over the years each providing more comfort and pressure relieving qualities"

"More density and better quality"

Comments from people who said no:

"While saying this it is very important to keep abreast of new developments"

"Top covers have changed not base materials"

"Slight changes: different medical grade Porons, increase use of stock insoles"

"Tried and tested methods"

Results were varied as some clinicians may be happy with the materials they use and are therefore not interested in changing, while others may be more open to exploring new and different treatment options. For many clinicians time and funding resources are limited and therefore their materials choice may be restricted. Another restriction that may be placed on clinicians is that within their clinic they are contracted to work with certain material providers which again may limit their choices; this is more evident in NHS clinics than private practice. While the results of the questionnaire provided valuable information on clinical practice which supported methodology development for future studies this study was limited by the low number of respondents (only 14 of the 29 questionnaires were returned).

The findings from the literature review and questionnaire study (Chapters 2 and 3) informed the methodology for the subsequent laboratory based study (Chapter 4). As evidenced from the review article (Chapter 2) there are limited studies which have examined the performance of insole materials during walking, with previous studies utilising bench testing and simulated in-shoe testing methods. Therefore, it was decided that it would be beneficial to conduct in-shoe lab testing of orthosis materials to gain objective information

on their performance as an orthosis. As polyurethane (PU) and ethyl vinyl acetate (EVA) were two of the most used materials among the questionnaire respondents (Chapter 3), and had received limited testing within the studies identified in the review (Chapter 2), they were selected for testing in the laboratory study.

The objective of this study was to gain a greater understanding of the characteristics of orthosis materials and how they affect gait so to enhance the clinical decision-making process. Two materials (PU and EVA of two different densities) were tested in the laboratory; assessing the effect of the materials on both plantar pressures and kinematics. The selected materials are used extensively by clinicians, based on the findings of the questionnaire study (Chapter 3).

Findings from this study provide information for a clinician to draw an evidence-based orthosis prescription based on material properties. While some clinicians provided anecdotal evidence for the suitability of PU as an orthotic material in the questionnaire study (Chapter 3) results from this lab based testing provide quantitative results to support its use. Findings from this study support the view that it is not appropriate for researchers to simply recommend a material by name; this is evidenced from the difference in the off-loading capabilities of the PU and EVA materials in their low and medium density compositions. This finding is extremely important information for clinicians as they need to be aware of the effect of different densities of the same material on its offloading capabilities when selecting a material for an orthotic treatment intervention.

Limitations of this study include that the participants did not have diabetes and that the sample size was small. This was a preliminary study and currently through the DiaBSmart project the PU material is being tested on a larger sample of patients with diabetes who are considered at risk of foot ulceration to examine its effectiveness on pressure reduction.

Diabetic footwear for the prevention and treatment of ulceration

Progressing from examining materials used in orthoses the effect of off-loading interventions, namely diabetic footwear, on the prevention and treatment of ulceration were assessed. While there are a number of reviews available in the literature which have examined off-loading interventions these generally included a limited discussion of diabetic footwear which is why it was considered necessary to complete these two reviews (Chapter

5 and 6). Off-loading interventions are used within clinical practice in an effort to reduce ulcerations however the effectiveness of these interventions is unclear.

The aim of the first systematic review (Chapter 5) was to examine the effectiveness of footwear as an intervention for prevention of diabetic foot ulcers. Given the seriousness of diabetic foot complications and the prevalence of ulcerations and amputations it was surprising that no previous research has examined the prevention of first ulceration; instead research has focused on preventing reulceration. There was a large diversity in the styles of footwear in the eligible studies which ranged from running shoes and off the shelf therapeutic footwear to custom made therapeutic footwear. It was concluded that while there was support for the use of rocker sole footwear and custom orthoses generic recommendations on these features are not possible as the optimal design will be patient specific. In this review article limitations of the eligible reviewed articles were discussed and recommendations for future research were provided.

The subsequent review (Chapter 6) examined the effectiveness of footwear and other removable off-loading devices in the treatment of foot ulcers. While there is a lack of randomised controlled studies in the area it appeared that currently available therapeutic footwear were the least effective removable intervention for ulcer treatment behind removable cast walkers (RCWs) and half or heel relief footwear.

Both these reviews identified that there is a limited amount of good quality research in the area of diabetic footwear. While randomised control trials (RCTs) are considered the gold standard design for a clinical trial the use of this methodology in the eligible studies was low in both review articles. In the prevention review (Chapter 5) only 1 of the studies was a RCT and in the treatment review (Chapter 6) 9 of the 17 studies (just over 50%) were RCTs. There is also a lack of longitudinal studies which have examined the effectiveness of footwear in ulcer prevention with 8 of the 12 identified studies using a cross sectional repeated measures design.

The comments provided by the respondents in the questionnaire study (Chapter 3) about their use of guidelines questioned the suitability and usability of the currently available clinical guidelines. Different organisations and researchers have developed guidelines which aim to provide information to clinicians for the prevention of diabetic foot ulcers. Examples of the information provided in these guidelines are provided below:

"*There are five key elements which underpin foot management:*

1. *Regular inspection and examination of the foot at risk.*
2. *Identification of the foot at risk.*

3. Education of patient, family, and healthcare providers.
4. Appropriate footwear.
5. Treatment of non-ulcerative pathology."

"If the fit is too tight because of deformities or if there are signs of abnormal loading of the foot (e.g. hyperaemia, callus, ulceration), patients should be referred for special footwear (advice and/or construction), including insoles and orthoses" (Bakker et al., 2012)

"To achieve maximal reduction of peak plantar pressures in footwear prescription, custom-moulded insoles should be incorporated in the therapeutic footwear as long as sufficient space exists." (Bus et al., 2008)

While it is a positive step forward in ulcer prevention that guidelines now highlight the importance of appropriately fitting footwear these guidelines are too general; not all insoles/orthoses and therapeutic footwear will be effective in off-loading. This is evidenced in the lab based study of insole materials in Chapter 4 which showed differences in pressure reduction for different materials, and in the supporting work which examined the effect of different diabetic footwear on plantar pressures (Published work 19). This supporting work compared the design features and plantar pressures between four types of diabetic footwear and the participant's own footwear which was an Oxford style brogue shoe. Results showed that all four pairs of diabetic footwear resulted in reduced peak plantar pressures when compared to the participant's own footwear, with reductions as large as 50% in some areas. However, there were large variations in pressure reduction between the different diabetic footwear, highlighting the importance of accessing a footwear's offloading ability prior to prescribing then to "at risk" patients. For these guidelines, it is likely that it is their lack of specificity that contributes to the low acceptance of them by clinicians. More specific guidelines on the types of therapeutic footwear and the materials used in the insoles/orthoses are needed for clinicians.

In terms of ulcer treatment, guidelines have also been developed for clinicians by various groups, for example the International Working Group on the Diabetic Foot (Bakker et al., 2012). This guideline like many others promotes the use of total contact casts as the gold standard in ulcer treatment, however recently researchers have surveyed treatment interventions used in clinical practice and found that TCCs are not the most commonly used treatment intervention. Studies from both America and Europe which examined clinical practice found a minority of patients are treated using a TCC; Wu et al. (2008) reported that 41% of the clinics they assessed attempted to offload with shoes and less than 2% used TCCs, Fife et al. (2010) found only 6% of patients received a TCC and Prompers et al. (2008) found that on average 35% (range 0-68%) of patients received a TCC. A recent study from Australia which surveyed practitioners found that while the majority of

respondents considered TCCs the gold standard for offloading hallux and forefoot ulcers they ranked third for the most used modalities behind felt padding and removable cast walkers (Raspovic & Landorf, 2014).

While TCC's are considered the gold standard for offloading an active ulcer there are some disadvantages to their use which often lead to the use of other off-loading modalities. Training and experience are required for correct application of TCCs and many centres may not have someone with this training, they can cause skin irritation and further ulceration, they do not allow daily assessment and cleaning of the wound, they may disturb sleeping and the patient's ability to work, they make bathing difficult, they may exacerbate postural instability and they are contraindicated for wounds with soft-tissue infections and osteomyelitis (Armstrong et al., 2004). For these reasons it is important that there are suitable alternative treatment interventions available to clinicians.

Measurement of plantar pressure is a valuable resource to clinicians when assessing patients with diabetes where high plantar pressure has been shown to be a major risk factor for the development of ulcers. In clinical settings plantar pressure is usually monitored by clinicians during infrequent visits in a clinical environment that can only provide a brief window into the loading of that foot over the course of a day. This information is then used to prescribe shoes/orthoses to address the issues relating to abnormal plantar pressures which contribute to ulceration. The availability of a plantar pressure measuring device that could continually monitor the patient's plantar pressures would be a beneficial tool for clinicians. WalkinSense® is such a system and as it is a new system it was necessary to test the measurements provided by this system. A study was completed (Chapter 7) which compared WalkinSense® to the Tekscan F-Scan system which is known to be reliable for clinical measurement. Results showed that WalkinSense® was as repeatable as the F-Scan. This study provides clinicians and researchers with confidence in the systems repeatability and support for its use in clinical practice and research. Also as identified in the systematic review articles (Chapter 5 and 6) the ability of researchers to monitor a participant's compliance to a treatment intervention is a limitation of research to date. The use of systems like WalkinSense® could be utilised in future studies to monitor patient compliance, plantar pressures and to quantify daily ambulation.

In addition to the published work included in the main body of the text (Chapters 2-7) additional relevant publications within the area of therapeutic footwear and diabetes have also been completed. Supporting work has shown that patients with diabetes and who are at risk of ulceration are found to have a significant reduction in ankle muscle strength with a decrease in muscle force during dorsi and plantar flexion (Published work 1). This finding

has implications for treatment interventions as clinicians should look at the possibility of utilising exercise programs to maintain ankle strength in this population. It also has implications in footwear design; many of the available diabetic footwear are heavier than standard footwear and if these patients has reduced ankle strength then the extra weight of the diabetic footwear may make walking more difficult for the patient. This should be taken into consideration when manufacturers are selecting the materials within the outsole of the footwear. Research also shows that patients with diabetes and neuropathy have impaired postural stability which may put them at a higher risk of falling (Boucher et al., 1995). Published work 2 assessed the effect of diabetic footwear on postural stability, concluding that the rocker outsole shoe tested did not negatively affect postural stability in patients with diabetic neuropathy. Supplementary research has utilised plantar pressure measurement to examine the effect of foot type on plantar pressures (Published work 17) and to access the effect a novel diabetic shoe design on peak plantar pressures (Published work 29).

The use of different methodologies within this body of work, with both qualitative and quantitative methodologies used, provides valuable information to the field of orthoses and prescription footwear research. This research has assessed the significance of previous research (Chapter 2, 5 and 6), gained insight into current clinical practice (Chapter 3) and utilised laboratory testing to examine the material properties of orthosis materials widely used in clinical practice (Chapter 4) and newly developed pressure measurement equipment (Chapter 7). The findings of this work extend the knowledge in the area of footwear science and clinical biomechanics.

The completion of review articles (Chapter 2, 5 and 6) which examined research to date in the area of orthoses and prescription footwear allowed the identification of gaps in the literature and address limitations of previous research. The information gained from these reviews facilitated the design of the subsequent studies within this research profile, ensuring the chosen methodologies were appropriate to answering the research questions. As identified in the materials review (Chapter 2) most of the previous research in the area of material testing was outdated and it was therefore necessary to gain an up to date insight of current clinical practices on which to base the laboratory testing which is why a questionnaire was developed to gain information from practicing clinicians (Chapter 3). Results from this questionnaire allowed the identification of the most popular materials used in clinical practice and this along with the information gained from the materials review on testing methodologies (Chapter 2) were used to design a quantitative assessment of material performance when used as an insole/orthotic while walking (Chapter 4).

While some researchers have examined various aspects of prescription footwear such as insoles, materials and design, these have been examined independently. The work within this thesis examined the combined contribution of these factors which bridges a gap in prescription footwear research. Work in this area continues and in the near future research will be published from the clinical trial of insole materials conducted as part of the DiaBSmart project.

Clinical implications, and recommendations for future research

Given that there are no standardised testing methods for assessing materials used in orthoses and that much of the research examining materials is outdated there is a need for high quality research in this area. While some materials performance indexes have been proposed in the literature they have limitations and future research should address these limitations. I have been involved in the preparation of a research proposal for the development of a materials performance index which intends to examine the relationship between mechanical testing of materials and testing completed on the insoles/orthoses during gait with an aim of establishing an easy to use index to assist clinicians in material selection; and are currently looking for a funding body to support this research.

Findings from the testing completed on the two materials (EVA and PU) in Chapter 4 provide evidence to clinicians on the suitability of PU as an insole and orthotic materials, where previously no evidence existed in the literature. In the flat insoles medium density PU was superior to the other materials for pressure off-loading and when constructed into an orthotic PU provided similar off-loading capabilities as the EVA materials. Future research should focus on examining the durability of PU and other orthotic materials as longitudinal studies on material performance are limited.

Significant changes in the orthotics industry are anticipated in the near future due to advances in both material science and technology. While traditionally orthoses were hand crafted recent advances initiated the use of CAD/CAM manufacturing and more recently additive manufacturing/3D printing has started to be utilised in orthoses production. The use of additive manufacturing will result in the use of different materials in the production of the orthoses and the materials properties of these materials will need to be examined. Additionally, while up until now clinicians have had to select materials for orthoses from what is available in the market, recently it is being proposed to develop materials whose properties are optimised to treat individual patients. This is currently being examined through the DiaBSmart project and by other research groups (Luo et al., 2011).

For both systematic reviews (Chapter 5 and 6) a quality assessment form was utilised to examine the quality of the eligible studies with many similar limitations found across both reviews. A major oversight in the majority of the identified studies in both reviews was the limited information presented on the participants' characteristics. As certain factors has been identified as risk factors for ulceration i.e. duration of diabetes, presence of neuropathy/peripheral vascular disease and history of ulceration/amputation it is important for studies to provide this information for their participants. Limited descriptions

of the footwear/off-loading interventions were also evident with some studies only providing the brand name and model of the footwear intervention. This information is essential to allow research findings to be translated into recommendations for clinical practice and the importance of the inclusion of this information should not be overlooked in future studies.

Findings from the prevention review (Chapter 5) highlighted that no research to date has examined the use of footwear in the prevention of first ulceration; with all previous research examining the use of footwear in preventing reulceration. Also, there is a lack of longitudinal studies of footwear interventions which the vast majority of research using a cross sectional study design. Through the clinical trial within the ongoing DiaBSmart project both these limitations are being addressed with the effect of a footwear intervention on the plantar pressures of patients at risk of ulceration but with no previous history of ulceration being examined over a period of one year.

As seen in the findings from recent research the use of TCCs in clinical practice is low and therefore work is needed in the area to maximise their use where applicable through adequate training for clinicians in TCC application. For those patients where TCC application is contraindicated and in patients not willing to consent to using a TCC, due to its negative impact on their lifestyle, there is a need for large scale clinical trials to determine the best alternative off-loading modality and for this information to be provided in guidelines for ulcer treatment. This research is needed as it was found from the systematic review that research in this area is limited (Chapter 6). Guidelines should not replace the importance of a clinicians experience in treating each patient as an individual but they should provide evidence based information to assist clinicians in the development of their treatment plans.

While it was concluded that footwear was the least effective intervention for the treatment of ulceration in the systematic review (Chapter 6), there are situations where the gold standard total contact cast is contraindicated or not accepted by patients as discussed above, and in these circumstances a footwear intervention may need to be prescribed. It is for this reason that future research should further examine the effectiveness of therapeutic footwear in ulcer treatment and aim to examine ways of optimising footwear to increase its effectiveness in ulcer treatment. From the limited available research available on removable off-loading devices the DH pressure relief walker (Royce Medical, Camarillo, CA, USA) appears to be the most effective RCW for pressure off-loading and could be considered by clinicians as a treatment option where the application of a TCC is contraindicated or not accepted by a patient.

The use of plantar pressure measurement systems in research allows for the quantification of the off-loading ability of interventions but results from these systems can

be greatly affected by factors should as walking speed and step protocols. It is advised that future research make use of standardised and well described plantar pressure measurement protocols. Previous research in this area by our research team (Published work 12) and others (Arts & Bus, 2011; Bus & de Lange, 2005) supplies researchers with evidenced based recommendations for plantar pressure measurement in patients. Additionally, clinicians should be aware of these plantar pressure measurement protocols and utilise them, where applicable, in their clinical practice. Utilising these protocols will ensure the results of the pressure measurements they utilise to inform their clinical practice will be both reliable and repeatable. The publication on the WalkinSense® pressure measurement system supports its use in clinical practice and research; it would be a useful measurement modality in future longitudinal research as it allows for monitoring of plantar pressures, footwear compliance and participant activity levels.

Summary

Clinical implications

- Initial evidence for the suitability of PU in offloading orthoses.
- Some evidence for the use of DH pressure relief walker for ulcer treatment when TCC contraindicated or not accepted by a patient.
- Importance of using standardised protocols for plantar pressure measurement to ensure the validity and repeatability of results.

Recommendations for future research

- Development of material performance index is needed to aid clinicians in choosing materials for orthoses.
- Future research should focus on examining the durability of PU and other orthotic materials as longitudinal studies on material performance are limited.
- Future research should provide more detailed information on the characteristics of their participants and detailed descriptions of the footwear/off-loading/orthoses interventions.

- In relation to diabetic footwear research should focus on examining the effectiveness of footwear in preventing first ulceration and utilise a longitudinal as opposed to cross sectional study design.
- Research is needed to identify the best alternative off-loading modality for ulcer treatment when the use of a TCC is contraindicated or not accepted by a patient.
- More specific guidelines regarding appropriate footwear and orthoses for people with diabetes is needed to aid clinicians in developing treatment interventions.

Impact of work

Dissemination

To facilitate wide reaching impact this work was disseminated in a range of both scientific and clinical forums. The published work (Chapters 2-7) are all published in different journals with readership in both the scientific and clinical communities; Footwear Science, Podiatry Now, The Foot, Prosthetics and Orthotics International, Current Diabetes Reviews and Journal of Diabetes and its Complications.

Presentations of this work were made to the scientific community at the Footwear Biomechanics Symposiums in 2011 and 2013 (Published work 37 and 54). Additionally, this work was presented at a number of clinical conferences: Clinical Applications of Foot Pressure Measurement User Group Meeting, 2011 (Published work 55); Diabetes UK Professional Conference in 2013 and 2014 (Published work 33 and 40); Diabetes Foot Study Group, 2013 (Published work 38); and Staffordshire Conference on Clinical Biomechanics in 2010, 2011, 2013 and 2014 (Published work 32, 36, 54 and 57).

Dissemination was also conducted through the provision of workshops in plantar pressure and biomechanics for clinicians at two conferences: the 11th Annual Meeting of Diabetic Foot Society of India, 2012 (Published work 62) and the International Advanced Diabetes Workshop for Physicians, 2012 (Published work 63).

Known citations of published work

The following section provides information on research articles and theses which have cited the published work (Chapters 2-7) contained within this thesis. Further information on the research articles and theses are provided in Appendix 3.

Chapter 2: Materials used for Footwear Orthoses: A Review.

This research was published in Footwear Science, an international peer reviewed journal, and it has received considerable interest having been viewed on the journals homepage 122 times (as of 3rd February 2015). It has been cited in recent articles in Footwear Science and the Journal of Rehabilitation Research and Development. The paper has also recently

been cited in a PhD thesis on the design of diabetic footwear from the University of Salford, UK.

Chapter 3: An investigation into the prescription procedures and material choice involved in the provision of bespoke foot orthoses for diabetic patients

The study was published in Podiatry Now, which is issued by The Society of Chiropodists & Podiatrists, UK and has a wide readership of clinicians in the UK.

Chapter 4: Effect of insole material on lower limb kinematics and plantar pressures during treadmill walking

This article was published in Prosthetics and Orthotics International (Impact factor 1.073 (2013)). It has been cited three times in recent publications in international peer reviewed journals; with one article in Gait & Posture (Impact factor 2.299; 5-year impact factor 2.985 (2013)) and two articles in Prosthetics and Orthotics International.

Chapter 5: The effectiveness of footwear as an intervention to prevent or to reduce biomechanical risk factors for ulceration: a systematic review

This article was published in the Journal of Diabetes and its Complications which has an impact factor of 1.925 (2013), 5-year impact factor of 2.060 (2013) and is a highly regarded journal in the field of diabetes. While this article was only published in 2013 it has had considerable interest and has already received six citations. Four citations are in international journals: The International Journal of Lower Extremity Wounds (Impact factor 1.194 (2013)), ROBOMECH Journal, Journal of Clinical & Translational Endocrinology and Journal of Diabetes Research (Impact factor 3.536 (2013)). The remaining two citations are within PhD theses from University of Amsterdam, Netherlands and University of Salford, UK.

Chapter 6: The effectiveness of footwear and other removable off-loading devices in the treatment of diabetic foot ulcers: a systematic review

This study was published in Current Diabetes Reviews and is currently listed on the journal's homepage as one of their most accessed articles (as of 3rd February 2014).

Chapter 7: Repeatability of WalkinSense® in shoe pressure measurement system: A preliminary study

This article was published in The Foot and it has so far been cited four times by other researchers in peer reviewed journals; with two articles in the journal Sensors (Impact factor 2.048 (2013); 5-year impact factor 2.457 (2013)), one in BioMEd Research International (Impact factor 2.706 (2013); 5-year impact factor 2.69 (2013)) and one in Diabetes Research and Clinical Practice (Impact factor 2.536 (2013); 5-year impact factor 2.853 (2013)).

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Appendices

Appendix 1: Statements by the collaborating researchers

Publication Title: Healy, A., Dunning, D. and Chockalingam, N. (2010). Materials used for Footwear Orthoses: A Review. Footwear Science, 2(2): 93-110.

The undersigned hereby certify that Aoife Healy made substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data, and drafting and final approval of the article version to be published.

Name	Signature	Date
Dave Dunning		**23/01/15**
Nachiappan Chockalingam		**23/01/15**

Publication Title: Healy, A., Dunning, D., Naemi, R. and Chockalingam, N. (2010). An investigation into the prescription procedures and material choice involved in the provision of bespoke foot orthoses for diabetic patients. Podiatry Now, 13(9): 26-29.

The undersigned hereby certify that Aoife Healy made substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data, and drafting and final approval of the article version to be published.

Name	Signature	Date
Dave Dunning		**23/01/15**
Roozbeh Naemi		**28/01/15**
Nachiappan Chockalingam		**23/01/15**

Publication Title: Healy, A., Dunning, D.N., and Chockalingam, N. (2012). Effect of insole material on lower limb kinematics and plantar pressures during treadmill walking. Prosthetics and Orthotics International, 36(1): 53-62.

The undersigned hereby certify that Aoife Healy made substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data, and drafting and final approval of the article version to be published.

Name	Signature	Date
Dave Dunning		23/01/15
Nachiappan Chockalingam		23/01/15

Publication Title: Healy, A., Burgess-Walker, P., Naemi, R. and Chockalingam, N. (2012). Repeatability of WalkinSense® in shoe pressure measurement system: A preliminary study. The Foot, 22(1): 35-39.

The undersigned hereby certify that Aoife Healy made substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data, and drafting and final approval of the article version to be published.

Name	Signature	Date
Phil Burgess-Walker		03/02/15
Roozbeh Naemi		28/01/15
Nachiappan Chockalingam		23/01/15

Publication Title: Healy, A., Naemi, R. and Chockalingam, N. (2013). The effectiveness of footwear as an intervention to prevent diabetic foot ulceration or to reduce biomechanical risk factors for ulceration: a systematic review. Journal of Diabetes and Its Complications, 27 (4): 391-400.

The undersigned hereby certify that Aoife Healy made substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data, and drafting and final approval of the article version to be published.

Name	Signature	Date
Roozbeh Naemi		28/01/15
Nachiappan Chockalingam		23/01/15

Publication Title: Healy, A., Naemi, R. and Chockalingam, N. (2014). The Effectiveness of Footwear and Other Removable Off-loading Devices in the Treatment of Diabetic Foot Ulcers: A Systematic Review. Current Diabetes Reviews, 10(4):215-230.

The undersigned hereby certify that Aoife Healy made substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data, and drafting and final approval of the article version to be published.

Name	Signature	Date
Roozbeh Naemi		28/01/15
Nachiappan Chockalingam		23/01/15

Appendix 2: Questionnaire – Chapter 3 - An investigation into the prescription procedures and material choice involved in the provision of bespoke foot orthoses for diabetic patients

An investigation into the prescription procedures and material choice involved in the provision of bespoke foot orthoses for diabetic patients

This questionnaire is being sent to orthotists and podiatrists involved in the prescription of bespoke foot orthoses. The aim is to identify current clinical practice in the prescription and material choice of bespoke foot orthoses for patients with diabetes

Please read the questionnaire fully before answering the questions.

PROFESSIONAL BACKGROUND

1) **What environment do you work in?**

- ☐ Community
- ☐ Hospital/Acute
- ☐ Own clinic
- ☐ Part of private hospital/clinic

2) **How many bespoke orthoses do you prescribe per month?**

- ☐ 0-5
- ☐ 6-10
- ☐ 11+

ABOUT YOUR PRACTICE

3) What percentage of your case load are

Diabetics	☐ 0-20% ☐ 21-40% ☐ 41-60% ☐ 61-80% ☐ 81-100%
Rheumatoid	☐ 0-20% ☐ 21-40% ☐ 41-60% ☐ 61-80% ☐ 81-100%
Children	☐ 0-20% ☐ 21-40% ☐ 41-60% ☐ 61-80% ☐ 81-100%
Sport/MSk	☐ 0-20% ☐ 21-40% ☐ 41-60% ☐ 61-80% ☐ 81-100%

4) What percentage of your entire case load are

High Risk	☐ 0-20% ☐ 21-40% ☐ 41-60% ☐ 61-80% ☐ 81-100%

CASTING TECHNIQUE

5) What casting technique do you predominantly use?

☐ Foam box technique

☐ Suspension plaster casting technique

☐ Other (specify) _____

6) Does your casting technique vary with the type of patient?

☐ Yes

☐ No

If yes, please provide comments on why?

_____

_____

_____

_____

_____

7) Please rate the importance of the following factors when choosing your casting technique.

	Very important	Quiet important	Not very important	Not at all important
Time	☐	☐	☐	☐
Cost	☐	☐	☐	☐
Resources (availability of materials, equipment, etc.)	☐	☐	☐	☐
Training	☐	☐	☐	☐
Receptivity of patients	☐	☐	☐	☐

PRESCRIPTION PROCESS

8) Do you follow a specific set of guidelines when prescribing orthoses?

☐ Yes

☐ No

If yes, which one?

☐ Commissioners

☐ Your own

☐ Employer/Manager

☐ Laboratory

☐ Other (specify) _____

Please feel free to comment on the above

_____

_____

_____

_____

_____

9) Which of the following are available to you to help in the biomechanical assessment process?

Kinematic		If available to you please rate how often you use it			
		Never	Rarely	Regularly	Always
Video	☐ with digitising	☐	☐	☐	☐
	☐ without digitising	☐	☐	☐	☐
Opto-electronic systems (motion analysis)	☐	☐	☐	☐	☐
Electro-magnetic systems	☐	☐	☐	☐	☐
Accelerometer based systems	☐	☐	☐	☐	☐
Goniometers/Isokinetic	☐	☐	☐	☐	☐

Kinetic		If available to you please rate how often you use it			
		Never	Rarely	Regularly	Always
Force platforms	☐	☐	☐	☐	☐
Pressure	☐ mat	☐	☐	☐	☐
	☐ in-shoe	☐	☐	☐	☐

		If available to you please rate how often you use it			
		Never	Rarely	Regularly	Always
Electromyography (EMG)	☐	☐	☐	☐	☐

Standard clinic observation only	☐

10) Please rate the importance of the following factors when choosing to use/not use the equipment you have selected as being available to you in question 9.

	Very important	Quiet important	Not very important	Not at all important
Time	☐	☐	☐	☐
Training	☐	☐	☐	☐
Receptivity of patients	☐	☐	☐	☐

ORTHOSES

11) Which of the following types of orthoses do you find yourself predominantly prescribing for your patients with diabetes?

☐ Accommodative (pressure relieving, total contact insole)

☐ Functional

☐ I prescribe equal amounts of both accommodative and functional orthoses

12) How frequently do you prescribe the following orthoses to your patients with diabetes?

		Which of the following materials do you predominantly choose when prescribing these orthoses?	Please provide detail on your reason/s for choosing this material.
Rigid foot orthoses	☐ 0-20% ☐ 21-40% ☐ 41-60% ☐ 61-80% ☐ 81-100%	EVA (Ethylene Vinyl Acetate) ☐ High density ☐ Medium density ☐ Low density Polyurethane ☐ Medium density ☐ Low density Plastazote ☐ High density ☐ Medium density ☐ Low density ☐ Polypropylene ☐ Polyethylene ☐ Carbon fibre ☐ Other (specify)_____ _____	

Please note question 12 is continued overleaf

12) Continued...

		Which of the following materials do you predominantly choose when prescribing these orthoses?	Please provide detail on your reason/s for choosing this material.
Semi rigid foot orthoses	☐ 0-20% ☐ 21-40% ☐ 41-60% ☐ 61-80% ☐ 81-100%	EVA (Ethylene Vinyl Acetate) ☐ High density ☐ Medium density ☐ Low density Polyurethane ☐ Medium density ☐ Low density Plastazote ☐ High density ☐ Medium density ☐ Low density ☐ Polypropylene ☐ Polyethylene ☐ Carbon fibre ☐ Other (specify)_____ _____	
Accommodative foot orthoses	☐ 0-20% ☐ 21-40% ☐ 41-60% ☐ 61-80% ☐ 81-100%	EVA (Ethylene Vinyl Acetate) ☐ High density ☐ Medium density ☐ Low density Polyurethane ☐ Medium density ☐ Low density ☐ Polypropylene ☐ Poron Plastazote ☐ High density ☐ Medium density ☐ Low density ☐ Cleron ☐ Elastomer gels e.g. Maxacane ☐ PPT ☐ Other (specify)_____ _____	

Please note question 12 is continued overleaf

12) Continued...

Diabetic shoes	☐ 0-20% ☐ 21-40% ☐ 41-60% ☐ 61-80% ☐ 81-100%

13) Please rate the importance of the following factors when choosing a material for a bespoke foot orthoses for a patient with diabetes.

	Very important	Quiet important	Not very important	Not at all important
Cost	☐	☐	☐	☐
Comfort	☐	☐	☐	☐
Manufacturing time	☐	☐	☐	☐
Perceived patient compliance	☐	☐	☐	☐
Previous patient feedback	☐	☐	☐	☐
Life expectancy of the device	☐	☐	☐	☐
Patient's lifestyle	☐	☐	☐	☐
Patient's current footwear	☐	☐	☐	☐

14) In the last 5 years has the material you choose for the manufacture of foot orthoses for a patient with diabetes changed significantly?

☐ Yes

☐ No

If yes, please provide details on why?

_____

_____

_____

_____

_____

15) Do you feel that the range of materials available for bespoke orthoses for patients with diabetes are appropriate?

☐ Yes

☐ No

If no, please provide comments on why?

_____

_____

_____

_____

_____

Thank you for taking the time to fill out this questionnaire

Appendix 3: Information for known citations of published work

Self-citations are shown in *italics*

Reference	Citation
Healy, A., Dunning, D. and Chockalingam, N. (2010)	1) Price, C., Cooper, G. and Jones, R. (2015) The manipulation of midsole properties to alter impact characteristics in walking. Footwear Science, 7(1):9-16. 2) Chapman, J.D. (2014) Improving the design of the curved rocker shoe for people with diabetes, PhD thesis, University of Salford, UK. *3) Healy, A., Naemi, R. and Chockalingam, N. (2013)* *4)* Majumdar, R., Laxton, P., Thuesen, A., Richards, B., Liu, A., Aran-Ais, F., Parreno, E.M. and Nester, C.J. (2013) Development and evaluation of prefabricated antipronation foot orthosis. Journal of Rehabilitation Research and Development, 50(10):1331-1342. 5) *Healy, A., Dunning, D.N., and Chockalingam, N. (2012)*
Healy, A., Dunning, D.N., and Chockalingam, N. (2012)	1) Gijon-Nogueron, G., Cortes-Jeronimo, E., Cervera-Marin, J.A., Diaz-Mohedo, E., Lopezosa-Reca, E., Fernandez-Sanchez, M. and Luque-Suarez, A. (Epub ahead of print) The effects of custom-made foot orthosis using the Central Stabilizer Element on foot pain. Prosthetics and Orthotics International. 2) Aminian, G., Safaeepour, Z., Farhoodi, M., Pezeshk, A.F., Saeedi, H. and Majddoleslam, B. (2013) The effect of prefabricated and proprioceptive foot orthoses on plantar pressure distribution in patients with flexible flatfoot during walking. Prosthetics and Orthotics International, 37(3):227-232.

	3) Telfer S., Abbott, M, Steultjens, M, Rafferty, D and Woodburn, J. (2013) Dose–response effects of customised foot orthoses on lower limb muscle activity and plantar pressures in pronated foot type. Gait & Posture, 38(4):443-9.
Healy, A., Burgess-Walker, P., Naemi, R. and Chockalingam, N. (2012)	1) Deschamps, K. and Messier, B. (In press) Pressure reducing capacity of felt: A feasibility study using a new portable system with thin sensors. Diabetes Research and Clinical Practice. 2) Crea, S., Donati, M., De Rossi S.M.M., Oddo, C.M. and Vitiello, N. (2014) A Wireless Flexible Sensorized Insole for Gait Analysis. Sensors, 14(1):1073-1093. 3) De Castro, M.P., Meucci, M., Soares, D.P., Fonseca, P., Borgonovo-Santos, M., Sousa, F., Machado, L. and Vilas-Boas, J.P. (2014) Accuracy and Repeatability of the Gait Analysis by the WalkinSense System. BioMEd Research International, Epub. *4) Branthwaite, H., Chockalingam, N. and Greenhalgh, A. (2013) The effect of shoe toe box shape and volume on forefoot interdigital and plantar pressures in healthy females. Journal of Foot and Ankle Research, 6:28.* *5) Johnson, S, Branthwaite, H., Naemi, R and Chockalingam, N. (2012) The effect of three different toe props on plantar pressure and patient comfort. Journal of Foot and Ankle Research, 5(1):22.* *6)* Razak, A.H.A., Zayegh, A., Begg, R.K. and Wahab, Y. (2012) Foot Plantar Pressure Measurement: A Review. Sensors, 12(7):9884-9912.
Healy, A., Naemi, R. and Chockalingam, N. (2013)	1) Lázaro-Martínez J.L., Aragón-Sánchez J., Alvaro-Afonso F.J., García-Morales E., García-Álvarez Y. and Molines-Barroso R.J. (Epub ahead of print) The Best Way to Reduce Reulcerations: If You Understand Biomechanics of the Diabetic

	Foot, You Can Do It. The International Journal of Lower Extremity Wounds. 2) Chapman, J.D. (2014) Improving the design of the curved rocker shoe for people with diabetes, PhD thesis, University of Salford, UK. 3) *Healy, A., Naemi, R. and Chockalingam, N. (2014)* 4) Takano, M., Noguchi, H., Oe, M., Sanada, H. and Mori, T. (2014) Development and evaluation of a system to assess the effect of footwear on the in shoe plantar pressure and shear during gait. ROBOMECH Journal, 1:4. 5) Tang, U.H., Zügner, R., Lisovskaja, V., Karlsson, J., Hagberg, K. and Tranverg, R. (2014) Comparison of plantar pressure in three types of insole given to patients with diabetes at risk of developing foot ulcers – A two-year, randomized trial. Journal of Clinical & Translational Endocrinology, 1(4):12-132. 6) Wang, X., Chen, L., Lie, W., Su, B. and Zhang, Y. (Epub 2014) Early Detection of Atrophy of Foot Muscles in Chinese Patients of Type 2 Diabetes Mellitus by High-Frequency Ultrasonography. Journal of Diabetes Research. 7) Arts, M.L.J. (2013) Custom-made footwear in diabetes: Offloading, usability and ulcer recurrence. PhD thesis, University of Amsterdam, Netherlands.