Footwear and insole prescription for people with diabetes and neuropathy who are at high risk of plantar forefoot ulceration

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DECLARATION

I certify that the work presented in this thesis is, to the best of my knowledge and belief, original, except as acknowledged in the text, and that the material has not been submitted, either in whole or in part, for a degree at this or any other university. I acknowledge that I have read and understood the University's rules, requirements, procedures and policies relating to my higher degree research award and my thesis. I certify that I have complied with the rules, requirements, procedures and policies of the University (as they may be from time to time).

Name

Signature Date

FOREWORD

I am a certified pedorthist custom maker-Australia with a tertiary degree in footwear engineering, having extensive experience in large-scale conventional footwear manufacturing, product development, materials properties and performance, and quality assurance and technological innovation. I also have over 12 years of experience designing, manufacturing, modifying, fitting, and retailing pedorthic appliances, including therapeutic footwear and custom-made orthoses/total contact innersoles in Australia. I work as an interdisciplinary team member at high-risk foot clinics in Nepean and St Vincent's Hospitals, Sydney. I am also one of the co-authors of the National Association of Diabetes Centres collaborated High-Risk Foot Service standards for Australia. I receive many referrals of patients with diabetes-related foot complexities every week from podiatrists, orthotists, vascular and orthopedic surgeons from high-risk foot clinics, and podiatrists in private and community clinics to provide offloading devices for patients with diabetes to prevent ulceration.

There are several challenges repeatedly encountered in this practice area, which present potential barriers to achieving the optimal clinical outcome(s), and the offloading goals for the diabetes foot. Footwear is a complex intervention not just in terms of the potential impact on mechanical outcomes but also psychosocial ones. Competing priorities may occur; for example, features that provide optimal offloading may be deemed aesthetically unacceptable to the patient. In practice, I find solutions to these challenges in individual cases but have found the research literature on these issues needing improvement. Furthermore, shared language and expectations among referrers, funders, providers, and manufacturers need to be improved. These clinical challenges and knowledge gaps were the impetus for conducting this research and the subject of this thesis, which was to try to identify standards for the prescription of footwear for people with diabetes. As I discovered by undertaking this thesis, footwear prescription is a deceptively complex intervention, compounded by the range of circumstances of the wearers. While I have not been able to answer all of the questions I had hoped to, I believe this thesis sheds new light on the complexity of footwear as an intervention and, in particular, the need to recognise the individual needs and preferences of service users.

In addition, the pedorthic profession in Australia is very small (fewer than 80 practising members) and has a very limited research background. Therefore, a substantial amount of this thesis involved understanding the current practice of pedorthists, the types of patients who use pedorthists, and their requirements.

ABSTRACT

Background

Diabetes-related foot complications are a common reason for hospitalisation and one of the main precursors to lower limb amputation worldwide. In Australia, foot complications are the leading cause of diabetes-related hospitalisation, and lead to over 4000 preventable yearly amputations. Footwear is a key intervention in managing diabetic foot, particularly for preventing plantar forefoot ulceration. As the risk of foot ulceration increases, the footwear needs of the individual become more complex. This footwear is manufactured and provided by pedorthists as part of multidisciplinary care. Footwear prescription remains more of an art form than an evidence-based practice. Few studies explore footwear design parameters influencing clinical outcomes and patient satisfaction.

Aim

This thesis aims to develop a set of design principles for footwear and insole design that prevents neuropathic plantar forefoot ulcers in people with diabetes.
Three objectives will contribute to the aim:

1. Collate and summarise the current literature on the effectiveness of footwear and insoles in reducing peak plantar pressures and preventing diabetes-related neuropathic forefoot ulceration.
2. a) Explore the population of patients who use pedorthic services
2. b) Explore current pedorthic practices in footwear prescription and manufacture
3. Examine footwear, the influence of features on plantar pressure, patient satisfaction, and adherence

Methods

The research involved four core components: **Study-1:** a systematic literature review examining the effectiveness of footwear and insoles in reducing peak plantar pressures and preventing diabetes-related neuropathic forefoot ulceration. **Study-2:** a retrospective clinical audit of characteristics of patients presenting to a pedorthics clinic **Study-3:** a survey exploring Australian pedorthists' prescription and manufacturing practices for this population. **Study-4:** a series of N-of-1 trials that evaluate footwear design parameters

influencing offloading of the plantar forefoot for people with diabetes and neuropathy. This informs the development of a set of design principles for footwear and insole prescription for this purpose.

Results

The systematic review revealed that customised insoles with a high contact area, metatarsal additions and rocker soles reduce plantar pressures in a manner that may reduce ulcer occurrence. However, the methodological quality of the existing study varies, and evidence around footwear and insole prescription and adherence-related information remains limited. The retrospective clinical audit revealed the complexity of this patient population. It highlighted the variations in social issues, funding models, cultural needs and personal preferences that may influence the desired outcome. The survey revealed diverse prescribing habits of footwear and insoles and various strategies employed by pedorthists to overcome patient adherence-related challenges. The series of N-of-1 studies revealed that footwear and insole prescription is successful when patient-specific factors are considered, and patient satisfaction and adherence are prioritised. Other key insights arising from this study included the person-specific nature of plantar pressure cutoffs, the positive influence of walking aids, the importance of a culturally sensitive approach and social supports in enhancing adherence.

Conclusions

Principles developed from this thesis for footwear and insole design for people with diabetes and neuropathy at risk of plantar forefoot ulceration include a multidisciplinary and person-centric team approach; comprehensive assessment of the lower limb; understanding the person's needs and setting treatment goals; assessing footwear history and footwear wearing period; determine foot measurements, shape and footwear type; prescribe appropriate footwear features; evaluate offloading and ensure pressure redistribution; and provide education and regular follow-up.

The set of design principles and knowledge gained from this thesis would benefit future researchers exploring personalised medical device design for other healthcare domains. Further research is encouraged for improved clinical and adherence-related outcomes.

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I want to express my profound thanks to **Dr Alex Barwick** and **Professor Susan Nancarrow**, who believed in me and helped me through my research journey in the challenging area of health science, as my early academic career was in engineering and business. I must mention the extraordinary support from **Dr Alex Barwick**, who was always there with a positive gesture, helped me overcome many of my challenges with this research, and allowed me to continue my research journey toward my goals. A debt of gratitude is owed to you both, **Dr Alex Barwick** and **Professor Susan Nancarrow**. You all, as a team, allowed me to develop my skills in the area of academic and clinical research. At times, that was challenging for me, but you all came forward to guide me on the journey toward completing the project.

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I must thank my friends and close family who sacrificed a lot to exempt me from many social and family events while I was engaged in doing my research, and soon it will be a good occasion to catch up.

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LIST OF PUBLICATIONS

This thesis includes chapters that have been written based on the following published journal articles.

1. Ahmed, Sayed, Alex Barwick, Paul Butterworth, and Susan Nancarrow. "Footwear and insole design features that reduce neuropathic plantar forefoot ulcer risk in people with diabetes: a systematic literature review." *Journal of foot and ankle research* 13, no. 1 (2020): 1-13.
2. Ahmed S, Butterworth P, Barwick A, Sharma A, Hasan MZ, Nancarrow S. Footwear and insole design parameters to prevent occurrence and recurrence of neuropathic plantar forefoot ulcers in patients with diabetes: a series of N-of-1 trial study protocol. Trials. 2022 Dec 16;23(1):1017. doi: 10.1186/s13063-022-06968-5. PMID: 36527100; PMCID: PMC9755781.

STATEMENT OF THE CONTRIBUTION OF OTHERS

The Statements of Contribution signed by co-authors can be found in Appendix A.

1. Ahmed, Sayed, Alex Barwick, Paul Butterworth, and Susan Nancarrow. "Footwear and insole design features that reduce neuropathic plantar forefoot ulcer risk in people with diabetes: a systematic literature review." *Journal of foot and ankle research* 13, no. 1 (2020): 1-13.

The candidate (SA) participated during all stages of the development of this paper. SA designed the experiments, collected the data, ran the analyses, and wrote the first draft of the manuscript. All co-authors revised with feedback and approved the final manuscript.

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The candidate (SA) participated during all stages of the development of this paper. SA designed the experiments, collected the data, ran the analyses, and wrote the first draft of the manuscript. All co-authors revised with feedback and approved the final manuscript.

TABLE OF CONTENTS

LIST OF FIGURES

LIST OF TABLES

GLOSSARY OF TERMS AND ABBREVIATIONS

AHPA	Allied health professions Australia
APRB	Australian pedorthists registration board
BMI	Body mass index
CDSD	Clinical decision support database
Consumers	People with diabetic foot complications and receivers of relevant therapies
CVD	Cardiovascular disease
DFA	Diabetes feet Australia
DPN	Diabetes-related peripheral neuropathy
HRFS	High-risk foot services
NADC	National Association of Diabetes Centres
Offloading	Reducing pressure on a particular area by redistributing the pressure below a target threshold.

PAA	Pedorthic association of Australia
Pedorthic footwear	Synonym for "Medical grade footwear". Can be either prefabricated (in that case synonym for "Prefabricated medical grade footwear") or custom-made (in that case, synonym for "Custom-made medical grade footwear").
PPP	Peak plantar pressure
PTI	Pressure time integral
PTS	Plantar tissue stress
PVD	Peripheral vascular disease
RCT	Randomised controlled trial
Standard shoe	Shoes designed for regular comfort and protection but no consideration on therapeutic goals
TCI	Total contact insole

Therapeutic shoe	Shoes designed and constructed to achieve therapeutic goals on top of comfort and protection. May refer to both custom-made or prefabricated medical grade footwear
TMA	Transmetatarsal amputation

CHAPTER 1 | INTRODUCTION

Diabetes is a global epidemic of significant concern impacting population health outcomes and healthcare expenditure. About 9.3% of the global population has diabetes, or approximately 463 million people with this condition (Saeedi et al., 2019). The number of people with diabetes is forecast to increase to 578 million by 2030 (Saeedi et al., 2019) in part due to an increase in population (Sicree & Shaw, 2007) but also an increase in predisposing health conditions (Mokdad et al., 2003).

Diabetes and diabetes-related conditions incur increased costs and the expenses of public health systems. In Australia, the annual cost burden for the disease is $14.6 billion (Diabetes Australia, 2023). . In the United Kingdom, the annual cost estimation is £13.75 billion (Diabetes UK, 2023). Consequently,10% of the NHS budget is spent on diabetes in the UK (McInnes, 2012). In the United States, it is estimated that about 15% of total healthcare costs are spent on providing healthcare to people with diabetes (Bandyk, 2018; van Netten, Lazzarini, et al., 2018).

According to the Australian Bureau of Statistics (ABS) 2017-18 National Health Survey, an estimated 1.2 million Australians were diagnosed with diabetes (Australian Institute of Health & Welfare, 2020). Approximately 280 Australians develop diabetes each day (Diabetes Australia, 2023). In the UK, 2.9 million people have diabetes, and in North America, 11% of the population suffers from diabetes (Bandyk, 2018; Levin & O'Neal, 1988). Diabetes rates are increasing in most regions regardless of socioeconomic status (Liu et al., 2020)

Diabetes can cause a range of chronic micro- and macrovascular complications (Bandyk, 2018). Ischaemic heart disease and stroke are more common in people with diabetes compared to the population who do not have the condition. In the United States of America (USA), diabetes is one of the top three causes of death due to associated cardiovascular disease (Balakumar et al., 2016). Diabetes is one of the main reasons for blindness in adults, and it is estimated that 93 million people worldwide have diabetes-related retinopathy (Ibrahim, 2016). Renal disease is also caused by diabetes, with forty per cent of patients with diabetes requiring dialysis (Alicic et al., 2017). Of importance for this study is that over 30%

of people with diabetes will develop peripheral neuropathy (DPN) (Carls et al., 2011), and the incidence increases with age (Singh et al., 2005; van Schie, 2008). Diabetes-related peripheral neuropathy (DPN) is the central microvascular risk factor for developing plantar foot ulceration. Ischaemia is also another major risk factor for plantar foot ulceration.

Diabetes is one of the main causes of all non-traumatic lower-limb amputations (5). Foot ulceration is commonly seen in people with diabetes. When diabetes-related foot conditions, such as structural deformities, limited joint mobility, neuropathy, and peripheral arterial disease (PAD), are present, the risk of ulceration and potential infection increases (Bandyk, 2018). According to van Netten et al., 2% of all hospitalisation episodes in Australia are due to diabetes-related foot disease (van Netten, Lazzarini et al. 2018). Following the healing of initial ulceration, re-ulceration is very common. As this disease process occurs, the risk of losing the limb increases.

This chapter firstly outlines the background and context for the thesis, including the pathogenesis of diabetic foot disease, particularly plantar forefoot ulceration, the impacts of this ulceration on individuals, the community and the healthcare system, interventions that reduce the risk of plantar forefoot ulceration, therapeutic footwear as a preventative intervention and an overview of current guidance on footwear to prevent diabetic foot ulceration.

Secondly, the chapter outlines the overall aim and specific objectives of the thesis. Then, an overview of each study and how it addresses each respective objective, including research questions, is given before an overview of the structure of the remaining thesis. Finally, the intended outputs, contributions and implications of the research are presented.

1.1 Pathogenesis of diabetes-related foot ulceration

A foot ulcer is a deterioration of the skin and subcutaneous tissues as a result of trauma combined with underlying disease processes. Chronic, non-healing ulcers are characterised by a reduced ability to self-repair (Bandyk, 2018; Levin & O'Neal, 1988). In people with diabetes, several factors contribute to the development and influence the progression of foot ulceration. Predisposing disease states, including PAD, deformity, tissue glycosylation and neuropathy, influence plantar tissue resilience. Deformity and neuropathy increase the trauma

to the tissues in the form of plantar tissue stress. Further, neuropathy results in a lack of sensation and, therefore, protective behaviours.

Plantar tissue stress is a combination of direct plantar pressure and shear stress applied during weight-bearing activities. The total plantar tissue stress also takes into account the amount and type of weight-bearing activity (Lazzarini et al., 2019). Where tissue stress is beyond the resilience of the tissues, injury and ulceration will occur. Diabetes reduces the resilience of tissues with a loss of plantar tissue thickness and nutritional supply to cutaneous structures. Direct pressure applied to the plantar foot has been shown to be increased in people with diabetic neuropathy (Lazzarini et al., 2019; Reiber et al., 1999; Waaijman et al., 2012).

Foot ulcers are often characterised as neuropathic or ischaemic, with the most common ulcers being neuroischaemic, that is, involving both factors. In ischaemic ulcers, the foot suffers from insufficient or no blood circulation, and as a result, the skin becomes very prone to breakage and subsequent ulceration (Oyibo et al., 2001).

Approximately 70% of diabetes-related foot ulcers are neuropathic ulcers (Waaijman et al., 2012). Neuropathic wounds develop following hyperkeratosis development caused by intermittent pressure during walking (Oyibo et al., 2001). Hyperkeratoses further increase pressure under the foot and the subsequent risk of developing an ulcer (Chapman, 2014; Lázaro-Martínez et al., 2014). Neuropathic ulcers are the predominant diabetes-related foot ulcers (Lázaro-Martínez et al., 2014), and common sites (approximately 70%) are in the plantar forefoot region (Waaijman et al., 2012). Hence, this thesis focuses on preventing neuropathic forefoot ulcer occurrence and recurrence in the plantar forefoot region (Chapman, 2014).

1.1.1 Impacts of diabetes-related foot ulceration

The risk of hospitalisation increases significantly when a person develops a diabetic foot ulcer, usually due to infection. Diabetes-related foot ulceration increases treatment-related expenses and diminishes the quality of life (Apelqvist et al., 1995; Singh et al., 2005). Hospitalisation numbers for patients with diabetes-related foot ulcers can go as high as 35 714 per year in the United Kingdom (Phillips et al., 2016). According to a recent systematic review (Zhang et al., 2021), up to 50 000 people are hospitalised in Australia per year due to diabetes-related foot disease. There are also indirect costs associated with diabetes,

including loss of work, depression, and social isolation. Although it is difficult to calculate an exact number, this is likely to be substantial (Williams & Airey, 2000). Foot ulcers are the most expensive conditions to treat compared to any other conditions caused by diabetes.

Foot ulcers are one of the leading precursors to amputation in the lower extremities resulting from critical limb ischaemia or infection (Sicree & Shaw, 2007). Research has shown that nearly 34% of patients with diabetes will develop a foot ulcer in their lifetime (Armstrong et al., 2017). According to a recent study, the USA has the highest rates of lower limb amputation (Akinlotan et al., 2021), and Australia is second (Lazzarini et al., 2012). The lower limb amputation rate among people with diabetes in high-income countries is 12 per 1000 people, whereas the rate is approximately 20 per 1000 people in Australia (Lazzarini et al., 2012).

Based on a review of cost data for diabetic complications, lower-extremity amputation costs were: Au $31 338 (Australia); Au $28 944 (Canada); Au $54 096 (France); Au $37 335 (Germany); Au $17 196 (Italy); and Au $24 986 (Spain) (Ray et al., 2005). In the United States, $116 Billion was spent in 2007 on treating diabetes-related foot ulcers (Driver et al., 2010). This data represents the substantial health care costs related to the treatment of diabetes-related foot complications.

1.1.2 Reducing the risk of diabetes-related foot ulceration

Upstream prevention of foot complications of diabetes includes blood glucose control and lifestyle modification for related risk factors, for example, smoking cessation. By preventing the primary foot risk factors of neuropathy, deformity and PAD foot disease can be avoided.

Common foot-specific interventions to reduce the risk of foot ulceration in people with diabetes include regular screening, foot-specific structured education for the patients to educate on self-care, education for the health professionals, self-management of the foot, treatment of pre-ulcerative or other clinical signs of the foot, offloading interventions and foot function and mobility-related exercises (van Netten et al., 2020).

Foot-specific self-care education may include individual or group sessions on motivational interview, education via video or graphics, animations, and software or quizzes (van Netten et al., 2020). Foot self-management interventions may include a home monitoring system,

telemedicine, lifestyle adaptation, technology intervention, and peer group-supported programmes (van Netten et al., 2020).

Treating the pre-ulcerative or other clinical signs of ulceration risk may include callus removal, protecting from and treating blisters, dry skin and cracks, ingrown toenails and fungal infections (van Netten et al., 2020). Providing first aid to abrasions, cuts, and scratches is also part of this strategy. Evidence shows that removing callus can lower plantar pressures by 24-32% (Pitei et al., 1999), but regular podiatry treatment may not be accessible and affordable for each patient with diabetes (Chapman, 2014). Foot-related exercise may include changing foot-specific function parameters such as foot and ankle joint mobility or muscle strength that may prevent ulceration (van Netten et al., 2020). All preventative strategies for plantar forefoot wounds must consider the offloading of high-pressure areas. The high pressure resulting in ulceration in particular areas of the foot can be redistributed using offloading interventions that aim to prevent or heal foot ulcers or reduce or redistribute plantar foot pressure (Bus et al., 2008).

Footwear and insoles have demonstrated effectiveness at reducing pressure, with up to 50% pressure reduction being achieved through appropriate footwear, which reduces pressure in a targeted area (van Schie et al., 2000). Several studies have explored the efficacy of insoles (Bus et al., 2004; Guldemond et al., 2007; Janisse, 1995; Zequera et al., 2007), with this research showing that insoles can reduce pressure in levels between 20-35% (Guldemond et al., 2007; Lavery et al., 1997). Insoles are not a homogenous intervention; however, they usually require customisation and include various design parameters relevant to the material used, including thickness, softness, the moulding technique employed, and support features, to name a few.

People with diabetes and neuropathy are commonly recommended to wear specialised socks, seamless at the toe area and any other pressure-sensitive sites with an upper edge that does not restrict blood flow. These designs are free of seams, ridges, and holes that could chafe the skin (Bandyk, 2018; Levin & O'Neal, 1988). The socks ideally include enough padding to add cushion to the foot and are custom-fitted to avoid any wrinkles and gathering. Research has shown that socks with extra cushioning can reduce plantar pressure by 10% (Garrow et al., 2005).

1.1.3 Therapeutic footwear to prevent diabetes-related foot ulceration

The goal of footwear to prevent neuropathic foot ulceration is to reduce dorsal pressure, redistribute plantar pressure, and protect the insensate foot from any potential injury or trauma [20]. Some studies have investigated the effectiveness of therapeutic footwear in reducing the risk of initial plantar foot ulceration, and much research has explored the efficacy of therapeutic footwear in terms of offloading and reducing the risk of recurring plantar foot ulcers (Chantelau & Busch, 2003; Lavery et al., 2008; Uccioli et al., 1995).

Cardiovascular disease is prevalent in those with diabetes-related foot ulceration and or amputation (Brownrigg et al., 2012; Tuttolomondo et al., 2015). This is proven to be the primary cause of morbidity and mortality in people with diabetes (Matheus et al., 2013). Exercise and physical activity can reduce the risk of CVD episodes in people with diabetes (Kim et al., 2011). In order to reduce the risk of cardiovascular events, appropriate footwear with the optimum fit and peak pressure reduction capacity plays a vital role in this patient group (Lázaro-Martínez et al., 2014; van Netten et al., 2020).

Up to a 50% peak plantar pressure reduction can be achieved through therapeutic footwear (van Schie et al., 2000). Footwear intervention is not an invasive technique and provides continuous offloading when the patient wears the footwear. Footwear is also a cheaper intervention than surgical interventions and injections. General foot care, such as removing calluses from the plantar foot skin together with offloading methods such as therapeutic footwear interventions, provides improved clinical outcomes (Lázaro-Martínez et al., 2014). Optimisation in footwear specification with the view to reducing foot pressure can reduce foot ulceration risk substantially. The key benefits of optimised footwear include being cost-effective and removing the need for invasive interventions (Chapman, 2014).

Several studies have shown benefits from therapeutic footwear compared to standard footwear in preventing ulcer recurrence. Numerous studies suggest that therapeutic footwear has the benefit and effectiveness over regular footwear, reducing the risk of secondary ulceration (Dargis et al., 1999; Lázaro-Martínez et al., 2014; Litzelman et al., 1997; López-Moral et al., 2019; Uccioli et al., 1995; Zwaferink et al., 2020).

Due to the absence of a standardised approach, the efficacy of therapeutic footwear in ulcer prevention is limited by only a few features of footwear and insole design parameters

(Collings et al., 2021).. Studies (Rizzo et al., 2012; Zwaferink et al., 2020) reported a significant offloading rate using a predefined algorithm in footwear and insole prescription compared to standard footwear. The studies suggest the importance of using well-defined and standardised approaches to preventing foot ulcers using footwear (Rizzo et al., 2012; Zwaferink et al., 2020).

Various therapeutic footwear designs can be effective in offloading high-pressure areas on the foot. 'Rocker' soles are considered to be an effective intervention with custom-designed orthoses (insoles) and additional support such as metatarsal pads and domes. These arch supports can lower peak plantar pressure at the distal locations of the foot between 16% and 52% compared with controls (Beuker et al., 2005; S. A. Bus et al., 2004; Guldemond et al., 2007; Lord & Hosein, 1994; Praet & Louwerens, 2003; Schaff & Cavanagh, 1990; van Schie et al., 2000). Additionally, extra-depth shoes can keep the ulcer-prone area pressure-free and protect the toes (Maciejewski et al., 2004). Footwear and insoles are considered to be important interventions for preventing ulcer occurrence. However, most research has explored the efficacy of shoes and insoles in lowering peak plantar pressure rather than preventing foot ulcer occurrence and recurrence (Lázaro-Martínez et al., 2014).

The variations in the literature on the effect of footwear in preventing ulceration mean that no consensus exists on which footwear features and specifications to recommend to specific patient groups (Cavanagh et al., 2002; Chantelau & Busch, 2003; Praet & Louwerens, 2003; Reiber et al., 2002). However, research shows that dispensing correctly fitted therapeutic footwear to people with diabetes and at risk of foot ulcers is a cost-effective intervention (Tennvall & Apelqvist, 2001); therefore, footwear as an intervention for people with diabetes warrants further research.

1.1.4 Current guidance on footwear therapies for people with diabetes

Dahmen et al. (2001) developed an algorithm for prescribing therapeutic footwear for an insensate foot. This algorithm includes recommendations for the footwear design and manufacturing to be utilised based on the existing medical condition and foot deformities. The medical conditions can be neuropathy, ulceration, or amputation (Dahmen et al., 2001). Insole design, shoe height, sole stiffness, and rocker axis positioning are a few of the parameters for fabricating specialized, therapeutic footwear. For instance, for a person who

has lost a hallux, the algorithm suggests an ankle boot with a rigid sole, proximal rocker axis position, and a custom-made insole to increase propulsion and reduce plantar pressure. Although these step-by-step guidelines exist for prescribing footwear, the algorithm's efficacy has not been tested in cases of ulcer relapse.

The Dahmen algorithm is over two decades old and may not be representative of contemporary manufacturing methods or evidence. Further, it is limited by its lack of involvement of a multidisciplinary team, which is the modern standard of diabetes foot care models (NADC, 2018). Additionally, the consumers of the specialised footwear were not involved in developing the algorithm (Dahmen et al., 2001). Footwear has many psychosocial elements that can not be separated from the biomechanical outcomes in design. The algorithm also specifically reflects the diabetes foot care model of the Netherlands, which is quite different from that undertaken in other high-income countries where this care is funded by health funds and in low-income countries, the care is self-funded, and the foot care is not a priority when compared with other priorities. (ACI, 2013; NHMRC, 2016; Jain & Apoorva, 2021; Parker et al., 2019; van Netten et al., 2017).

The high cost of producing customised orthopaedic footwear means that funding models are an important consideration in the transferability of particular footwear models. For example, assessing and prescribing appropriate footwear and fabricating them requires a series of professional consultation sessions with a referring and prescribing clinician, plantar pressure measurements and analysis (barefoot and ins-shoe), casting or 3D scanning of the foot and individual design or modification for the appropriate footwear and insoles (Arts et al., 2015; Bus, Zwaferink et al., 2020). A large portion of the population with diabetes foot disease comes from low-income households or remains unemployed for a longer period due to the condition (Ahmed M. U. et al., 2022). This is one of the barriers to accessing the therapy and the footwear they need. Hence, the current guidelines recommend access to appropriate funds for an individual with a diabetes foot disease (NADC, 2018; Kaminski et al., 2021).

Another common reference point for therapeutic footwear prescription is the Risk Stratification model proposed by the Australian Diabetic Foot Network (ADFN). This model includes information on various sources of funding available for the prescription and dispensing of diabetic footwear in Australia. The ADFN model, however, does not specify

clinician and manufacturer guidelines about the actual footwear design, construction method, or footwear materials employed (Bergin et al., 2013).

Diabetes Feet Australia (DFA) has published an evidence-based guideline on preventing, identifying, and managing foot complications in diabetes to align with other international and national guidelines from various high-income countries (Kaminski et al., 2022). This guideline includes a section that provides broad recommendations on preventing diabetic foot complications through footwear. However, the guideline does not detail the prescription parameters for diabetic footwear or compare the cost-effectiveness of different approaches. Additionally, a recent survey found some challenges associated with applying such guidelines in podiatry practice to manage diabetes foot disease, such as using non-removable casts in numerous public hospitals and private podiatry clinics (Quinton et al., 2015).

An essential but often overlooked component of the research on diabetic footwear is the amount of time the person spends wearing the shoes. Footwear can only be effective when and if it is worn. Adherence to the prescribed footwear is a substantial obstacle in dispensing therapeutic footwear and should be considered at a prescription level. One older study reported that adherence to the prescribed therapies is generally low in the population with diabetes concerning using the therapeutic footwear prescribed (Knowles & Boulton, 1996). Adherence is dependent on the patient believing in the efficacy of the footwear and the acceptability of the visual appearance of the footwear (Macfarlane & Jensen, 2003; Williams & Nester, 2006). This situation suggests that a more patient-led approach would be more successful. This would involve the patient in footwear selection, enabling individual patients to have some choice in choosing footwear that is appropriate to individual lifestyles and needs. Bus and van Netten (2015) suggested a shift of priorities toward achieving professional and patient adherence to therapies and footwear to prevent ulcer recurrence in people with diabetes in a recent study. This also reflects the more contemporary approaches of user-led design, patient engagement in healthcare and personalised care (Abey et al., 2022; Lazzarini et al., 2019; McNichol, 2012; Thornton et al., 2003).

This research aims to address these gaps by researching to provide guidance and design principles for providing therapeutic footwear (pedorthic footwear) for people with diabetes to prevent neuropathic forefoot plantar ulcers. This research reframes the intervention of footwear for people with diabetes away from just a tool of medical intervention and instead

sees it as an element of multidisciplinary high-risk foot management, a biomechanical intervention, and an item of clothing with sociocultural significance and informed by patient preference. Specifically, this research will identify the value of these approaches in managing the foot at risk.

1.2 Research Aim

This thesis aims to develop a set of design principles for footwear and insole design and modification prescription to prevent and manage neuropathic plantar forefoot ulcers in people with diabetes that takes into account patient preferences and contextual factors.

1.2.1 Research objectives

Three objectives will contribute to the aim

1. Collate and summarise the current literature on the effectiveness of footwear and insoles in reducing peak plantar pressures and preventing diabetes-related neuropathic forefoot ulceration.

2. a) Explore the population of patients who use pedorthic services

2. b) Explore current pedorthic practices in footwear prescription and manufacture

3. Examine footwear, the influence of features on plantar pressure, patient satisfaction, and adherence

1.3 Research design

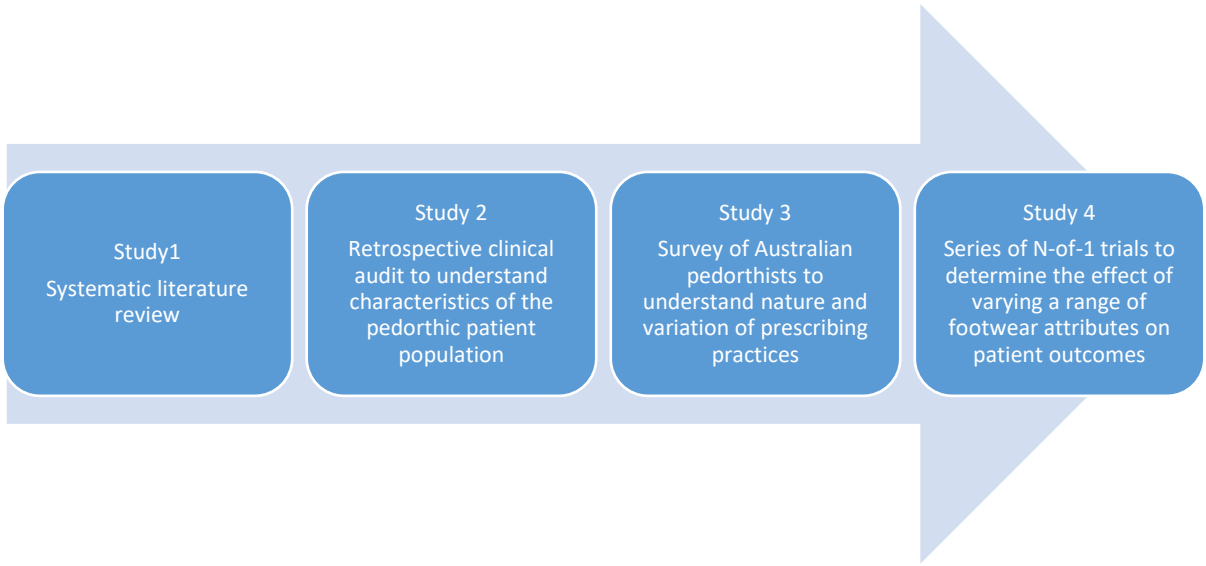
This research used four separate studies to address each aim: a systematic literature review, a retrospective clinical audit, a survey of Australian pedorthists, and a series of N-of-1 trials, each of which is outlined below. Each study drew on evidence from the previous sequential study to help develop evidence to help underpin the development of a set of design principles for footwear and insole design and modification to prevent diabetes-related neuropathic ulceration at the plantar forefoot.

The lack of evidence from the pedorthic profession in Australia (or generally) meant that Studies 2 and 3, which are largely descriptive, were required to help understand the nature of

the pedorthists' patient population and prescribing practices. This information was then used to develop the series of N-of-1 trials in study 4.

Figure 1.1

Research Design



1.3.1 Study 1: Systematic literature review

A systematic literature review was undertaken to summarise and evaluate the evidence for footwear and insole features that reduce pathological plantar pressures and the occurrence of diabetic neuropathy ulceration at the plantar forefoot in people with diabetic neuropathy. It identifies evidence and gaps in current research. The evidence found was used to inform the development of patient case studies for study three. Gaps identified in knowledge were used to inform the series of N-of-1 trials.

Literature review research questions:

What are the referral and prescription parameters for footwear design for effective offloading of the foot to prevent the occurrence and recurrence of neuropathic plantar forefoot ulcers in people with diabetes?

What are the parameters that influence adherence to using the therapeutic footwear by the patient?

1.3.2 Study 2: Retrospective clinical audit

A retrospective clinical audit of a full twelve months of clinical records from a single Pedorthic practice (n=420) identified 70 patients with diabetes who attended for the provision of appropriate footwear and insoles to prevent neuropathic forefoot plantar ulcer occurrence and recurrence. These records were further interrogated to address the following research question:

What are the sociodemographic, foot pathology and comorbidity characteristics of individuals who present to pedorthic services for footwear intervention to prevent diabetes-related neuropathic plantar forefoot ulceration?

This study provided insights into the population of interest in this thesis and was used to inform the development of patient case studies to help understand pedorthists' prescribing practices.

1.3.3 Study 3: Australian pedorthists' survey

All pedorthists (n=43) registered with the Australian Pedorthists Registration Board (APRB) and practising in Australia were invited to participate in an online survey to explore their prescribing practices. The survey provided a set of four individual hypothesised case studies of patients at risk of diabetic forefoot neuropathic ulceration which was based on the clinical audit from Study 2 and the systematic literature review (Study 1) (Ahmed et al.,2020). Pedorthists were asked to describe their prescribing approach for each case study. This was to address the research questions:

What are the common practices for prescribing footwear and insole to prevent neuropathic plantar forefoot ulceration in people with diabetes?

What factors influence adherence in these populations, and what strategies do pedorthists follow to improve adherence?

This study's outcomes were used to ensure the clinical and user relevance of the set of design principles and to help guide the parameters examined in the series of N-of-1 trials (Study-4).

1.3.4 Study 4: A series of single-patient or N-of-1 trials

In recognition of the large number of variables to be considered in the development of a footwear-based intervention for people with diabetes, it was not possible, appropriate, or ethical to consider a 'standardised' approach to the prescription of footwear for people with diabetes. The outcomes of the three studies above and the person-centred focus of this research reinforced the need for a highly individualized footwear intervention that can be tailored to the specific individual needs, preferences, personal context, budget and social circumstances of each patient.

Therefore the most appropriate approach was considered to be a series of N-of-1 clinical trials to determine useful footwear prescription parameters to achieve a target reduction of plantar pressure from baseline pressure data at the forefoot in patients with diabetes and neuropathy. The target was determined in line with the needs and foot pathology of the patient. An in-shoe pressure analysis system was used to measure the efficacy of footwear design or modification to achieve the targeted plantar pressure reduction (Arts et al., 2015). Factors influencing adherence were also explored.

1.4 Design principles

The intended outcome of the thesis is a set of design principles that can be used to guide the prescribing of appropriate (custom-made or prefabricated) medical-grade footwear and insole design and modifications, personalised to an individual's pathologies, comorbidities, and lifestyle in patients with diabetes, neuropathy and at risk of plantar forefoot ulceration.

Based on the current literature as outlined in 1.1, goals for treatment should consider four domains, outlined below: the aims for the N-of-1 trials and the set of design principles.

a. Protect the foot from injury and cause no further injury to the foot: Diabetes feet are prone to ulceration with external trauma and internal shear from inappropriate footwear, and the risk increases when neuropathy presents (Armstrong & Lavery, 1998). Appropriate footwear and insole can reduce these risk factors in those populations (Clayton & Elasy, 2009).

b. Reduce peak plantar pressure to reduce risk factors for ulcer recurrence: Peak plantar pressure is one of the major risk factors for ulcer occurrence and recurrence in diabetes feet (Owings et al., 2009). Hence, reducing the peak plantar pressure below the risk threshold is one of the key strategies for reducing foot ulceration risk (Arts et al., 2012; Bus, Armstrong, et al., 2016; Bus, Van Deursen, et al., 2016; Jorgetto et al., 2019).
c. Ensure that balance and mobility are not compromised: Reduced balance and mobility are commonly seen in people with diabetes, and the incidence increases with the presence of neuropathy (Hewston & Deshpande, 2016). Several strategies are applied to improve balance and mobility in these populations, including exercise (Allet et al., 2010; Hijmans et al., 2007; Paton et al., 2013).
d. Optimise patient satisfaction and adherence to therapy: Patient satisfaction and adherence are key to the success of offloading strategies (Bus & van Netten, 2015) (Paton et al., 2014). This requires a clear understanding of the patient's goals, aesthetic requirements, socioeconomic perspective and patient education (Paton et al., 2014; Waaijman et al., 2013).

The set of design principles is expected to guide the prescription and manufacturing or modification of footwear and insoles to ensure adequate and effective offloading at the forefoot to prevent the occurrence and recurrence of plantar forefoot neuropathic ulcers in patients with diabetes. The desired offloading threshold should be >30% reduction in dynamic in-shoe plantar pressure from the baseline or <200 kPa to ensure ulcer-free survival at the forefoot (Bus et al., 2020).

1.5 Structure of the thesis

There are eight chapters and eight appendices in this thesis.

Chapter 1: Introduction. This chapter provides the background information, current knowledge and what is unknown, the rationale of this research and a brief outline of each study conducted.

Chapter 2: Systematic literature review (Study 1). This chapter provides information on the systematic literature review and the findings, the gap in the literature and future research recommendations.

Chapter 3: Methodology. This chapter provides brief information on the methodology followed in the thesis for each study.
Chapter 4: Methods, results, discussion and conclusions of Study 2. This chapter describes the methods and presents the results from Study 2 (retrospective clinical audit). Then it discusses these results in context.
Chapter 5: Methods, results, discussion and conclusions of Study 3. This chapter provides information on the common practice of Australian pedorthists when they prescribe footwear and insole design and modification to prevent diabetes-related neuropathic plantar forefoot ulcer occurrence and recurrence.
Chapter 6: Methods, results, discussion and conclusions of Study 4. This chapter provides information on the series of N-of-1 trials that explored footwear and insole design features that influence plantar pressure reduction and patient adherence.
Chapter 7: Discussion of the thesis and the resulting set of design principles for footwear and insole design prescriptions for people with diabetes and neuropathy
Chapter 8: Conclusion of the thesis. This chapter presents the conclusion of the studies carried out as part of the thesis.

1.6 Contributions of the research

This research will make several contributions. Understanding the complex evidence around footwear as an intervention for the prevention of diabetes-related foot ulceration and amputation: This study (Study 1) (Ahmed et al., 2020) aims to explore various design and modifications features of footwear and insoles to offload the peak plantar pressure (PPP) at the plantar forefoot and what factors influence the adherence to them by the people with diabetes and neuropathy.

The role of the pedorthists in the Australian health care system for high-risk foot management. This study (Study 3) aims to provide evidence around the scope of practice for pedorthists in the interdisciplinary high-risk foot care team.

A tailored set of design principles for footwear and insole interventions in people with diabetes and neuropathy: This study (Study 4) aims to help the development of a tailored set of design principles that incorporates the individual needs of patients with diabetes-related foot complications while delivering the best evidence-based care to support those needs.

Policy improvement for clinical practice and health fund guidance. This research outcome aims to improve the policies around high-risk clinical practice for footwear and insole prescription and improve patient adherence. This also aims to help health funds make informed decisions for the funding of footwear and insoles in the target population.

Optimisation of foot care service models. This research aims to help optimise health services and scale up models to serve many more people who need high-risk foot care services in long-term offloading.

CHAPTER 2 | Footwear and insole design features that reduce neuropathic plantar forefoot ulcer risk in people with diabetes: a systematic literature review

This chapter is an amended* version of the following published peer-reviewed manuscript:

Ahmed S, Barwick A, Butterworth P, Nancarrow S. (2020). Footwear and insole design features that reduce neuropathic plantar forefoot ulcer risk in people with diabetes: A systematic literature review. *Journal of Foot and Ankle Research 13*(1).

**These amendments only relate to spelling or grammatical errors that have been identified since publication. No changes to methodology, results or findings have been made.*

Abstract

Background: In people with diabetes, offloading high-risk foot regions by optimising footwear or insoles may prevent ulceration. This systematic review aimed to summarise and evaluate the evidence for footwear and insole features that reduce pathological plantar pressures and the occurrence of diabetic neuropathy ulceration at the plantar forefoot in people with diabetic neuropathy.

Methods: Six electronic databases (Medline, Cinahl, Amed, Proquest, Scopus, Academic Search Premier) were searched in July 2019. The search period was from 1987 to July 2019. Articles in English using footwear or insoles as interventions in patients with diabetic neuropathy were reviewed. Any study design was eligible for inclusion except systematic literature reviews and case reports. Search terms were diabetic foot, physiopathology, foot deformities, neuropath*, footwear, orthoses, shoe, footwear prescription, insole, sock*, ulcer prevention, offloading, foot ulcer, plantar pressure.

Results: Twenty-five studies were reviewed. The included articles used repeated measure (n = 12), case-control (n = 3), prospective cohort (n = 2), randomised crossover (n = 1), and randomised controlled trial (RCT) (n = 7) designs. This involved a total of 2063 participants. Eleven studies investigated footwear, and fourteen studies investigated insoles as an intervention. Six studies investigated ulcer recurrence; no study investigated the first

occurrence of ulceration. The most commonly examined outcome measures were peak plantar pressure, pressure-time integral and total contact area. Methodological quality varied. Strong evidence existed for rocker soles to reduce peak plantar pressure. Moderate evidence existed for custom insoles to offload forefoot plantar pressure. There was weak evidence that the insole contact area influenced plantar pressure.

Conclusion: Rocker soles, custom-made insoles with metatarsal additions and a high degree of contact between the insole and foot reduce plantar pressures in a manner that may reduce ulcer occurrence. Most studies rely on reduction in plantar pressure measures as an outcome rather than the occurrence of ulceration. There is limited evidence to inform footwear and insole interventions and prescriptions in this population. Further high-quality studies in this field are required.

Keywords

Diabetic foot, Footwear, Insoles, Plantar pressure

2.1 Background

Foot ulcers are a common consequence of diabetes due to the development of peripheral neuropathy, peripheral vascular disease, limited joint mobility and foot deformity (Boulton et al., 2005; Ghanassia et al., 2008; Molines-Barroso et al., 2013; Peters et al., 2007; Pound et al., 2005; Waaijman et al., 2014). Nearly 34% of persons with diabetes will develop a foot ulcer in their lifetime (Armstrong et al., 2017). This can lead to infection and amputation; diabetes is the main reason for non-traumatic lower limb amputation (Lazzarini et al., 2015; Levin & O'Neal, 1988). Previous foot ulcer or amputation is a risk of future amputation (Boulton et al., 2005; Cavanagh et al., 2002; Ghanassia et al., 2008; Pound et al., 2005). Additional risk factors include higher Body Mass Index (BMI), and structural foot deformities (Ghanassia et al., 2008; Molines-Barroso et al., 2013; Peters et al., 2007; Waaijman et al., 2014), such as hammertoes and hallux valgus (Bus, 2008; Lázaro-Martínez et al., 2014).

Diabetic peripheral neuropathy (DPN) is the central risk factor for the development of plantar foot ulceration (Reiber et al., 1999). Over 30% of persons with diabetes will develop DPN (Carls et al., 2011), and the incidence increases with age (Singh et al., 2005; van Schie,

2008). DPN can affect the autonomic, sensory and motor nervous systems. Sensory neuropathy interrupts the protective feedback mechanism of touch and pain (Hidmark et al., 2014). Motor neuropathy results in compromised muscle innervation, reduction in strength, and, combined with limited joint mobility, the development of foot deformities. These deformities may lead to an increase in plantar foot pressures, particularly in the forefoot (Fernando et al., 2013; Guiotto et al., 2013; Ko et al., 2011; Sawacha et al., 2012). Autonomic neuropathy leads to diminished sweating and changes to skin perfusion, leading to dry skin and hyperkeratosis. As skin integrity is compromised, patients are more susceptible to trauma, which may precipitate a diabetic foot ulcer (Chao et al., 2011; Chen et al., 2010; Guiotto et al., 2013; Pai & Ledoux, 2010).

Neuropathic ulcers in diabetic feet occur mostly at the plantar forefoot (Chapman, 2014; Lázaro-Martínez et al., 2014; van Netten, van Baal et al., 2018) and correspond to areas of peak plantar pressure (Cavanagh & Ulbrecht, 1994). Bennetts et al. (2013) demonstrated that most peak pressure areas are located in the forefoot regions in this population. A limited range of motion at the forefoot joints is also likely to contribute to the peak plantar pressures (PPP) observed in this region (Rao et al. 2010). For this reason, plantar pressure mapping is used to guide footwear and insole manufacture and judge their effectiveness (Bus et al.,2011).

Reducing plantar pressures is considered a key factor for wound healing and prevention of ulcer recurrence (Bus, 2012; Jeffcoate & Harding, 2003). Footwear and insoles are an essential treatment modality for offloading these pressures (Collings et al., 2017; van Netten, Lazzarini, et al., 2018). The desired offloading threshold should be >30% reduction in dynamic in-shoe plantar pressure from the baseline or <200 kPa to ensure ulcer-free survival at the forefoot (Bus et al., 2020). This systematic review aimed to summarise and evaluate the evidence for footwear and insole features that reduce pathological plantar pressures and the occurrence of diabetic neuropathy ulceration at the plantar forefoot in people with diabetic neuropathy.

2.2 Methods

The systematic search was performed according to the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) Statement (Moher et al., 2009).

Search strategy

In July 2019, six electronic databases were searched (Medline, Cinahl, Amed, Proquest, Scopus, Academic Search Premier) using medical subject headings followed by a keyword subject heading. The search period was from 1987 to July 2019. The search terms can be seen in Figure 2.1 and Supplementary file 1.

Eligibility criteria

All studies included in the systematic review were obtained from full-text peer-reviewed journals published in English. Studies that did not use footwear or insole as a mode of intervention for long-term offloading were excluded. Letters to the editor, opinion pieces, conference proceedings, and editorials were also excluded. All study designs except systematic reviews and case reports were eligible for inclusion. The titles and abstracts of the articles were screened by one reviewer (SA). Full-text articles were reviewed based on the following criteria: i, participants adults (>18 years), and had diabetes; ii, all or some of the participants had neuropathy and foot deformity, history of plantar forefoot ulcers but no Charcot foot, history of heel ulcer or active foot ulcers; iii, studies used footwear or insoles as a long-term offloading intervention; iv, the outcome of the study was either (re)occurrence of forefoot ulcer or change in forefoot plantar pressure outcomes; v, the footwear or insole interventions had to be sufficiently described to be able to draw useful conclusions; vi, conventional materials and manufacturing techniques were used; and vii, closed-in footwear was used. The reference lists of studies obtained through the database search were also searched to identify relevant citations.

Quality assessment

Quality assessment was performed independently by two reviewers (SA and AB). The quality assessment form was adapted from the McMaster Critical Review Form – Quantitative Studies (Law et al., 1998).

2.3 Results

The literature search identified 1787 articles. Twenty-five articles met the eligibility criteria to be included in the review (Figure 2.1). The study designs included repeated measures (n = 12), case-control (n = 3), prospective cohort (n = 2), randomised crossover (n = 1), and RCT (n = 7) studies.

Study characteristics are shown in Tables 2.1 and 2.2.

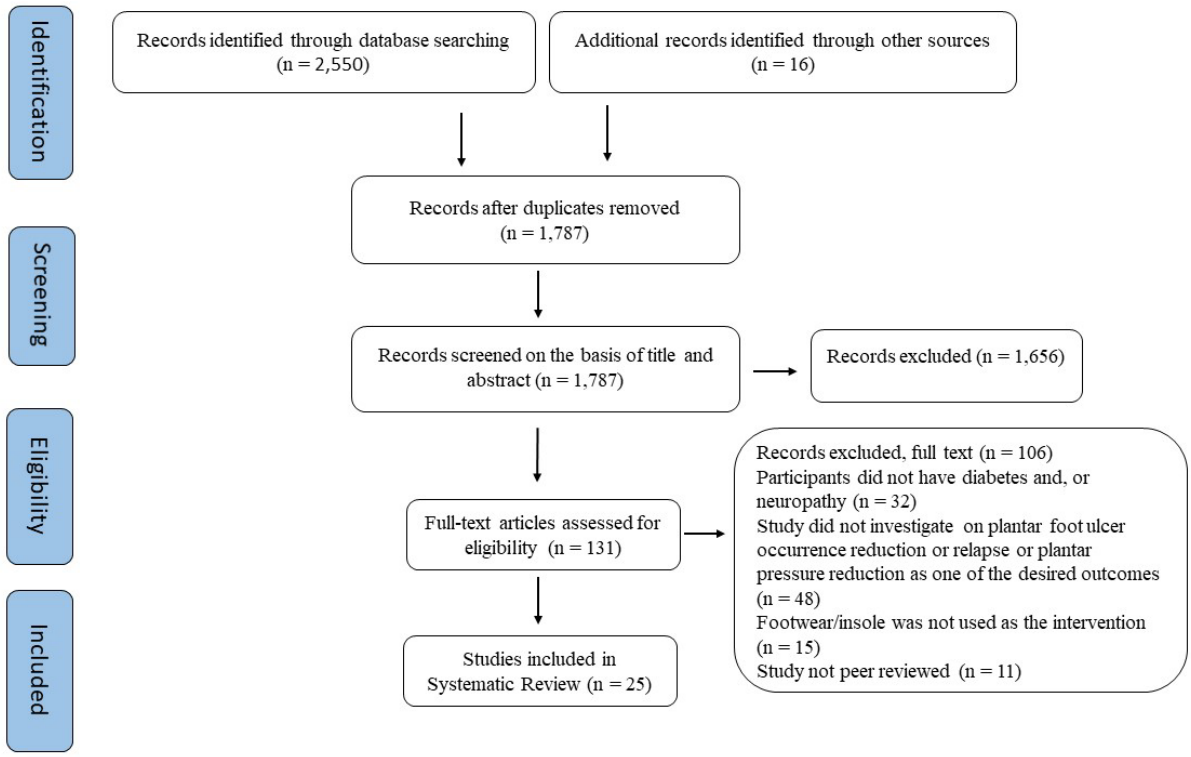
Figure 2.1

Database search terms

	Explode	**Explode**	**Explode**
Or			
	diabetic foot	footwear/orthoses	ulcer prevention
	physiopathology	shoe	offloading
	foot deformities	footwear prescription	foot ulcer
	neuropath*	insole	plantar pressure
		sock*	
	And →		

Figure 2.2

PRISMA Study Selection Flow Diagram



Participants and settings

The participants were over 18 years of age, and the sample sizes ranged from 10 to 299. All participants in treatment groups had diabetes, and the majority had neuropathy. Participants had active or healed plantar foot ulcers, amputation, foot deformities, increased barefoot plantar pressure, or peripheral vascular disease. Most (88%) of the studies recruited participants from developed countries within high-risk foot clinics and 12% from developing countries (Department of Economic and Social Affairs of the United Nations Secretariat, 2014). Study duration ranged from a single session to five years.

Table 2.1

Characteristics of the selected studies that used pressure reduction as the primary outcome measure

Author, date	Location	Study design	Follow up period	Sample size	Sample characteristic	Intervention & Comparison	Outcome measures	Result
Arts et al. 2012 (Arts et al., 2012)	Netherlands	Repeated measures	Same day	171 (336 feet)	Diabetic neuropathy Previous plantar ulcer	Custom-made footwear Semi-customised footwear Barefoot	Peak plantar pressure (PPP) of <200kPa considered successful	Custom-made footwear is least effective in pressure reduction (<200 kPa) at the forefoot compared to midfoot and known ulcer locations (29% vs 81% and 62%)
Arts et al. 2015 (Arts, de Haart, et al., 2015)	Netherlands	Repeated measures	Same day	85	Diabetic neuropathy Previous plantar foot ulcer	Various footwear modifications to custom or semi-custom footwear Footwear before modification	% plantar pressure reduction	MP, local cushion and plastazote top cover reduce PP respectively by15.9%, 15%, 14.2% and combinedly 24% and 22% at the forefoot.
Bus et al. 2011 (S. A. Bus, R. Haspels, & T. E. Busch-Westbroek, 2011)	Netherlands	Repeated measures	Not reported	23	Diabetic Neuropathy, Foot deformity Foot ulcer	Fully custom-made footwear and insoles	In-shoe plantar pressure reduction by more than 25% (Criteria A) or below the absolute value of 200 kPa (Criteria B)	MB or MP, replacing the top cover, early rocker can reduce pressure at hallux and metatarsal area ranging from 10.1% to18.6% as an individual modification.

Table 2.1

Characteristics of the selected studies that used pressure reduction as the primary outcome measure (continued)

Author, date	Location	Study design	Follow up period	Sample size	Sample characteristic	Intervention & Comparison	Outcome measures	Result
Bus et al. 2004 (S. A. Bus et al., 2004)	Netherlands	Repeated measure	Not reported	20	Diabetic Neuropathy, History of healed plantar foot ulcers Foot deformity	Insoles; 9.5mm thick flat PPT insole and custom-made insoles out of open-cell urethane foams of hardness 60-80. Custom-made insoles were made by CADCAM process.	Plantar pressure reduction FTI	Custom-made insoles reduce plantar pressure and FTI significantly at medial and lateral heal, MTH1 and FTI at lateral MTHs when compared with flat PPT insoles.
Charanya et al. 2004 (Charanya, Patil, Narayanamurthy, Parivalavan, & Visvanathan, 2004)	India	Case-control study	Six months	25	Diabetic Neuropathy History of active and healed plantar ulcers Non-diabetic (Control)	Footwear with an insole made of 12 mm MCR, shore value 20º, Toughened rocker profile rubber outsole	Foot sole hardness reduced close to normal, shore value 20º	Plantar ulcers healed in three-four weeks, foot sole skin hardness reduced to 25-30 from 45 to 50 shore values.
Guldemond et al. 2007 (Donaghue et al., 1996; Guldemond et al., 2007)	Netherlands	Repeated measures	Not reported	17	Diabetic Neuropathy Higher barefoot plantar pressure (≥700 kPa)	Insole with various height arch supports and with and without a metatarsal dome	In-shoe plantar pressure reduction (36 % & 39%), Walking convenience on a 10-point rating scale	Extra arch support and MD are respectively effective in 39% & 36% pressure reduction in central and medial regions of the forefoot

Table 2.1

Characteristics of the selected studies that used pressure reduction as the primary outcome measure (continued)

Author, date	Location	Study design	Follow up period	Sample size	Sample characteristic	Intervention & Comparison	Outcome measures	Result
Hastings et al. 2007 (Hastings et al., 2007)	USA	Repeated measure	Twenty-two months	20	Diabetic Neuropathy History of plantar foot ulcers No active foot ulcers No Charcot neuropathy	Three footwear conditions; extra depth footwear with 1) Total Contact Insoles (TCI), 2) TCI with proximal Metatarsal Pad (MP), 3) TCI with distal MP, CT Scan	PPP CT Scan for positioning of MP against MTHs	Highest (57%) PPP reduction occurred at 2nd MTH when MP placed at 10.6 mm proximal to MTH line. Variable PPP under the 2nd MTH varied between 32±16% when positioning of MP varies between 6.1 mm to 10.6 mm proximal to MTH line.
Lin et al. 2013 (Tung-Liang et al., 2013)	China	Repeated measure	Not reported	26	Diabetic Neuropathy	Insole with pre-plug removal, post-plug removal, and post-plug removal + arch support	Mean peak pressure (MPP), maximum force, contact area	Removing insole plug is effective in offloading MPP by 32.3% and adding arch support reduces further 9.5% at the forefoot
Lott et al. 2006 (Lott, Hastings, Commean, Smith, & Mueller, 2007)	USA	Repeated measure	Not reported	20	Diabetic Neuropathy History of midfoot or forefoot plantar ulcers	Four different conditions; 1) Barefoot, 2) Footwear, 3) Footwear + TCI, 4) Footwear + TCI + MP	Plantar pressure reduction Soft tissue thickness (STT)	PP & ST strain under 2nd MTH are highest at the barefoot condition and lowest at footwear + TCI + MP condition. Mean PP for all four conditions under 2nd MTH is 272 kPa, 173 kPa, 140 kPa and 98 kPa.

Table 2.1

Characteristics of the selected studies that used pressure reduction as the primary outcome measure (Continued)

Author, date	Location	Study design	Follow up period	Sample size	Sample characteristic	Intervention & Comparison	Outcome measures	Result
Martinez-Santos et al. 2019 (Martinez-Santos, Preece, & Nester, 2019)	UK	Repeated measure	Not reported	60	Diabetic Neuropathy No previous ulcers	Insole with three different metatarsal bar (MB) positioning, two different types of materials	PPP	Maximum pressure reduction can be achieved by positioning metatarsal bar at 72% length of insole, irrespective of material type
Mueller et al. 2006 (Mueller et al., 2006)	USA	Repeated measure	Not reported	20	Diabetic Neuropathy history of plantar ulcers	Three footwear conditions: 1) Footwear, 2) Footwear with TCI, and 3) Footwear with TCI + MP	PPP PTI STT	TCI and metatarsal pad caused reductions of pressure under the metatarsal heads
Owings et al. 2008 (T. M. Owings, Woerner, Frampton, Cavanagh, & Botek, 2008)	USA	Repeated measure	Not reported	20	Diabetic Neuropathy Higher (>750 kPa) barefoot plantar pressure at MTH region	Three different type custom-made insoles (X, Y from shape-based and Z combined foot shape with plantar pressure data). Footwear with rigid rocker sole and flexible sole	Peak pressure FTI	Shape and pressure-based insoles (Z) showed improved offloading by 32 and 21%, PTI reduction 40 and 34% when compared to shape-only-based insoles (X-Polypropylene base, Y- EVA base). A similar trend was observed in flexible and rocker bottom shoes for the same insoles.

Table 2.1

Characteristics of the selected studies that used pressure reduction as the primary outcome measure (Continued)

Author, date	Location	Study design	Follow up period	Sample size	Sample characteristic	Intervention & Comparison	Outcome measures	Result
Paton et al. 2012 (Paton, Stenhouse, Bruce, Zahra, & Jones, 2012)	UK	RCT	18 months	119	Neuropathic diabetic foot ulceration	Prefabricated and custom-made insole	In-shoe pressure reduction, PTI, forefoot rate of load, total contact area	Prefab versus custom insoles, PPP≥6%,
Praet et al. 2003 (Praet & Louwerens, 2003)	Netherlands	Repeated measure	Not reported	10	Diabetic Neuropathy No active ulcer, No major foot deformities	Three different types of footwear designs	Peak pressure reduction at multiple areas under the foot	Rocker sole can offload the forefoot area by 65%
Preece et al. 2017 (Preece, Chapman, Braunstein, Brüggemann, & Nester, 2017)	UK	Case-control	Not reported	168	Diabetic Neuropathy (n=17) Healthy control (N=66)	Eight types of rocker sole design	Pressure reduction threshold of ≤200 kPa	Rocker apex position at 52%, 20º rocker angle, 95º apex angle yields effective offloading at most

Table 2.1

Characteristics of the selected studies that used pressure reduction as the primary outcome measure (Continued)

Author, date	Location	Study design	Follow up period	Sample size	Sample characteristic	Intervention & Comparison	Outcome measures	Result
Tang et al. 2014 (Hellstrand Tang et al., 2014)	Sweden	RCT	Two years	114	Diabetic neuropathy Angiopathy Foot deformities Previous ulcers or amputation	Three types of insoles, custom made (35 & 55º shore hardness EVA) vs prefab insoles with hardcore EVA + soft microfiber top cover (Control)	PPP PTI	The overall PPP for the insoles was between 180 kPa to 211 kPa, PTI differences 14 kPa/sec & 20 kPa/sec with Control.
Teffler et al. 2017 (Telfer, Woodburn, Collier, & Cavanagh, 2017)	UK	Random-ised crossover	Not reported	20	Diabetic neuropathy Increased forefoot plantar pressure No Charcot foot or partial amputation	Three types of insoles 1) Standard (Shape-based), milled insoles, 2) Milled, virtually optimised insoles and 3) 3D printed virtually optimised insoles	PPP	Virtually optimised insole reduced PPP by a mean of 41.3 kPa for milled and 40.5 kPa for 3D printed insoles in the same participants' group.
Tsung et al. 2004 (Tsung, Zhang, Mak, & Wong, 2004)	China	Case-control	Not reported	14	Diabetic neuropathy No Charcot foot or partial amputation Control: no foot deformity	Five support conditions including footwear-only, flat insoles; and three custom-made insoles with three weight-bearing conditions; 1) Full weight-bearing (FWB), 2) Semi-weight-bearing (SWB) and 3) Non-weight-bearing (NWB)	MPP PTI Mean contact area	For 2-3 MTH regions, SWB insoles yield maximum offloading comparing to two other insoles type. For MTH1, NWB insoles provide maximum offloading. FWB insoles show maximum PTI comparing to NWB & SWB conditions. NWB insoles provide maximum arch support and contoured shaped insoles.

Intervention

Eleven studies (Arts et al., 2015; Arts et al., 2012; Bus et al., 2011; Bus et al., 2013; Busch & Chantelau, 2003; Chantelau & Busch, 2003; Chantelau et al., 1990; López-Moral et al., 2019; Praet & Louwerens, 2003; Preece et al., 2017; Rizzo et al., 2012) used footwear and insoles as the intervention. Of these, three studies (Arts et al., 2012; Bus et al., 2013; Rizzo et al., 2012) used footwear that was manufactured according to a consensus-based algorithm proposed by Dahmen et al. (2001). One study (Preece et al., 2017) specifically examined footwear rocker sole profiles. High footwear upper design feature was investigated by one study (Praet & Louwerens, 2003), and it reported that higher upper increased contact area but did not improve pressure reduction at the forefoot area.

Fourteen studies (Arts et al., 2015; Arts et al., 2012; Bus et al., 2011; Bus et al., 2004; Chantelau et al., 1990; Guldemond et al., 2007; Hastings et al., 2007; Hellstrand Tang et al., 2014; Lott et al., 2007; Mueller et al., 2006; Owings et al., 2008; Praet & Louwerens, 2003; Rizzo et al., 2012; Ulbrecht et al., 2014) reported on the prescribers, manufacturers and modifiers of the therapeutic footwear and insoles. The footwear prescribers reported in the studies were rehabilitation physicians (Arts et al., 2012; Bus et al., 2011), diabetologist, podologist (Rizzo et al., 2012), podiatric physician (Owings et al., 2008). The manufacturers of therapeutic footwear were orthopedic shoe technicians (Arts et al., 2015; Arts et al., 2012; Bus et al., 2011; Praet & Louwerens, 2003; Rizzo et al., 2012), and orthopedic shoemakers (Bus et al., 2004; Chantelau et al., 1990; Guldemond et al., 2007), where orthopedic shoe technicians have similar training like certified pedorthists (Bus et al., 2011). Reported insole manufacturers or modifiers were orthotic technicians (Hellstrand Tang et al., 2014), pedorthist (Hastings et al., 2007; Owings et al., 2008), pedorthist or orthotist (Lott et al., 2007; Mueller et al., 2006; Owings et al., 2008; Ulbrecht et al., 2014).

Fourteen studies (Bus et al., 2004; Guldemond et al., 2007; Hastings et al., 2007; Lavery et al., 2012; Lin et al., 2013; Lott et al., 2007; Martinez-Santos et al., 2019; Mueller et al., 2006; Owings et al., 2008; Paton et al., 2012; Tang et al., 2014; Telfer et al., 2017; Tsung et al., 2004; Ulbrecht et al., 2014) used insoles as a primary intervention in standardised or participant's footwear. All studies reported on the type of footwear they used with varying descriptions of the design features, and almost all studies reported on the description of insole design features used by the studies, respectively, except Preece et al. (2017). Studies that are

focused on the insole as a primary intervention have used prefabricated extra-depth footwear or regular retail footwear (Bus et al., 2004; Guldemond et al., 2007; Hastings et al., 2007; Hellstrand Tang et al., 2014; Lott et al., 2007; Martinez-Santos et al., 2019; Mueller et al., 2006; Owings et al., 2008; Paton et al., 2012; Telfer et al., 2017; Tsung et al., 2004; Tung-Liang et al., 2013; Ulbrecht et al., 2014).

Insole features have been described by some studies (Arts et al., 2015; Busch & Chantelau, 2003; Chantelau & Busch, 2003; Charanya et al., 2004; Hellstrand Tang et al., 2014; Lavery et al., 2012; Lin et al., 2013; López-Moral et al., 2019; Martinez-Santos et al., 2019; Owings et al., 2008; Paton et al., 2012; Tang et al., 2014; Telfer et al., 2017; Tung-Liang et al., 2013; Ulbrecht et al., 2014) such as base, mid-layer, and top cover materials. The same authors also assessed hardness, thickness, casting and manufacturing technique, metatarsal dome or metatarsal bar, and arch support. Ten studies (Bus et al., 2004; Busch & Chantelau, 2003; Charanya et al., 2004; Guldemond et al., 2007; Lavery et al., 2012; Lin et al., 2013; Martinez-Santos et al., 2019; Mueller et al., 2006; Tang et al., 2014; Tsung et al., 2004) examined insole material thickness and hardness. Other components of insole configurations reported were application of metatarsal pad, metatarsal dome, or metatarsal bar (Arts et al., 2015; Bus et al., 2011; Bus et al., 2004; Bus et al., 2013; Guldemond et al., 2007; Hastings et al., 2007; Lott et al., 2007; Martinez-Santos et al., 2019; Mueller et al., 2006; Rizzo et al., 2012; Tang et al., 2014) and their positioning (Guldemond et al., 2007; Hastings et al., 2007; Lott et al., 2007; Martinez-Santos et al., 2019; Mueller et al., 2006; Tang et al., 2014), arch support (Arts et al., 2015; Bus et al., 2011; Bus et al., 2004; Bus et al., 2013; Guldemond et al., 2007; Praet & Louwerens, 2003; Rizzo et al., 2012; Tang et al., 2014; Tsung et al., 2004), top cover (Arts et al., 2015; Bus et al., 2011; Bus et al., 2013; Busch & Chantelau, 2003; Guldemond et al., 2007; Lavery et al., 2012; Lin et al., 2013; Owings et al., 2008; Paton et al., 2012; Praet & Louwerens, 2003; Rizzo et al., 2012; Tang et al., 2014; Telfer et al., 2017; Tsung et al., 2004; Ulbrecht et al., 2014), adding local cushion to insole (Arts et al., 2015; Bus et al., 2013; Owings et al., 2008; Rizzo et al., 2012; Ulbrecht et al., 2014). The size of the metatarsal dome or pad used by the studies is between 5 to 11 mm (Guldemond et al., 2007; Hastings et al., 2007; Martinez-Santos et al., 2019) in height, 66 to 74 mm in length, and 51 to 63 mm width (Hastings et al., 2007). The positioning of the metatarsal dome, bar or pad was between 5 to 10.6 mm proximal to MTHs (Guldemond et al., 2007; Hastings et al., 2007; Lott et al., 2007) and at a line of 77% of PPP (Martinez-Santos et al., 2019). The size of the extra arch

support was 5 mm thick Lunalastic (NORA Freudenberg GmbH, Weinheim, Germany) in addition to the arch support resulting from the casting technique (Guldemond et al., 2007). Casting techniques for custom-insoles making, insole design, and manufacturing processes also have been reported by some studies (Bus et al., 2004; Martinez-Santos et al., 2019; Owings et al., 2008; Telfer et al., 2017; Tsung et al., 2004; Ulbrecht et al., 2014).

Outcome measures

Eighteen studies (Arts et al., 2015; Arts et al., 2012; Bus et al., 2011; Bus et al., 2004; Charanya et al., 2004; Guldemond et al., 2007; Hastings et al., 2007; Lin et al., 2013; Lott et al., 2007; Martinez-Santos et al., 2019; Mueller et al., 2006; Owings et al., 2008; Paton et al., 2012; Praet & Louwerens, 2003; Preece et al., 2017; Tang et al., 2014; Telfer et al., 2017; Tsung et al., 2004) measured PPP as the primary outcome, and the majority measured this in-shoe. Most of the studies (Arts et al., 2015; Arts et al., 2012; Bus et al., 2011; Bus et al., 2013; Lin et al., 2013; Martinez-Santos et al., 2019; Paton et al., 2012; Preece et al., 2017; Tang et al., 2014) used 200 kPa as an upper threshold to classify the intervention as successful offloading the foot. The remaining studies compared a baseline pressure assessment without the intervention to peak pressure reductions with the interventions. PTI and Force Time Integral (FTI) have also been assessed as parallel outcome measures in some studies (Bus et al., 2004; Mueller et al., 2006; Owings et al., 2008; Paton et al., 2012; Praet & Louwerens, 2003; Tang et al., 2014; Tsung et al., 2004). Other studies (Lin et al., 2013; Paton et al., 2012; Praet & Louwerens, 2003; Tsung et al., 2004) also measured contact area and soft tissue thickness (STT) (Lott et al., 2007; Mueller et al., 2006) as a parallel outcome. Some single parameters measured by the studies were maximum force, contact area (Lin et al., 2013), and walking convenience (Guldemond et al., 2007). One study (Charanya et al., 2004) reported foot-sole hardness as an indicator and reduction in shore hardness value. Six studies (Bus et al., 2013; Busch & Chantelau, 2003; Chantelau et al., 1990; Lavery et al., 2012; López-Moral et al., 2019; Rizzo et al., 2012) reported ulcer recurrence as a primary outcome measure, and another study (Ulbrecht et al., 2014) reported on ulcerative and non-ulcerative lesions as the primary outcome. Three studies (Bus et al., 2013; Chantelau et al., 1990; López-Moral et al., 2019) measured patient adherence in their study as a secondary outcome.

The Pedar-X system (Novel GmbH, Germany) was the most commonly used in-shoe plantar pressure device by studies (Arts et al., 2015; Arts et al., 2012; Bus et al., 2011; Bus et al., 2004; Bus et al., 2013; Martinez-Santos et al., 2019; Owings et al., 2008; Paton et al., 2012; Telfer et al., 2017; Tung-Liang et al., 2013) followed by the F-Scan system (Tekscan Inc. USA) (Guldemond et al., 2007; Hastings et al., 2007; Hellstrand Tang et al., 2014; Lott et al., 2007; Mueller et al., 2006; Tsung et al., 2004). Other systems included RS Scan system (RSScan, Ole, Belgium) (Praet & Louwerens, 2003). Charanya et al. (2004) used a pedobarograph system developed by Patil et al. (Patil et al., 1996; Patil et al., 1999; Patil & Srinath, 1990) to capture the walking foot pressure image and data analysis.

The sensor's thickness of the Pedar-X system is 2 mm (Arts et al., 2015; Bus et al., 2004), F-Scan 0.18 mm (Tsung et al., 2004), and RS Scan 0.7 mm (Praet & Louwerens, 2003). Both sensors of Pedar-X and F-Scan collect pressure data at 50Hz (Hastings et al., 2007; Martinez-Santos et al., 2019), and both have four sensors per cm^2 (Arts et al., 2012; Hellstrand Tang et al., 2014). RS Scan sensors collect data at 500 Hz (Praet & Louwerens, 2003). Studies using Pedar-X systems used steps between 20 to 40 (Bus et al., 2004; Martinez-Santos et al., 2019; Owings et al., 2008; Telfer et al., 2017) and 10 to 20 m walk-way (Arts et al., 2012; Owings et al., 2008; Tung-Liang et al., 2013). Studies using F-Scan systems used walk-way lengths between 6.1 to 10 m (Hastings et al., 2007; Tsung et al., 2004). RS Scan collected dynamic in-shoe pressure data for 8 seconds (10-16 steps) (Praet & Louwerens, 2003).

Table 2.2.

Study characteristics of selected articles for ulcer recurrence as the primary outcome measure

Author, date	Location	Study design	Follow up period	Sample size	Sample characteristics	Intervention & Comparison	Outcome measures	Result
Busch et al. 2003 (Chantelau & Busch, 2003)	Germany	Prospective cohort	Up to 42 months	92	Diabetes Neuropathy Peripheral vascular disease (PVD)	Lucro SDS vs non-SDS standard footwear	Ulcer recurrence	Annual ulcer recurrence SDS 15% vs Non-SDS 60% when severe foot deformity is non-existent
Bus et al. 2013 (S. A. Bus et al., 2013)	Netherlands	RCT	18 months	171	Diabetes Neuropathy Healed plantar ulcers	Custom-made footwear with and without modifications based on in-shoe pressure analysis	Ulcer recurrence Adherence of ≥80% steps taken	Modified custom-made footwear are only useful in offloading forefoot area if they are worn as per advised (Adherence ≥80%)
Chantelau et al. 1990 (Chantelau et al., 1990)	Germany	Prospective cohort	25 months	50	Diabetes Neuropathy PVD History of healed plantar foot ulcer Partial or forefoot amputation	Custom-made footwear with rocker soles and custom-made insoles with 10mm thickness,	Ulcer recurrence Adherence (regular vs irregular wearing of footwear and insoles)	Regular wearing of footwear and insoles reduced the relative risk of foot ulceration to 0.48 (95% confidence interval 0.29 to 0.79), compared with irregular wearing

Table 2.2.

Study characteristics of selected articles for ulcer recurrence as the primary outcome measure (Continued)

Author, date	Location	Study design	Follow up period	Sample size	Sample characteristics	Intervention & Comparison	Outcome measures	Result
Lavery et al. 2012 (Lavery et al., 2012)	USA	RCT	18 months	299	Diabetes Neuropathy Healed foot ulcers Foot deformity	Shear reduction insole (SRI) with standard therapy group (STG) with therapeutic footwear, diabetic foot education and care	Ulcer recurrence	SRI group were 3.5 times less likely to develop foot ulcers comparing to the STG group. No significant difference in the frequency of footwear and insole usage in SRI or STG group.
López-Moral et al. 2019 (López-Moral, Lázaro-Martínez, García-Morales, García-Álvarez, et al., 2019)	Italy	RCT	18 months	51	Diabetes Neuropathy Healed plantar ulcers	Semi-rigid (control) and rigid rocker sole (test) therapeutic footwear	Ulcer recurrence Adherence >60%	Rigid rocker sole can reduce risk of re-ulceration at forefoot by 64% compared to semi-rigid rocker sole
Rizzo et al. 2012 (Rizzo et al., 2012)	Italy	RCT	Five years	298	Diabetes Neuropathy Healed plantar foot ulcer Minor amputation	Standard comfort footwear vs custom insoles and footwear as per Dahmen et al. algorithm	Ulcer recurrence	Ulcer recurrence rates in 1, 3 & 5 years are 11.5% vs 38.6%, 17.6% vs 61%, 23.5% vs 72% where forefoot deformities are predominant among the participants.

Table 2.2

Study characteristics of selected articles for ulcer recurrence as the primary outcome measure (Continued)

Author, date	Location	Study design	Follow up period	Sample size	Sample characteristics	Intervention & Comparison	Outcome measures	Result
Ulbrecht et al. 2014 (Ulbrecht et al., 2014)	USA	RCT	15 months	150	Diabetes Neuropathy Healed plantar foot ulcer (MTHs) Increased barefoot plantar pressure	Control: Standard custom-made insoles from three different suppliers Experimental: Insoles made according to the protocol in Owings et al. 2008.	Ulcerative or non-ulcerative lesions at the plantar forefoot in MTHs regions	Foot shape and plantar pressure-based custom insoles provide superior offloading than insoles made from foot shape and clinical insights.

Note. MP, Metatarsal Pad; MB, Metatarsal Bar; MD, Metatarsal Dome; SDS, Stock Diabetic Shoes; MTH1, First Metatarsal Head; FTI, Force Time Integral; PTI, Pressure Time Integral; MPP, Mean Peak Pressure; TCI, Total Contact Insoles; SRI, Shear Reducing Insoles; STG, Standard Therapy Group

Reductions in forefoot plantar pressure

Arts et al. (2012) reported on the effectiveness of footwear and insole design based on the algorithm proposed by Dahmen et al. (2001). The rate of pressure reduction was lower at the metatarsals area (29-50%) compared to midfoot (81%) and known ulcer location (62%) (Arts et al., 2012) when footwear and insoles are designed according to Dahmen's algorithm.

Sole design (rocker sole) was the most reported design feature, and some reported on detailed configurations such as rocker apex position (Arts et al., 2012; Bus et al., 2011; Busch & Chantelau, 2003; Charanya et al., 2004; Paton et al., 2012; Praet & Louwerens, 2003; Preece et al., 2017; Rizzo et al., 2012), rocker apex angle (Preece et al., 2017), rocker angle (Bus et al., 2011; López-Moral et al., 2019; Praet & Louwerens, 2003; Preece et al., 2017), rigidity or hardness (Arts et al., 2012; Bus et al., 2011; Busch & Chantelau, 2003; Charanya et al., 2004; Guldemond et al., 2007; López-Moral et al., 2019; Rizzo et al., 2012; Tang et al., 2014) and, material type (Charanya et al., 2004; López-Moral et al., 2019; Paton et al., 2012; Praet & Louwerens, 2003; Rizzo et al., 2012). A rocker sole configuration with an apex position at 52% of the footwear length, 20º rocker angle, and 95º apex angle can yield peak pressure <200 kPa in 71-81% of cases (Preece et al., 2017).

Some studies reported on footwear upper design features, such as upper height (high footwear 16 cm, Bottine 12.5 cm, Low footwear (6.5 cm) (Arts et al., 2012; Praet & Louwerens, 2003; Rizzo et al., 2012), footwear depth (Arts et al., 2015; Bus et al., 2013; Busch & Chantelau, 2003; Lin et al., 2013; López-Moral et al., 2019; Paton et al., 2012), leg and tongue profile (Arts et al., 2012; Bus et al., 2013; Rizzo et al., 2012). Other design features are upper material, collar, lining, toe puff (Busch & Chantelau, 2003; Chantelau & Busch, 2003; López-Moral et al., 2019; Paton et al., 2012), heel counter, fastening system (López-Moral et al., 2019; Tang et al., 2014) and active heel height (Praet & Louwerens, 2003).

Non-weight-bearing (NWB) casting technique yields more effective custom-made insoles to offload the hallux region, and the semi-weight-bearing (SWB) casting technique is more effective inoffloading 1-3 metatarsal heads (MTHs) (Tsung et al., 2004). The NWB insoles also yield the highest arch support compared to insoles made by other casting techniques (Tsung et al., 2004).

Insoles designed based on foot shape and plantar pressure data are more effective in offloading the forefoot region compared to insoles designed based on foot shape only (Owings et al., 2008; Telfer et al., 2017; Ulbrecht et al., 2014). The outcome can be between 32 to 21% improvement from shape-only and traditionally manufactured insoles out of polypropylene base (Owings et al., 2008).

Custom-made insoles with multi-density, softer materials have demonstrated improved forefoot offloading compared to higher-density EVA (55º shore A). Extra arch support, metatarsal pads, a plastazote top cover, and local cushioning can further reduce plantar forefoot pressure (Guldemond et al., 2007; Lin et al., 2013). Metatarsal pad, local cushion and a plastazote top cover can reduce peak pressure by 14% to 15.9% on their own. A plastazote top cover combined with a metatarsal pad and local cushioning reduces 24% and 22% PPP at the forefoot (Arts et al., 2015).

Reductions in ulcer recurrence

López-Moral et al. (2019) explored the effect of two rocker soles: semi-rigid (Wellwalk technology with Vibram Strips) and rigid, on the recurrence of ulceration. By using, a rigid rocker sole, the risk of re-ulceration at the forefoot was reduced by 64% when compared with semi-rigid rocker sole footwear.

Busch and Chantelau (2003) examined the effect of two different footwear (Lucro stock diabetic footwear versus regular retail footwear) with insoles on ulcer relapse of 92 participants with high-risk neuropathy feet at 12 and 42 months. The footwear was available in three different widths with differing features: rocker bottom outsoles and soft upper with three layers. This combined footwear and insoles reduced ulcer relapse by 45% compared with standard footwear within the first year.

Rizzo et al. (2012) compared a treatment group who were given therapeutic footwear designed as per Dahmen et al. (Bus et al., 2013; Dahmen et al., 2001) and custom-made insoles to a control group who received standard footwear. The participants were assessed for ulcer occurrence and relapse at 12, 36 and 60 months. Ulcer relapse rates were significantly lower (11.5 % versus 38.6% at 12 months, 17.6% versus 61% at 36 months and 23.5% versus 72% at 60 months) in the treatment group than controls.

Lavery et al. (2012) examined the effect of shear-reducing insoles on ulcer recurrence when compared with standard insoles in the same style of footwear. Shear-reducing insoles were 3.5 times less likely to create ulcers in the study participants compared to the standard insoles, although both insole types demonstrated equivalent plantar pressure reduction (Lavery et al., 2005).

In another study (Bus et al., 2013) based on the algorithm proposed by Dahmen et al. (2001), the treatment group received custom-made footwear that was adjusted following in-shoe pressure analysis. Controls received custom-made footwear without the in-shoe pressure analysis. The primary outcome was ulcer relapse after 18 months. The outcomes were not significantly different due, in part, to variance in patient adherence.

2.4 Discussion

Footwear and insoles are complex biomechanical interventions due to variances in design, materials, manufacturing methods, individual preferences and rates of adherence. This complexity is compounded when it is considered alongside the range of foot pathologies that co-exist with diabetes. Forefoot structural deformities are prevalent in this patient group (11, 12), increasing in-shoe plantar pressure at the metatarsal heads. The importance of footwear and insoles in offloading PPP for preventing plantar forefoot foot ulceration is well documented (Bus, van Deursen, et al., 2016; Healy et al., 2013). However, the specifications of design parameters and materials that can reduce PPP at the forefoot area are not precise. Reduction of PPP is one of the major factors to reduce the risk of ulcer occurrence and recurrence. This review explores the identification of critical design features and materials used in footwear and insole manufacturing that can reduce PPP at the forefoot and prevent ulcer occurrence and recurrence. A summary of those features that are available in the literature has been presented in Appendix 1 and 2.

Several studies have suggested rocker sole profile as the most recommended design to offload PPP at the forefoot (Arts et al., 2015; Bus et al., 2011; Busch & Chantelau, 2003; López-Moral et al., 2019; Praet & Louwerens, 2003; Preece et al., 2017; Rizzo et al., 2012). The studies showed strong evidence for the rocker sole with evidence pointing towards specific variations of the rocker sole: such as apex position, apex angle, rocker angle and rigidity of sole materials. An RCT (López-Moral et al., 2019) showed that a rocker sole

configuration with the pivot point under the metatarsal heads and rigid sole materials improves plantar pressure offloading at the forefoot compared to rocker sole made with semi-rigid materials. In a six-month follow-up, the plantar ulcer recurrence rate was 23% and 64% among the experimental and control groups where sole rigidity was the only variant. Preece et al. (Preece et al., 2017) and Praet et al. (Praet & Louwerens, 2003) compared apex position and rocker angle for rocker sole design in their studies. They recommended an apex position at 52-63% of shoe length and rocker angle of 20-23º to provide effective offloading at the forefoot (<200 kPa), finding it more effective than any other lower or higher values of those respective parameters.

Arts et al. (Arts et al., 2012) in the Netherlands and Rizzo et al. (Rizzo et al., 2012) in Italy tested the effect of footwear design suggested by the consensus-based algorithm proposed by Dahmen et al. (2001). The key footwear design features in Dahmen algorithm are based on medical conditions. For example, the recommendations for a person with diabetes and a history of neuropathic ulcers are footwear with a high upper (above ankle boots), stiffened tongue and leg uppers, rigid rocker soles with early pivot points. Both studies used above-ankle boots with custom-made insoles to offload pressure at the forefoot area. Both studies found that footwear and insoles designed according to this algorithm are effective in offloading the neuropathic diabetic foot. However, Arts and colleagues (Arts et al., 2012) found that the algorithm is not as effective for footwear specifications to offload plantar pressure at the metatarsal heads.

There is a lack of guidance in the literature on footwear modifications that offload the forefoot. Footwear modification (also known as footwear customisation or optimisation) is common in both prefabricated and fully custom-made footwear. Most frequent footwear modifications are a re-configuration of rocker sole profile, such as an early or significant pivot point (rocker angle) and stiffening of the outer sole (Arts et al., 2015; Bus et al., 2011). Footwear modification success (≤200 kPa) is least at the forefoot (Arts et al., 2015; Arts et al., 2012). Bus et al. (2011) recommended in-shoe plantar pressure analysis as an effective tool to guide the modifications for offloading the target regions in the neuropathic foot.

Insole modification features include local cushioning, replacing top covers with plastazote and applying a new or re-positioning existing metatarsal bars and metatarsal domes (Arts et al., 2015; Bus et al., 2011; Martinez-Santos et al., 2019; Rizzo et al., 2012), removing plugs,

and adding arch supports (Lin et al., 2013; Rizzo et al., 2012). These are the most effective (PPP reduced ≤200 kPa) modifications in offloading or reducing PPP in targeted regions (Arts et al., 2015; Bus et al., 2011). The targeted regions were determined by the history of ulceration or from PPP measurement data. These modifications in the insole are proven to be effective in offloading plantar pressure at an optimal level. However, they are least effective in offloading pressure at the metatarsal heads (Arts et al., 2015; Arts et al., 2012).

Pedorthists commonly use a higher upper height in their treatment of neuropathic forefoot ulcers. Dahmen et al. (2001) and Diabetic Feet Australia (DFA) guidelines (van Netten, Lazzarini, et al., 2018) support such practice. However, Praet and Louwerens (2003) showed that high-ankle boots did not influence plantar pressure offloading when compared with low-cut footwear. The authors suggest that although high-ankle boots do not change plantar pressures, they may reduce shear forces inside the shoe at the forefoot by increasing the contact area around the ankle. Considering these findings, further studies assessing high-ankle boots will help to inform clinicians working in this field.

Many design features were not examined in the literature. Higher quality research is required to scientifically examine other important footwear design parameters, including heel height, toe height, upper materials, sole materials, heel counters, and closure systems for this therapeutic target.

There was moderate evidence (Andrews et al., 2013) to suggest using total contact insoles (Owings et al., 2008; Rizzo et al., 2012; Tsung et al., 2004; Ulbrecht et al., 2014), metatarsal pads (Bus et al., 2004; Hastings et al., 2007; Lott et al., 2007; Mueller et al., 2006; Ulbrecht et al., 2014), metatarsal bars (Martinez-Santos et al., 2019; Rizzo et al., 2012) and plastazote top covers (Arts et al., 2015) to reduce PPP. Arts et al. (2015) recommended plastazote as a top cover over leather due to its superiority in peak pressure offloading, but they need to be replaced every six months. Two studies (Paton et al., 2012; Tang et al., 2014) also included prefabricated insoles as interventions, which also showed a reduction in forefoot plantar pressure.

In practice, the use of custom-made insoles over prefabricated devices needs to be considered in relation to cost versus benefit. Paton and colleagues (Paton et al., 2012) used two different insoles, made out of EVA and Poron, and compared cost as well. Custom devices were 18% higher cost in delivery than prefabricated insoles. The main difference was where the foot

was cast to make the insoles, or insoles were selected from stock. There was no significant difference in PP reduction between the two types of insoles. Custom-made insoles were, however, found to reduce PTI more than prefabricated insoles and lasted longer (Paton et al., 2012). Customised devices may be preferred in practice as they account for structural changes in the diabetic foot, which is likely the reason that they reduce PTI more than prefabricated devices. Other studies (Bus et al., 2011; Bus et al., 2004; Hellstrand Tang et al., 2014; Lott et al., 2007; Mueller et al., 2006; Tsung et al., 2004) that compared PPP reduction capacity of the custom-made insoles with prefabricated insoles and not examined the cost, those found custom-made insoles to be more effective in pressure offloading in almost every region of the foot.

Most common insole base materials are EVA with the hardness of 50-55º Shore A and 30-35º Shore A (Hellstrand Tang et al., 2014; Martinez-Santos et al., 2019) and the latter material showed improved performance in offloading PPP. However, the medium-density EVA base (30-35º Shore A) insoles need more frequent replacement than the higher density EVA group insoles due to material fatigue.

PPT or Poron as mid-layer (Busch & Chantelau, 2003) and top cover materials either MCR, plastozote or microfiber are effective in plantar forefoot pressure offloading. PPT or Poron is also used as a top cover in some insole designs (Busch & Chantelau, 2003; Lin et al., 2013). Use of a leather top cover is of limited benefit due to its poor pressure reduction capacity (Arts et al., 2015).

None of the studies looked at the prevention of initial neuropathic plantar forefoot ulcer occurrence rather than a subsequent recurrence ulcer. Additionally, studies did not assess forefoot ulceration in isolation, but whole foot ulceration. PPP reduction in different regions requires different types of offloading. Further, different footwear and insole design features show differences in pressure reduction efficacy in different regions of the foot. The articles relied on in-shoe plantar pressure measurement data as a predictor of ulceration. However, other factors such as co-morbidity and lack of adherence to treatment also contribute to ulcer occurrence.

Plantar tissue stress incorporates vertical plantar pressure, horizontal shear pressure, and the frequency at which it is applied (Lazzarini et al., 2019). The reliance on plantar pressures as a predictor of ulceration may, therefore, be only one part of the picture. Lavery et al. (Lavery et

al., 2012; Lavery et al., 2005) reported that two different insoles (shear-reducing and standard insoles) with equivalent plantar pressure reduction capacity could have a significantly different outcome in ulcer recurrence where shear-reducing is the only differentiation factor. Shear-reducing insoles had 3.5 times higher ulcer prevention capacity than the standard insoles in the study participants. Since design features are likely to influence footwear function, and therefore, adherence, it is important to consider which features may prevent ulceration.

There is limited data in the literature to determine the efficacy of footwear in preventing ulcer occurrence. Preece et al. (2017) and Martinez-Santos et al. (2019) explored the efficacy of footwear and insole design features, but could not make any recommendations for preventing ulcer occurrence.

In this review, the articles were excluded if the participants had heel ulcer, Charcot foot or any active, dorsal foot ulcers, and these might limit the representation of complete diabetic foot conditions. This may limit the footwear and insole feature recommendations for those feet that have those conditions.

Heterogeneity in study designs, interventions, outcome measures and footwear and insoles design features make it also very difficult to come to a conclusion. Greater variations in participant's inclusion criteria and foot deformities, footwear and insole types, their measuring, casting and designing techniques, in-shoe pressure analysis systems may result in inconsistent data. Hence, we cannot make a clear comparison or pool data to analyse further.

Because of the need to customise to the individual, the success of custom-made footwear as an intervention in offloading the plantar foot is dependent on the knowledge and skills of the prescribers and manufacturers (Bus et al., 2011; Bus et al., 2004; Tsung et al., 2004). The studies in this review used a variety of skilled practitioners in these roles, such as orthopedic shoemakers, pedorthists depending on the region. The presence of these practitioners in the interdisciplinary team approach in high-risk foot services is increasingly recognised (NADC, 2019; van Netten, Lazzarini, et al., 2018).

Several studies (Bus et al., 2011; Bus et al., 2013; Guldemond et al., 2007; López-Moral et al., 2019; Paton et al., 2012; Rizzo et al., 2012) explored patient satisfaction and adherence to wearing footwear and insoles. Patient adherence to wearing therapeutic footwear is vital to

ensure improved offloading and ulcer prevention (Bus et al., 2013; López-Moral et al., 2019; Rizzo et al., 2012). No difference was found in patients' perceptions of custom-made versus prefabricated insoles (Paton et al., 2012). Adding arch support and large metatarsal domes to basic insoles reduces patient adherence and walking comfort, despite evidence that these features improve pressure offloading (Guldemond et al., 2007).

Studies did not report the factors that influence adherence to therapy, which also limits the application of our findings. Consideration of patient expectations, effective education on footwear and activity-specific device designs are limited in the literature. Studies also did not consider geographical and socioeconomic factors. Most studies (Arts et al., 2015; Arts et al., 2012; Bus et al., 2011; Bus et al., 2013; Busch & Chantelau, 2003; Guldemond et al., 2007; López-Moral et al., 2019; Martinez-Santos et al., 2019; Mueller et al., 2006; Paton et al., 2012; Praet & Louwerens, 2003; Preece et al., 2017; Rizzo et al., 2012; Tang et al., 2014) were carried out in developed countries (Department of Economic and Social Affairs of the United Nations Secretariat, 2014) with climates conducive to using ankle-high boots. Also, the practicality of these ankle-high boots for countries with warmer climates needs revisiting concerning patient adherence.

There was no study to take a personalised-treatment approach to focus on an individual's need or preference to increase adherence. Footwear is a very personal item, and a pre-study participant's feedback on their future footwear is crucial as opposed to only post-study feedback as adherence plays a vital role in an individual's outcome (Bus et al., 2013; Chantelau et al., 1990; López-Moral et al., 2019; Praet & Louwerens, 2003). Study designs like the N-of-1 or single-patient-trial design (Lillie et al., 2011; Tate et al., 2013) may bridge the gap in the literature.

Appropriate footwear design that takes into consideration the needs of low-income countries and those with warmer climates are limited in the literature, even though the prevalence of diabetes tends to be higher among the populations in these regions (Shaw et al., 2010).

2.5 Conclusion

There is limited evidence to inform footwear and insole interventions, especially in conjunction with in-shoe plantar pressure reduction. The available evidence supports the identification of footwear and insole design and modification parameters that can influence

forefoot plantar pressure reduction. Prevention of ulcer occurrence or recurrence at the plantar forefoot region in diabetic patients is limited. Further research is needed to improve care for people with diabetic foot ulceration.

List of abbreviations

RCT: Randomised controlled trial; PRISMA: Preferred reporting items for systematic reviews and meta-analysis; BMI: Body mass index; DPN: Diabetic peripheral neuropathy; PPP: Peak plantar pressure; PTI: Pressure time integral; STT: Soft tissue thickness; DFA: Diabetic foot Australia; HRFS: High-risk foot services

CHAPTER 3 | Methodology

This chapter briefly outlines the methodological approach to the thesis and, subsequently, the rationale for the design and methods used in the individual studies, including the retrospective clinical audit (study 2), the survey of Australian pedorthists (study 3) and a series of N-of-1 trials (study 4) undertaken for this thesis. More detailed descriptions of the methods related to each study are embedded within the respective chapters, with this chapter focused on the overarching methodology used in the thesis.

The design and methods for Study 1 (systematic literature review) have already been outlined in Chapter 2 and will not be revisited in this chapter.

3.1 Methodology

The research performed in this thesis focuses on the three most direct stakeholders in the provision of diabetic footwear: referrers, manufacturers (providers, pedorthists) and consumers (patients).

Given this context and the conclusion derived from the literature review in Study 1 that there are few data in this field, the quantitative methodological approach facilitates access to stakeholders to commence basic data from the stakeholders.

A retrospective clinical audit results, along with the data derived from the literature review, helped to formulate the questionnaire for the Australian pedorthists survey, which was the benchmark of current practices in footwear and insole design practices to reduce the risk of neuropathic plantar forefoot ulcers.

This benchmark was tested through a series of N-of-1 trials to recommend a set of design principles for footwear and insole to prevent the risk of plantar forefoot ulceration in people with diabetes.

3.2 Study 2: Retrospective Clinical Audit

3.2.1 Study Aim

The purpose of the retrospective clinical audit was to capture the demographic, medical and foot-related characteristics of people with diabetes and neuropathy who present to pedorthic services at risk of plantar forefoot ulceration and to understand the referral pathways used to arrive at the service.

In the absence of any data on a pedorthic patient population, this study aimed to better understand the population requiring therapeutic footwear to prevent diabetes-related neuropathic plantar forefoot ulcer occurrence and recurrence and how they access these services. This information provides a basis to support the development of case studies for Study 3 of this thesis.

3.2.2 Methodological Rationale

Clinical audits are a study design commonly used to improve healthcare provision by providing insights into service attributes or practices and identifying potential mechanisms for change (Williams, 1996). The attributes examined in this study include the population characteristics such as sociodemographic information, pathologies and comorbidities of those accessing the services, referral pathways, fund providers and eligibility requirements for members referred to pedorthists for the provision of appropriate footwear and insoles. A descriptive analysis of such data gives a localised context to service provision (Williams, 1996). This was used to formulate the baseline information for the four hypothesised case studies for the Australian pedorthists survey (Study 3) used to examine current practices ensuring their authenticity.

3.3 Study 3: Survey of Australian Pedorthists

3.3.1 Study Aim

Study 3 aimed to survey Australian pedorthists to understand their current prescription habits when designing and altering footwear and insoles to achieve effective offloading for neuropathic plantar forefoot ulcer prevention and improved patient adherence.

3.3.2 Methodological rationale

Surveys are useful to explore the beliefs, experiences, current practices or views of an individual who can be considered representative of a large or specific group. Clinician surveys are common in healthcare services to explore current practices and establish an understanding of common treatment and prescription patterns for any specific conditions or patient group (Boer & Seydel, 1998; Chapman et al., 2018; Quinton et al., 2015). To the author's knowledge, no previous research has explored footwear and insole design prescription practices by pedorthists for people with diabetes (Ahmed et al., 2020). Therefore, this survey of Australian pedorthists aimed to explore current practices regarding how footwear and insoles are used as interventions to prevent plantar forefoot ulceration in people with diabetes and strategies pedorthists employ to improve patient adherence.

Other studies in allied health professions use Delphi techniques to obtain a consensus around prescribing habits (Landorf et al., 2001),; in the absence of any understanding of the nature of the variation in practice, the lack of existing evidence around footwear prescription, and with a small profession, a survey of current practice was an important starting point. The survey helps to understand the parameters within which pedorthists are practising, which could, in future, be used to direct future consensus-based approaches.

3.4 Study-4: Footwear and insole design parameters to prevent occurrence and recurrence of neuropathic plantar forefoot ulcers in patients with diabetes - A series of N-of-1 trials.

3.4.1 Study aim

The primary aim of this study was to identify the optimum footwear and insole design and modification parameters to effectively offload peak plantar pressure at the forefoot in the neuropathic diabetic foot in clinical practice.

The secondary aim of this series of N-of-trials was how participants' preferences could be incorporated into footwear and insole design to increase the adherence to prescribed footwear and insole in people with diabetes and neuropathy who were at risk of plantar forefoot ulcer occurrence and recurrence.

3.4.2 Methodological rationale

By its nature, footwear is an iterative, complex, individualised intervention. There is no 'one size fits all' in footwear intervention due to individual pathologies, comorbidities and sociodemographic variations. The success of this long-term treatment modality depends on persistent use; hence, the motivation of the individual to use the footwear needs to be high and take into account lifestyle and personal preferences. Therefore, a research method that recognised the need for individualised interventions was critical to adopt for this study.

N-of-1 trials are randomised, ideally double-blind, and multiple crossover comparisons of an intervention and a control treatment (Nikles et al., 2011). The Oxford Centre for Evidence-Based Medicine recommends this trial as Level 1 evidence for treatment decision purposes (Tate et al., 2013).

N-of-1 trials provide a technique to guide evidence-based treatment decisions for an individual participant. The most common methodological components of large clinical trials are used to measure treatment effectiveness in a single participant. These trials have practical and effective applications when circumstances preclude large-scale trials, such as investigations into rare diseases, comorbid conditions, or in participants using concurrent therapies (Vohra et al., 2015).

Methodologically robust N-of-1 trials provide an objective means of testing the effectiveness of complex treatments for individual participants. Aggregation of multiple cycles of identically conducted N-of-1 trials yields a population estimate of effect, potentially commensurate with that derived from other RCT designs. Trial participants contribute data for both intervention and control treatments, creating matched data sets while generally using smaller sample sizes than conventional RCT trials (Nikles et al., 2011).

Single-patient or N-of-1 trials are commonly used for personalising the treatment options when the subject has a chronic condition (Duan et al., 2013). Recent studies suggest that N-of-1 trials are effective tools for improving therapeutic precision, and participants and clinicians widely accept these as an effective modality in being participant-centred outcomes-based methods (Duan et al., 2013; Gabler et al., 2011). These approaches have also been proven to be a method to guide more effective prescriptions (Gabler et al., 2011; Nikles et al., 2005; Schork, 2015).

The literature review shows that participant adherence is key for successful offloading initiatives for a neuropathic diabetic foot. Footwear is an integral part of clothing, and participant preference plays a vital role in footwear usage and client adherence to recommendations. Therefore, a participant-centred study design that can recommend a precise prescription for personalised therapy or devices is very important. The N-of-1 trial is a unique trial that focuses on participant preferences and circumstances. This is also beneficial for personalised treatment decisions for participants with chronic conditions (Duan et al., 2013). In addition, this trial has generalisability and direct application to individual participant treatment as the best treatment method for that individual (Duan et al., 2013).

This trial method appeals to participants by generating feelings of being more involved and seeing accurate feedback to responses (Nikles et al., 2011). For example, participants' preferences on footwear style and color consideration and their suitability for the intended activity make the participant feel more involved and engaged in the process. This is also a more cost-effective trial than traditional phase iii clinical trials (Schork, 2015).

Therefore, a prospective series of N-of-1 trials was used to explore the effective design and modification parameters of footwear and insoles to provide optimum offloading at the forefoot for participants with diabetes and neuropathic feet. The effectiveness of offloading was measured by the in-shoe plantar pressure analysis system, with input from the participant on suitability and ease of walking. A secondary aim was to explore how participants' preferences are incorporated into footwear and insole design to increase the adherence to prescribed footwear and insole in people with diabetes and neuropathy who are at risk of plantar forefoot ulcer occurrence and recurrence.

CHAPTER 4 | Study 2 Retrospective clinical audit

This chapter describes the methods and presents the results from Study 2 (retrospective clinical audit). Then, it discusses these results in context. The purpose of this study is to capture the demographic, medical and foot-related characteristics of people with diabetes and neuropathy who present to pedorthic services, at risk of plantar forefoot ulceration and the referral pathways used to arrive at the service. This study aimed to understand better the population requiring therapeutic footwear to prevent diabetes-related neuropathic plantar forefoot ulcer occurrence and recurrence and how they access these services. This information provides a basis to ensure the development of authentic hypothetical cases for study three of this thesis.

It first presents the methods for the study. Then, the results, including sociodemographic characteristics of the participants in the study, then display key characteristics by age group and then outline the foot characteristics, funding body information, and comorbidities. The information has been presented in tables, figures and graphs as they fit and analysed contextually in the relevant sections. Following this, a discussion of these results as they relate to the development of cases and previous research is provided.

4.1.1 Population selection

This study involved a retrospective clinical audit of a consecutive cohort of all patients who attended a single pedorthic clinic in Sydney between January 2018 and July 2019 to identify the proportion of patients who are at risk of diabetes-related forefoot neuropathic ulceration and their attributes. This particular clinic was chosen due to convenient access to the patient data that were documented through a practice management software system. This clinic receives a patient referral from all around Sydney Metro, and captures a diverse range of patients of various demographics and be representative of other Sydney-based pedorthic practices.

All the files of patients accessing services from that clinic rea were included in the study if the inclusion and exclusion criteria in Table 4.1 were met. Patients who had plantar rearfoot or midfoot ulcers (or a history of them), were excluded as they would require different design

features to prevent the recurrence, and those features might be contradicting or compromising when preventing plantar forefoot ulcers.

Table 4.1

Patient inclusion and exclusion criteria for the retrospective clinical audit study

Patient inclusion criteria	**Patient exclusion criteria**
Adults (18+ years old)	History of the heel or rearfoot ulcer
Diabetes mellitus (T1DM or T2DM)	Charcot neuropathy
Neuropathy	Midfoot deformities
Forefoot deformities, HAV, Hammer toes, claw toes, crossover toes, or	History of midfoot ulcers
History of plantar forefoot ulceration	At the risk of rearfoot or midfoot ulcers
Bony prominences at the metatarsal heads	
Referred from major tertiary hospitals and relevant high-risk foot clinics in the Sydney metropolitan	

This referral base was chosen to represent the population of interest in the thesis (NADC, 2018; van Netten, Lazzarini, et al., 2018). The potential participant list included all patients who were presented to the clinic between January 2017 and July 2019, the clinical notes were examined to verify the inclusion criteria. Every patient appointment with all pedorthists during the study period was extracted into an MS Excel™-friendly CSV file, including

appointment notes from the practice management software "Cliniko". For patients deemed to meet the inclusion criteria, the relevant patient referral data were extracted from referral forms into the "Audit Data Collection Tool" by using an MS Excel™ spreadsheet. The referrals were in the form of email, a written referral on the clinic pad or a completed Enable NSW Prescription form (NSW Government, 2014). The referrals were helpful for obtaining the medical history of the patients, such as if they had diabetes, neuropathy, or other comorbidities, which were not within the scope of this pedorthist facility to clinically diagnose as regular care. Also, the information was important for the patients to access relevant health funds for their footwear when applicable.

4.1.2 Sample size selection

The population was selected using a consecutive cohort over a defined time period. The study aimed to include any patient who met the inclusion and exclusion criteria as outlined in Table 4.1 from all patient records from the participating pedorthic facility in New South Wales during the period under study (between January 2017 and July 2019). The time period was chosen to ensure a sufficient sample size to undertake meaningful analysis. Previous studies on similar populations had samples ranging from 42 to 193 (Antony & Terrazas, 2004; Mulligan et al., 2013), and our goal was to ensure a minimum of 60 patients.

4.1.3 Tool development

The audit tool is the key element of a clinical audit. The purpose of the audit tool was to gather the required information in a consistent format for data and statistical analysis. In the absence of commonly agreed standards for pedorthic prescription (Williams, 1996), the audit tool used in this study was adopted from the Enable NSW Footwear and Orthotics Request form (NSW Government, 2014). and adapted with stakeholder involvement.

The audit tool was piloted with practitioners and patients during a consultation to ensure all applicable clinical items were covered and mutually understood terminology was used. The resulting adaptations included clinical notes, adherence items and patient preference items. The key information in the tool was sociodemographic, foot morphology, comorbidity, and health fund-related information, and the details are described in the data collection section. The audit tool is available in Appendix 3

4.1.4 Data collection

Data was collected directly into the tool using a Microsoft Excel™ sheet. The data were categorised into three main categories:

1. Sociodemographic: age, gender, body weight, height, country of birth

2. Pathology and comorbidity: duration of diabetes and neuropathy, forefoot pathologies, foot morphology, foot disease outcomes and comorbidity, and

3. Footwear funding body: fund provider's name.

In the pedorthic facility in this study, standard clinical practice is to record all clinical information in a clinical practice management software package called Cliniko. Clinical data are recorded from a combination of sources, including self-report by the patients, GP referral notes with a medical history and current medications, and allied health practitioner referrals that have specific notes on medical conditions and comorbidity with the expected clinical outcome from the pedorthic interventions. The patient data were de-identified before analysis.

4.1.5 Data analysis

The data collected for the audit were entered directly into a Microsoft Excel™ spreadsheet. The populated data were tabulated, and then descriptive analyses were performed. The analysed data contained patients' demographic information, main pathology, comorbidity, footwear fund type and cultural diversity. Specifically, the mean and standard deviation of the continuous variables of age, duration of diabetes, duration of neuropathy, weight, height and BMI were calculated. Frequency counts and percentage of categorical variables diabetes type, gender, presence of deformities, foot morphology, comorbidity, birthplace and funding were calculated.

Variables were also cross-tabulated by age categories because age is a predictor of several comorbidities and a primary variable in the manufacture of footwear. This was determined to be the most appropriate way to organise data to inform the case studies best.

Relationships among variables were also examined. Differences in these variables (diabetes type, gender, presence of deformities, foot morphology, comorbidity, birthplace and funding) between those with and without the following characteristics were explored: HAV, hammer toe, claw toe, overriding digits, forefoot amputation, partial amputation, forefoot ulcer, bony prominence, flexible flatfoot, rigid flatfoot, limited joint mobility, cavus foot, PVD, and lymphoedema.

Use in the development of case presentations.

The data acquired from this clinical audit study (Study 2) were used to formulate case presentations (presentation of the hypothesised patients' diagnosis, comorbidities, and sociodemographic information included in section 1 of the cases) of the four hypothesised cases that contain the sociodemographic, main foot pathology and comorbidities-related information.

An important outcome of Study 2 was the development of a suite of clinical cases of 'typical' patients that a pedorthist might treat for diabetes-related peripheral neuropathy. The researcher, a team of high-risk foot podiatrists and senior pedorthists, developed these cases.

The cases used in the survey were developed in consideration of the clinical audit findings (frequency of common attributes, percentage of categorical variations); Diabetes Feet Australia (DFA) guidelines on footwear for people with diabetes (van Netten, Lazzarini, et al., 2018); and the findings from Chapter 2 (Ahmed et al., 2020), which recommended prescription guidelines on footwear and insoles design and modifications for effective offloading the peak plantar pressure at forefoot regions (Arts et al., 2015; Arts et al., 2012; Bus et al., 2011; Bus et al., 2013; Chantelau & Busch, 2003; Charanya et al., 2004; Guldemond et al., 2007; Hellstrand Tang et al., 2014; Mueller et al., 2006; Paton et al., 2012; Praet & Louwerens, 2003; Preece et al., 2017; Rizzo et al., 2012; Tung-Liang et al., 2013).

4.1.6 Ethical Considerations and Approvals

Southern Cross University Health and Human Research Ethics Committee gave the Ethics approval for this study, and the Approval number is 2020/028.

The ethical considerations for this study are, first, the handling of personal and identifying clinical records and, second, the role of the researcher in the organization in which the data were collected.

This researcher owns the pedorthic company "Foot Balance Technology", which provides pedorthic services to the targeted population for the study and is actively involved in the treatment of those patients. However, the researcher was not involved in collecting data for this study purpose, and the collected data were de-identified to him as another pedorthist working in practice has assisted with data collection. The privacy of participants was maintained through de-identification by the respective practitioner (pedorthist), other than the researcher. The clinical data input was provided by treating pedorthists, and there was no risk for the participant relating to clinician data or anonymity. The participant data were de-identified by the treating pedorthists; there was no risk for the participants in relation to data identification. Between 35 to 40 hours were required for the pedorthist in "Foot Balance Technology" to complete the audit.

Only authorised staff have access to data entry and editing; different users have different access, and only the clinicians (pedorthists) have access to enter and access treatment notes and medical records. Data were summarised to ensure that no individual participant was identifiable.

4.1.7 Risks and limitations

Study 2 was based on a clinical series of patients from the researchers' clinic. It was challenging to access other pedorthic facilities' private patient data as all pedorthic facilities are private practices set up in Australia (Australian Pedorthists Registration Board, 2019). Their patient data record-keeping system is not consistent (paper-based vs digital).

Clinical audits are commonly used to help understand poorly understood topics and clinical areas and provide a basis for understanding the population of interest to move forward with more rigorous studies. There is a risk of bias being the researcher's own clinic; however, another pedorthist in the clinic assisted with data collection. Also, there was another risk that the patient may not be representative of the Australian general patient group; however, the practice is based in the Western Sydney region, has a population of diverse cultural backgrounds, and few of the patients were from the Inner-West and Eastern part of Sydney.

This captures a majority of common Australian patient types that are seen in high-risk foot services. The sample size is relatively small, but it provides a valuable insight to be able to build data for future research due to the lack of data in the literature.

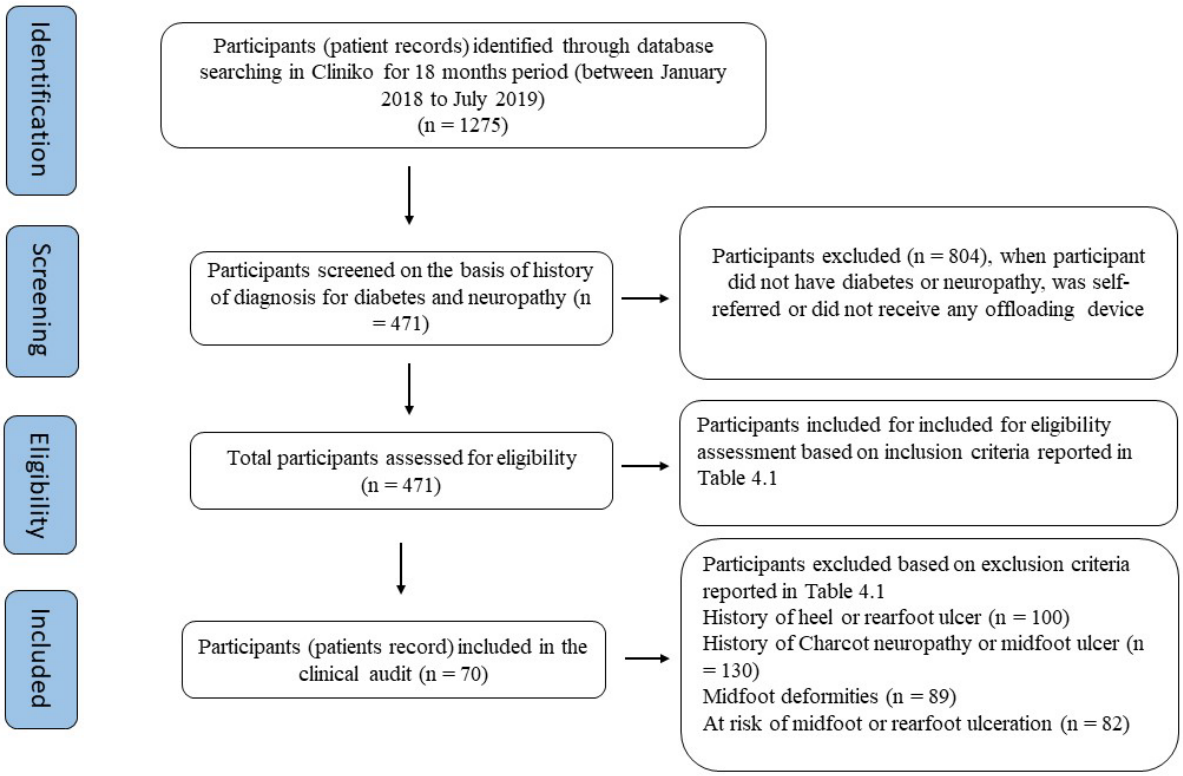
4.2 Results

A total of 421 adults with diabetes and neuropathy and at risk of plantar foot ulceration and re-ulceration received pedorthic services for foot plantar pressure offloading. A total of 70 patients met the inclusion criteria.

4.2.1 Participant characteristics

Figure 4.1

Participants' inclusion flow chart for the retrospective clinical audit (Study 2)



Seventy participants (patient records) were included in this study. As the sample size is relatively small, it did not have enough data to justify conducting a subgroup analysis (such as a Chi^2) test due to the small numbers in each category.

The mean age of participants was 64.69 (SD 11.78) years, ranging from 27 to 90 years old. Eighty per cent of participants were between 50 and 80 years of age. A total of 43 males (61.4%) and 27 females (38.6%) with diabetes were included in this study. All participants were overweight to obese, with a mean weight (kg) of 91.37 (SD 14.73), while the mean height (cm) was 171.7 (SD 8.85), ranging from 69kg to 140kg and 152cm to 192cm. The average BMI was 30.96 (SD 4.15).

Most (97.2%) participants had Type-2 diabetes mellitus (T2DM), and only a few (2.8%) had type-1 DM (T1DM). Australia was the birthplace of the highest number of participants (n=28), followed by England (n=11), China (n=5), Fiji (n=4), Germany and Lebanon (n=3) . About 5.7% (n=4) were of Aboriginal or Torres Strait Islander origin. Most participants (n=42) were born outside of Australia.

The duration of diabetes among the participants ranges from one to 35 years, with a mean of 14.09 years (SD 6.58). The median was 12 years. Categorically organised data revealed the highest number of participants (n=25) had diabetes for 11-15 years, followed by six to ten years (n=21), 21-25 years (n=10), and 16-20 years (n=9).

The mean duration of neuropathy was 8.56 (SD 4.16) years, and the median duration of neuropathy was eight years. When categorised into five-year intervals, six to ten years duration of neuropathy is the highest percentage (51.4%) among the participants, followed by 22.9% for 11-15 years duration, 11.4% for 16-20 years duration and 14.3 % for the 1-5 years duration.

Key demographics, as analysed by age group, are outlined by age group in Tables 4.2-4.4 and Figures 4.2-4.3.

Table 4.2

Percentage Distribution of the diabetes Participants by BMI within age groups

Age Categories	BMI (kg/m^2)% by age group				Total n= 70
	16-18.50	18.51-25.00	25.01-30.00	>30.00	Percentage
25-50 years	-	-	5.7	5.7	11.4
51-60 years	-	1.4	5.7	14.3	21.4
61-65 years	-	2.9	5.7	10	18.6
66-70 years	-	-	10	8.6	18.6
71-80 years	-	2.9	5.7	12.9	21.5
81-90 years	-	-	1.4	7.1	8.5
Total	**0**	**7.2**	**34.2**	**58.6**	**100.0**

Table 4.3

Percentage distribution of the participants by type of diabetes within age groups

Age categories	Diabetes type within the age group		Total n= 70
	T1DM (%)	T2DM (%)	Total percentage
27-50 years	1.4	10	11.4
51-60 years	1.4	20	21.4
61-65 years	-	18.6	18.6
66-70 years	-	18.6	18.6
71-80 years	-	21.4	21.4
81-90 years	-	8.6	8.6
Total	**2.8**	**97.2**	**100.0**

Figure 4.2

Frequency distribution of the participants by country of birth (Bar chart)

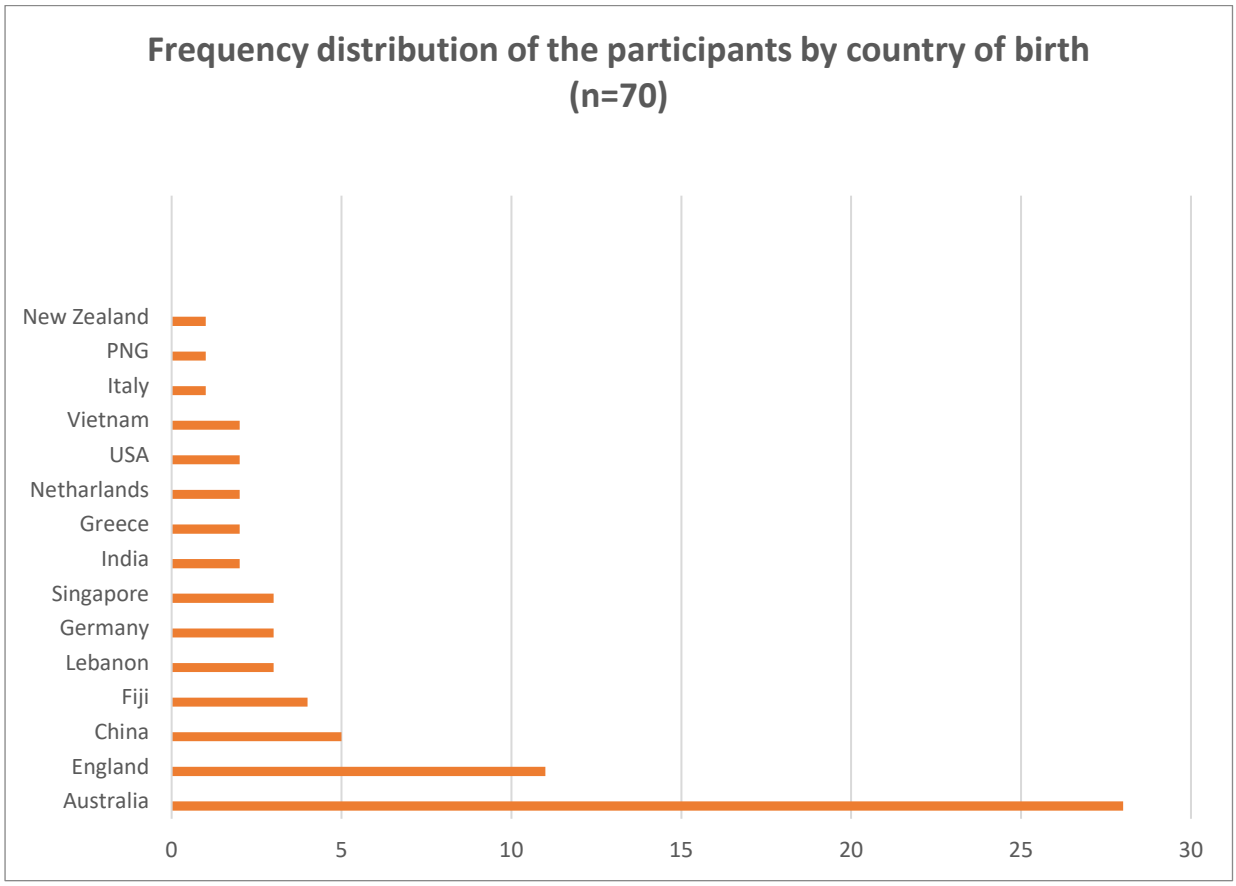


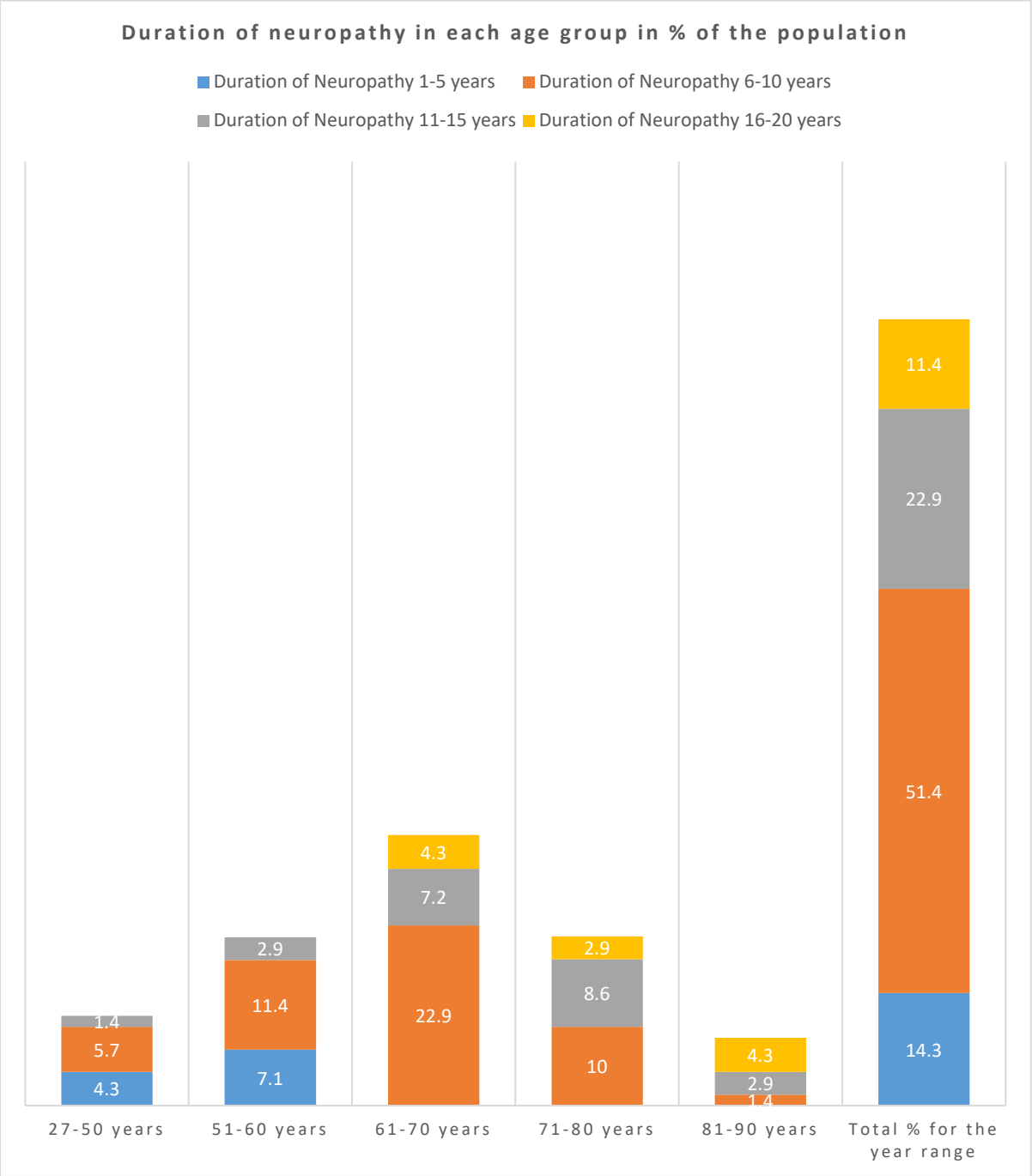
Table 4.4

Frequency and percentage distribution of age of the participants by the duration of diabetes

Age Categories	Duration of Diabetes and number of participants (n) within the age group											
	1-5 years		6-10 years		11-15 years		16-20 years		>20 years		Total	
	n	%	n	%	n	%	n	%	n	%	n	%
27-50 years	2	2.86	3	4.29	3	4.29	-		-		8	11.4
51-60 years	-		9	12.86	5	7.15	1	1.42	-		15	21.4
61-65 years	-		-		9	12.86	2	2.86	3	4.29	14	20
66-70 years	-		3	4.29	5	7.15	2	2.86	1	1.42	11	15.7
71-80 years	-		5	7.15	2	2.86	3	4.29	6	8.57	16	22.85
81-90 years	-		1	1.42	1	1.42	1	1.42	3	4.29	6	8.57
Total participants within a range of duration of diabetes	2	2.86	21	30.01	25	35.73	9	12.85	10	18.6	70	100

Figure 4.3

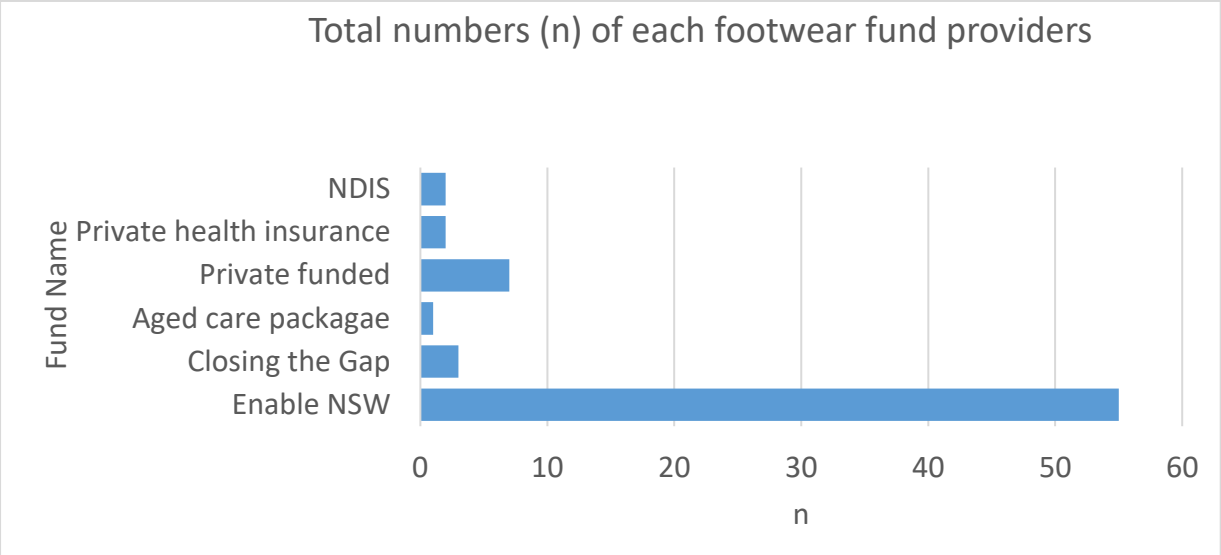
Frequency distribution of duration of neuropathy for each age group in % of the population



4.2.2 Funding providers

Figure 4.4

Frequency Distribution of Footwear Fund Providers



As shown in Figure 4.4, various fund providers fund the footwear in this population group; about 78% (n=55) were funded by Enable NSW (means tested for NSW residents who meet clinical criteria), followed by privately funded at 10% (n=7), Closing the Gap (designed for Aboriginal Australians and Torres Strait Islanders) at 4.3% (n=3), private health insurance 2.9% (n=2), and aged care package 1.4% (n=1). The pedorthic practice was based in New South Wales, and the participants' sociodemographic conditions and medical conditions made them more readily eligible for Enable NSW health fund access. Hence, the number of NSW Health-funded participants is higher in this study. Other states in Australia have similar fund support for those population groups.

4.2.3 Foot morphology and foot pathology

The foot morphology and foot pathology of the participants in the clinical audit are outlined in Figure 4.5.

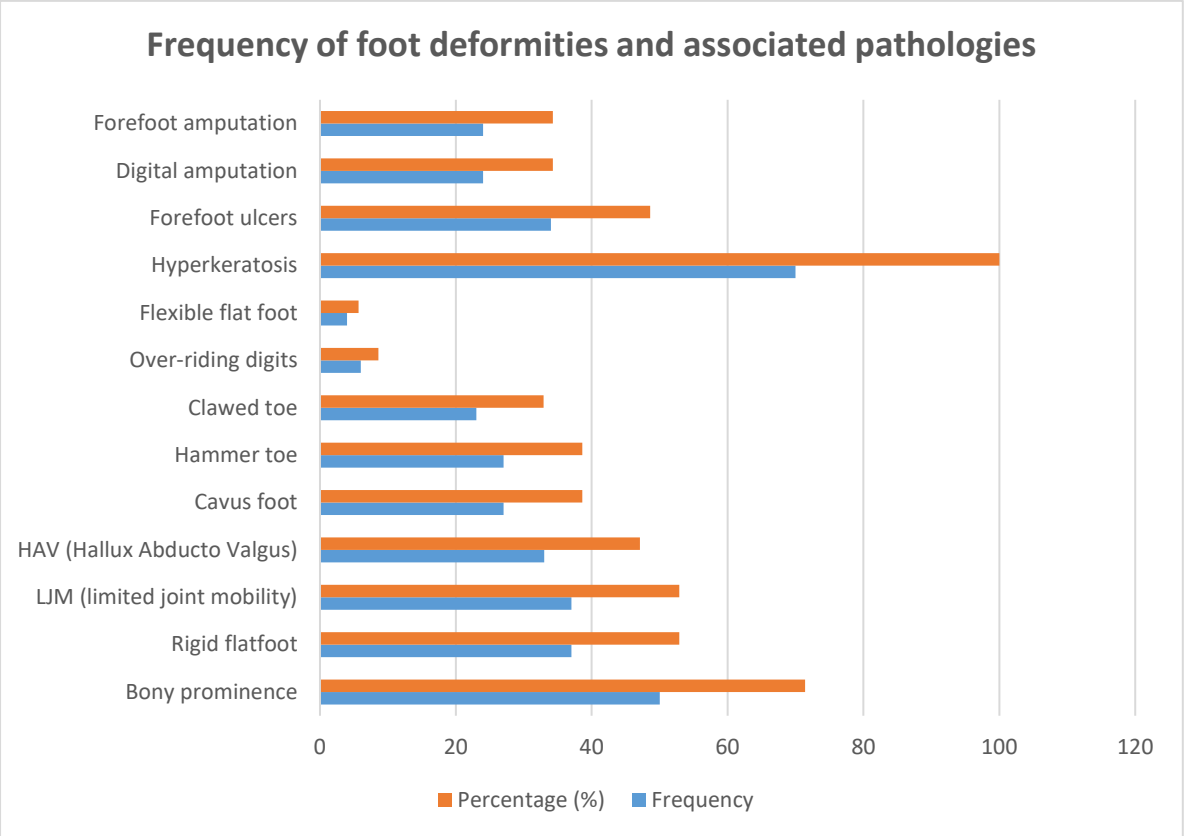
Common recorded conditions were: bony prominence at 71% (n=50) of respondents; rigid flat foot and limited joint mobility (LJM) (53%, n=37); approximately 47% (n=33) of participants had HAV; 39% (n=27) participants had hammertoe and cavus foot conditions, and 33% (n=23)

of participants had clawed toes. Fewer than 9% and 6% had overriding digits and flexible flatfoot, respectively**. All the participants had altered foot posture (n=70).**

Of the foot disease outcomes, hyperkeratosis was the most common condition in the participant group, and everyone (n=70) had this condition. About half (47%) of the participants had a history of forefoot ulceration. Around one-third, 34% (n=24) of participants, had forefoot amputation, and around 34% (n=24) had a history of digital amputation.

Figure 4.5

Frequency of Foot Deformities and Associated Pathologies

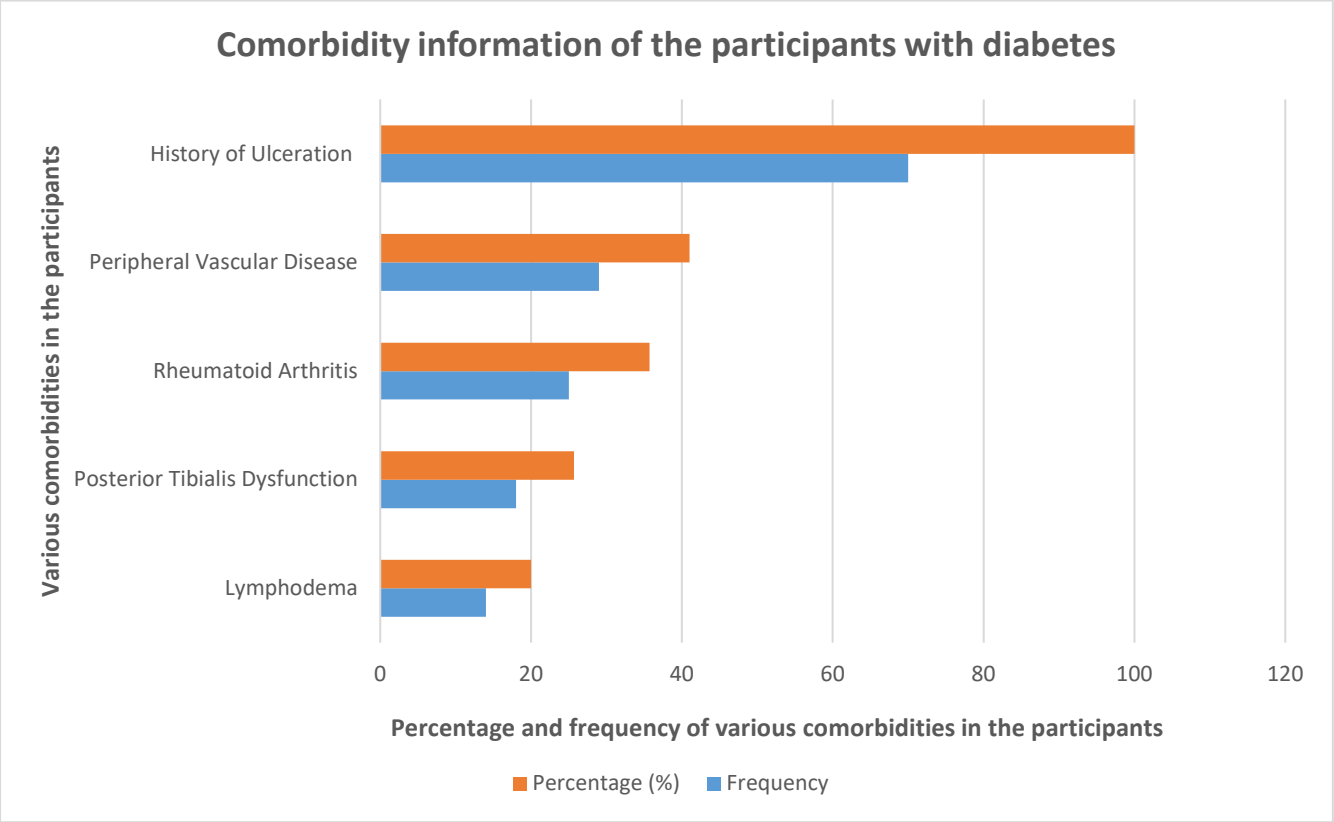


4.2.4 Comorbidities

Various comorbidities are common in this group of participants, and the predominant comorbidities in these studied populations are rheumatoid arthritis (RA) 36%, PVD 41%, lymphodema 20%, and posterior tibialis tendon dysfunction (PTTD) 26%. Detailed information is presented in Figure 4.6.

Figure 4.6

Comorbidity Information of the Participants with Diabetes



4.2.5. Foot morphology, digital deformity and foot disease outcomes

Due to a relatively small sample size, there was not enough data to conduct Chi² tests for each category of the variables. For the Chi² tests, expected cell counts were not more than five for the following variables: over-riding digits, forefoot amputation, flexible flatfoot (not enough instances), hyperkeratosis and history of ulceration (too many instances). There were no relationships found between the presence of digital deformity and foot morphology, nor the presence of deformity with foot disease ($P>0.05$ all).

4.3. Discussion

The purpose of this study was to provide data for Study 3 and to develop the case studies for section 1 of the pedorthist survey (participant characteristics, funding, foot morphology and foot disease outcomes). The information for those specific parameters is presented in Table 4.4. Then the data were compared with available literature (Ahmed, M. U. et al., 2022; Arts et

al., 2015; Bus et al., 2013; Perrin et al., 2022) to recommend the final information to represent a typical (modal, mean and median) Australian man and woman to formulate the case studies for capturing the typical cases commonly seen by pedorthists in their practices. Further adaptation to the case information for section 1 was modified following the feedback of podiatrists and pedorthists at the pilot stage to ensure a range of (four cases) typical male and female representatives are presented through the cases for better data capturing. This study shows more male patients than female patients presented to the pedorthic clinic for treatment, but health-specific population study data (general population, not specific to diabetes) (Del Core et al., 2018; Australian Institute of Health & Welfare, 2012, 2019) recommended an almost 50/50 ratio for males and females in Australia. A recent study (Ahmed, M. U. et al., 2022; Perrin et al., 2022) has shown that above 72% of males were recruited in the participants' group with similar medical conditions. This study also showed that the majority of the participants (n=42) were born outside of Australia, and this is well aligned with recent Australian epidemiological study data (Zhang et al., 2020).

Table 4.5

Gender-specific demography data used in the clinical audit

	Typical males in this study population	**Typical females in this study population**
Total (n, %)	43, 61.40%	27, 38.60%
Age (mean, median)	64.09, 63	65.62, 67
BMI (Avg)	31.20	30.70
Duration of diabetes (Avg)	14.34	13.66
Funding source/provider	Closing the Gap, n=3 Enable NSW, n=32 Private funded, n=5 Private health fund, n=1 Aged care package, n=1 NDIS, n=1	Enable NSW, n=23 Private funded, n=2 Private health fund, n=1 NDIS, n=1
Foot pathology	As per Table 4.5	As per Table 4.5
Comorbidities	As per Table 4.6	As per Table 4.6
Country of birth	As per Figure 4.2	As per Figure 4.2

Firm associations among factors were not found in the data in order to inform comorbidities and co-occurring foot characteristics. Instead, frequencies and age groups were considered with a more subjective approach to case development. The most common presentations were used with a purposive selection of cases that would elicit a diversity of practice. Consideration for a diversity of gender, culture, living arrangements, individual's activity level, level of care support and age with respect to the data on diabetes duration, comorbidities, foot morphology and ulceration.

The results of this chapter were used to develop the questionnaire for Section 1 of the Australian pedorthists survey on four hypothesised cases to inform the sociodemographic, foot morphology and comorbidity-related information.

4.4 Case study development

A case study is typically an intensive analysis of an individual unit (as a person or community) stressing developmental factors in relation to the environment.

Clinical cases are typically used in clinical education (Wilson et al., 2006) for research and teaching (McRae, 2012; Richard & Bryant, 2014).

For the purpose of this study, clinical cases were developed to represent 'typical' patients that might be seen in clinical practice to provide a focus for understanding the breadth and depth of variation in the prescribing practices of Australian pedorthists. The clinical audit data were used to help understand the attributes of the 'typical' patient. A series of case studies were developed with some variation for gender and cultural diversity (including some minor cultural group subjects to increase representability) and further refined in consultation with an expert panel (high-risk foot clinics podiatrists and senior pedorthists). The result was four cases from four unique culturally diverse backgrounds to capture the variations for socioeconomic, health fund eligibility and activity-specific factors. The information on the sociodemographic, diagnosis, activity and care support for the proposed cases are described in Table 4.6 with the justification of choosing the parameter for the individual attributes. Table 4.7 presents the summary of four hypothetical cases developed as an outcome of this study and to be used as baseline information for the Australian pedorthists survey (Study 3).

Table 4.6

Summary of justifications for the case parameters included in the cases developed for the survey of Australian pedorthists

Parameter	Attributes proposed for the cases	Justifications
Gender	Female X 2, Male X 2,	Gender was evenly split between men and women, although the data showed more men are at risk in this group.
Age	55-70 years,	The average age range in the literature is 63±10 years for this population, and our study is 64.09. Our range reflects this.
Height	170-178cm	
Weight, BMI	76-116 kg, 26.3-39.2,	In the literature, the population BMI for men and women range is 30.04±6.09, and our audit and range reflect that
Cultural diversity	Caucasian, Australian Aboriginal, Fiji Indian, Chinese	In the literature and our audit, reflect the same as our range
Living arrangements	Private home, alone, with husband, with daughter,	Data obtained from our audit and our range reflect that
Activity level	Active, low activity and minimal activity, smoker	In the literature and our audit, reflect the same as our range
Care Support	None to Three days/per week	Data obtained from our audit and our range reflect that
Duration of Diabetes	Between Ten to 39 years	In the literature and our audit, reflect the same as our range
Duration of Neuropathy	Seven to ten years	In the literature and our audit, reflect the same as our range
Comorbidities	PVD, Oedema, Nephropathy, Hypertension, Rheumatoid arthritis, Retinopathy	In the literature and our audit, reflect the same as our range
History of Foot Ulceration/ amputation	R plantar hallux ulceration Nil amputation, L plantar metatarsophalangeal joint three Hallux amputation R, R plantar metatarsophalangeal joint one L Transmetatarsal amputation, R plantar metatarsophalangeal joint L D3 amputation Achilles tendon lengthening (6/12 prior)	In the literature and our audit, reflect the same as our range

Table 4.6

Summary of justifications for the case parameters included in the cases developed for the survey of Australian pedorthists (Continued)

Parameter	Attributes proposed for the cases	Justifications
Hyperkeratosis location	Dorsal digits two and three, Lateral left D5, Nil pronounced, Severe plantar L D4, D5	In the literature and our audit reflect the same as our range
Foot morphology	Bilateral bony prominences MTH1,5 Lesser digit hammertoes HAV, B Rigid pes cavus, L Adductovarus 5 Lesser digit Hammertoes R>L, L Hallux limitus B Rigid Flatfoot, R Over-riding D2 on D3	In the literature and our audit, reflect the same as our range

Table 4.7

Summary of cases developed for the survey of Australian pedorthists

Parameter	Case-1	Case-2	Case-3	Case-4
Gender	Female	Male	Male	Female
Age	65 years	55 years	70 years	55 years
Height	170cm	178cm	172cm	170cm
Weight, BMI	86 kg, 29.8	98 kg, 30.9	116 kg, 39.2	76 kg, 26.3
Cultural diversity	Caucasian	Australian Aboriginal	Fiji Indian	Chinese
Living arrangements	Private home, with husband	Private home, alone	Community housing, alone	Private home, with her 30 y/o daughter
Activity level	Active	Active, smoker	Low activity	Minimal activity
Care Support	None	None	Three days/week	None
Duration of Diabetes	Ten years	Ten years	18 years	39 years
Duration of Neuropathy	Seven years	Five years	12 years	Ten years
Comorbidities	Peripheral vascular disease Oedema	Retinopathy Hypertension	Oedema Nephropathy Hypertension	Rheumatoid arthritis Retinopathy Hypertension
History of Foot Ulceration/ amputation	R plantar hallux ulceration Nil amputation	L plantar metatarsophalangeal joint three Hallux amputation R	R plantar metatarsophalangeal joint one L Transmetatarsal amputation	R plantar metatarsophalangeal joint L D3 amputation Achilles tendon lengthening (6/12 prior)
Hyperkeratosis location	Dorsal digits two and three.	Lateral left D5	Nil pronounced	Severe plantar L D4, D5
Foot morphology	Bilateral bony prominences metatarsal heads one and five Lesser digit hammertoes Hallux abductovalgus	B Rigid pes cavus L Adductovarus 5 Lesser digit Hammertoes R>L	L Hallux limitus B Rigid Flatfoot	R Over-riding D2 on D3 B hallux abductovalgus

This is a result of Study 2, and the full findings (Ahmed et al., 2020; van Netten, Lazzarini, et al., 2018) leading to these case studies are presented in Chapter 5.

4.5 Study limitation

This was a retrospective cohort study from a single clinic therefore, there is a risk of systematic bias arising from the patient pool. While there are some limitations to the interpretation of the data and broader implications, there are some key insights provided by this data. Interpretation is limited by the sample (Western Sydney area). The participants' data were collected from the clinic owned by the researcher. The majority of the participants were from the Western Sydney region with a population of diverse cultural backgrounds, and some of the participants were from Sydney Innrer-West and the Eastern region. The primary referrals to this clinic are from the High-risk foot services from the hospitals of these regions. The gender distribution, types of diabetes mellitus (1 and 2), foot types, hyperkeratosis, and foot morphology are more substantially varied than the literature suggests (Ahmed, M. U., et al., 2022; Perrin et al., 2022).

Additionally, as a clinical audit, data were not measured prospectively and systematically but rather recorded from clinical note-keeping. The reliability and validity of this approach are unknown.

4.6 Conclusion

The main outcome of this study was to understand the profile of a cohort of patients from a large, metropolitan pedorthics clinic, specifically those at risk of developing diabetic forefoot neuropathic ulceration. This information was then used to develop a series of clinical cases that formed the basis of the Australian pedorthists' survey (Study 3).

In combination with the published literature, the patient profiles identified in this chapter were used to identify a series of attributes that might be seen in a 'typical' pedorthic clinic in Australia.

The study's primary aim was to examine the authenticity of the cases for Study 3. This provided the baseline sociodemographic, foot pathology and comorbidity-related information that is common in the target population. This also provides some insights into the funding criteria and trends commonly seen in everyday practice.

CHAPTER 5 | Study 3 Survey of Australian Pedorthists

This chapter presents the methods, results and discussion of the survey of Australian pedorthists on their prescribing practices for footwear and insoles to prevent neuropathic plantar forefoot ulcer occurrence and recurrence for four clinical case studies of representative patients developed in Study 2 (Chapter 4).

The purpose of this study was to examine the current prescription habits of Australian pedorthists when designing and altering footwear and insoles to achieve effective offloading for neuropathic plantar forefoot ulcer prevention and improved patient adherence.

The characteristics of the respondents are outlined in this chapter, followed by a detailed description of the prescription habits of Australian pedorthists for four 'typical' patients deemed to be at risk of diabetic neuropathic forefoot ulceration. The results include details relating to patient adherence, strategies recommended to overcome them, and evaluation techniques of the offloading success of the prescribed devices. The information has been presented in tables, figures and graphs as they fit and analysed contextually in the relevant sections.

5.1 Methods

5.1.1 Sample

The target population for the survey study were all Australian pedorthists registered with the Australian Pedorthists Registration Board (APRB). Searches through the PAA (Pedorthic Association of Australia, 2019) and APRB (Australian Pedorthists Registration Board, 2019) websites were performed, identifying all registered pedorthists. During the study period, 42 certified pedorthists practising in Australia were registered under the APRB (Australian Pedorthists Registration Board, 2019), and all pedorthists were sent an invitation to participate.

5.1.2 Survey development

A survey questionnaire was designed to evaluate the current practice of footwear and insoles prescription by certified pedorthists in Australia. Four hypothesised 'typical' or 'illustrative' cases were developed to evaluate common practice. The development of these cases is outlined in Chapter 4, section 4.4. The survey included multiple-choice questions and text input options as required.

The questionnaire had three sections:

1) Section 1 – case presentations: presentation of the hypothesised patients' diagnosis, comorbidities, psychosocial factors and sociodemographic information. These were formed by the findings from Study 2.

2) Section 2 – footwear prescription: questions regarding the footwear the participant would prescribe for each case. This included footwear type, upper design, upper materials, heel height, toe spring, heel counter, opening, fastening, modifications, rocker parameters, and sole materials. This included multiple-answer questions and open-text comments. The questionnaire also prompted respondents to outline challenges they would face while recommending therapeutic footwear from patients' adherence perspectives and what strategies they would consider overcoming those challenges.

3) Section 3 – insole prescription: Questions regarding the insoles the pedorthists would prescribe for each case. This included insole type, casting method and materials. This included multiple-answer questions and open-text comments. The questionnaire prompted respondents to outline challenges they would face while recommending insoles from patient adherence perspectives and what strategies they would consider overcoming those challenges.

Following this, a multiple-choice question was asked on how the pedorthists would measure the offloading success of the prescribed footwear and insoles.

The full questionnaire is available in Appendix 4.

An expert panel, comprising three senior Australian pedorthists with over 20 years of clinical experience, piloted this draft survey tool. In addition, the pathology and comorbidity sections of the questions were verified by five senior podiatrists, each of whom has more than five years of experience working in high-risk foot clinics in public tertiary hospitals. They reviewed the contents of cases and questions to ensure sufficient variety in the cases to elicit the full variety of practice and for the authenticity of the cases. A summary of the cases is provided in Table 4.7.

The attributes included in sections 2 and 3 of the questionnaire were derived from the systematic literature review conducted by the researcher (Ahmed et al., 2020) and Diabetes Feet Australia (DFA) guidelines on footwear for people with diabetes (van Netten, Lazzarini, et al., 2018). These documents outline the key recommendations on footwear type, footwear upper design, rocker sole design profiles, insole characteristics such as insole type, casting methods, insole materials, various components of the insole design feature, and patient adherence-related information.

The expert panel piloted the full questionnaire, and their suggestions were incorporated into the survey tool for the final version. Based on the feedback of the expert panels, the diagnosis and comorbidity domains (section 1) were simplified, and the information on the footwear and insole prescriptions to allow participants to enter commercial names of the materials was added.

5.1.3 Data Collection

The survey questionnaire was distributed via email using an online survey tool, Qualtrics (2023), to the pedorthists who were registered with APRB. The online survey was open for the pedorthists to respond to from 20 July 2020 to 30 August 2020.

5.1.4 Data Analysis

A descriptive analysis of footwear practice recommended by the participants was undertaken, including footwear type, upper design, type of opening and fastening, type of insole and casting methods for each of the four cases. Furthermore, a descriptive analysis was performed on the following parameters for footwear features: heel height, toe spring, upper, lining, padding between upper and lining, reinforcement and heel counter, rocker sole design

parameters, bottom construction materials (midsole, outsole, sole and wedge, heel), insole/orthoses design materials (insole base, mid-layer and top cover), other insole/orthoses design/modification features (additional arch support, metatarsal dome, metatarsal bar, metatarsal pad and local cushioning) for all four cases. Furthermore, an evaluation of how offloading success was evaluated for all four cases was undertaken. Also, a statistical test (Fisher's Exact Test) was conducted to investigate the association between the casting method of making insoles and the sociodemographic characteristics (Case, Gender and Age Group)

The frequency of each of the above-listed manufacture characteristics for footwear and insoles was calculated. Qualitative information from open text questions related to how adherence was managed and challenges faced were integrated and categorised into common themes and presented through various graphs such as scatter plots, spider web, stacked bars and funnel charts.

The data derived from the audit and survey study, in combination with the published research evidence (Ahmed et al., 2020; van Netten, Lazzarini, et al., 2018), were used to guide the effective footwear design and modification parameters to be used in the clinical trial with the series of N-of-1 trials (Study 4).

5.1.5 Ethical considerations

Ethics approval for this study was given by Southern Cross University Health and Human Research Ethics Committee, and the Approval number is 2020/028. Participating in the online survey was deemed to be consent to participate. This was considered a low-risk research project. All collected data were de-identified.

The ethical considerations for this study were the confidentiality of pedorthists. This was addressed by no individual or practice identified in any public dissemination of results, and the identity of the pedorthists was not identified in the survey results.

Four hypothesised cases were built in a manner that is commonly treated by the pedorthists in regular clinical practice; hence, there was no risk for the participant relating to participant data identification. As clinical data input was given by prescribing pedorthist based on hypothesised cases, there was no risk for a participant relating to clinician data or anonymity.

Disruption of work activities for pedorthists: Most pedorthists are small business owners, and they are generally very busy with their patients and technical work. So, the interruption of work was a consideration. However, pedorthists earned CPD points, which are essential to keep their professional registration active, and that was encouraging for the participating pedorthists to complete the survey. This helped them to meet some CPD criteria to get involved in research activities.

Pedorthists in Australia are smaller in number and need to serve a large group of the population; most of them have a large clinical load. The anticipated time required to complete the questionnaire was from three to five hours. This might have been a challenge for some pedorthists

However, the questions were sent to the participating pedorthists in a structured format via online survey tools Qualtrics, where they could save and exit and complete the rest later if they had other immediate priorities, and they were offered CPD points for participating in the survey.

There was a risk of people not wanting to share information because of 'commercial-in-confidence' issues. It has been addressed by ensuring the researcher would provide feedback to the profession and was using it to inform and improve the quality of the professional practice of pedorthists.

The researcher owns the pedorthic company "Foot Balance Technology", which provides pedorthic services to the targeted population of this study and is actively involved in the treatment of those participants. While another pedorthist employed at this clinic completed the questionnaire, this was de-identified prior to data analysis, and the researcher had no input into the completion of the survey by this colleague or asserted any influence during the completion of the survey.

5.2 Results

5.2.1 Participants

At the time of the survey, 42 pedorthists in Australia were eligible to participate in this study.

Overall, 19 pedorthists out of 42 responded to the online survey (45% response rate). Two follow-up reminders were sent from the survey database to those who were sent the initial survey participation invitations and had filled out questionnaires partially. Reminders were also sent to the pedorthists through the monthly newswire of PAA and some personal phone calls and emails by the PAA executive officer to the members to increase the survey participants of the pedorthists.

Participating pedorthists were eligible to receive continuing professional development points as a result of their participation in this study.

Of 19 participating pedorthists, at least 10 pedorthists answered all four case questionnaires. In total, 19 participants responded to Case-1. Fewer pedorthists responded to Cases 2, 3 and 4 (n=11 (26%), 10 (24%) and 10 (24%)). The ratio of the responses to each case was expected considering the complexity level of the cases that relate to the skills level and service offering capacity.

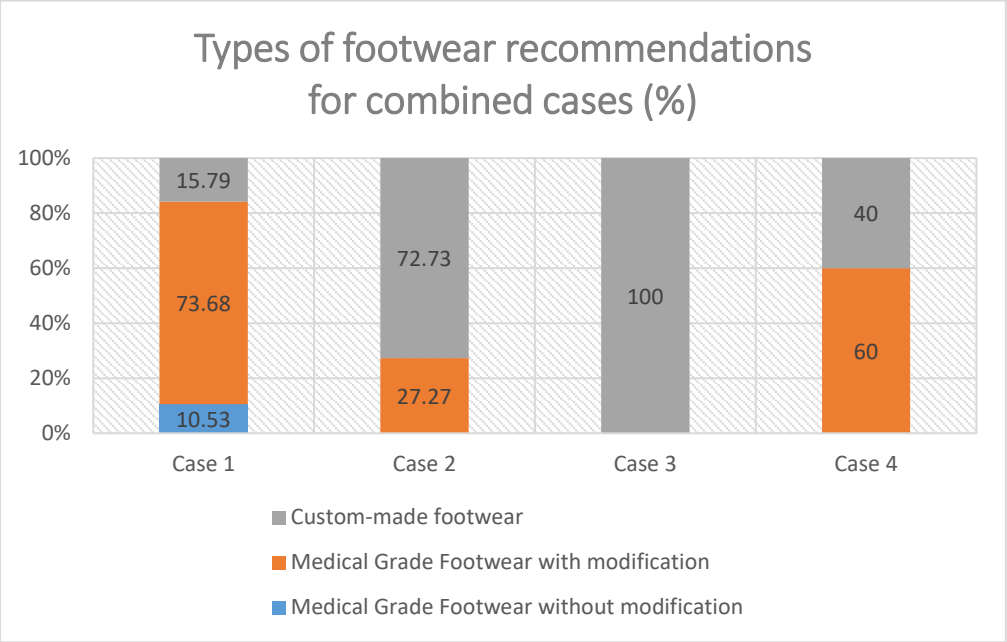
5.2.2 Footwear characteristics

The footwear characteristics of interest were footwear type, upper design, fastening system, heel height and toe spring, heel counter, materials for upper and lining, and footwear modifications to improve functions and usability. There were high levels of agreement in terms of upper-type, fastening systems and footwear modification recommendations for individual cases, but a great deal of variation around heel height and toe spring recommendations for individual cases. More consistency was seen for cases 3 and 2 and less for cases 1 and 4 in terms of the footwear characteristics recommendations.

These are outlined in more detail below with Figure 5.2 displaying the proportion of respondents recommending each overall footwear type (custom-made footwear or medical-grade footwear with or without further modification) for each case.

Figure 5.1

Types of Footwear Recommendations for Combined Cases



5.2.3 Upper design

Figures 5.2 and 5.3 shows the variation in recommendations from respondents regarding upper design, including overall design (low, bottine and above the ankle upper) and the degree (cm) of upper heights specified respectively.

Figure 5.2

Upper Designs Recommendation for Case-1, Case-2, Case-3, and Case-4 (Spider Web Graph)

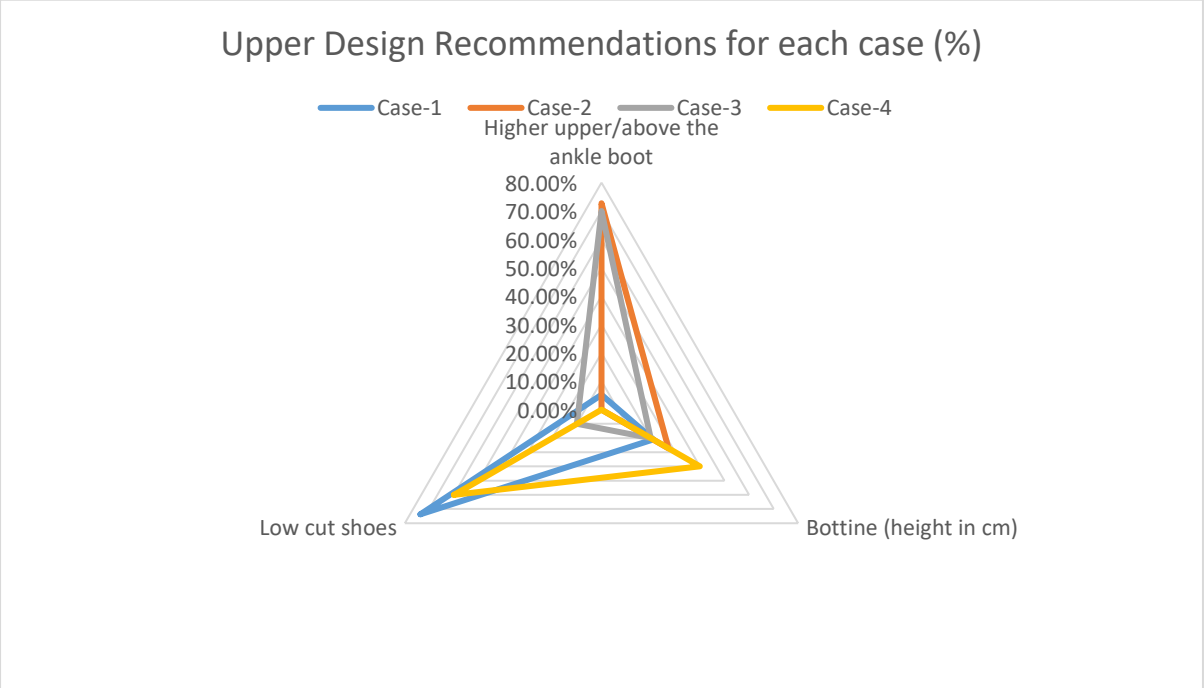
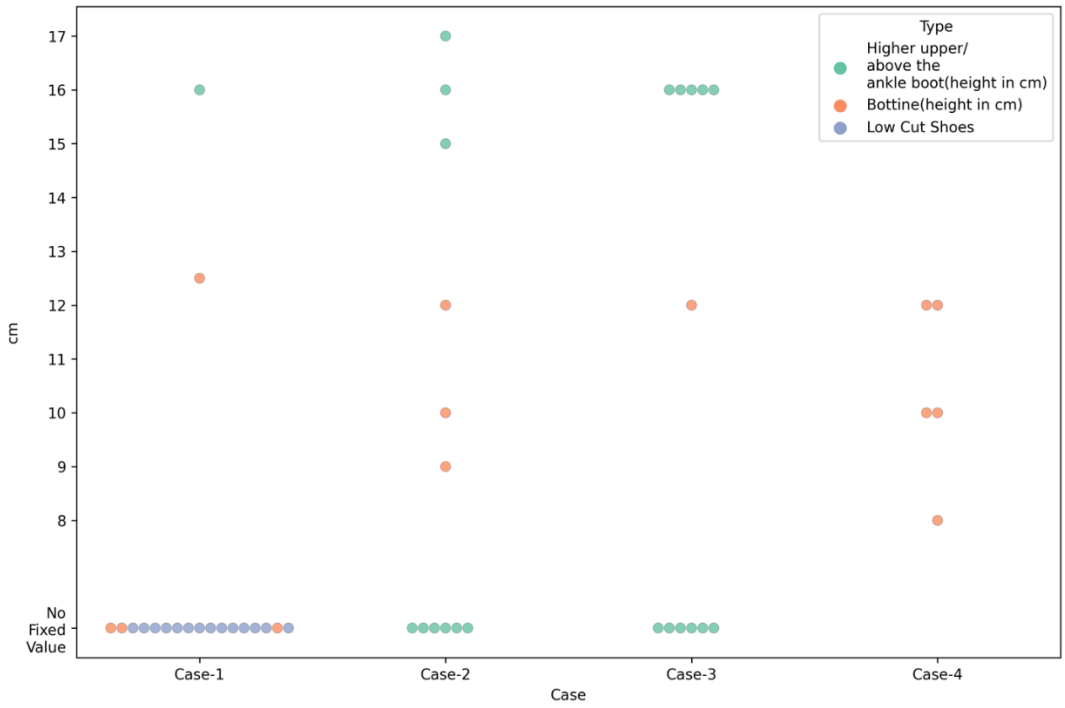


Figure 5.3

Upper Heights Recommendation for Case-1, Case-2, Case-3, and Case-4 (Scatter Plot)



5.2.4 Heel height

The recommendation by the pedorthists for heel height varies between 1cm to 3.5cm. Most respondents recommended around 2cm heel height (n=7 for Case-1, n=6 for Case-4) for women's shoes, whereas around 1 cm height was the second most recommended (n=5 for Case-1, n=4 for Case-4).

For men's shoes (Case-2 and Case-3), the commonly recommended heel heights by the pedorthists are around 1 cm, followed by around 2 cm heel height. Toe spring recommendations vary a lot, from 0.4 cm to 3 cm. Some participants commented on the balance issue of the person, and some tried to combine the rocker angle (Figure 5.10) and insole profile to determine the final functional toe spring. 1cm toe spring has been mostly preferred by the pedorthists for Case-1 (n=7) and Case-4 (n=4).

For Case-2 and Case-3, the recommended toe springs are a little higher due to the lower heel height recommendations because heel height and toe spring are recommended in reverse. The detailed recommendations on heel height and toe spring are presented in Figures 5.4-5.5 for

all four cases. The detailed information on recommendations for heel counters by pedorthists is in Table 5.1.

Figure 5.4

Heel Height Recommended for Case-1, Case-2, Case-3 and Case-4 (Scatter Plot).

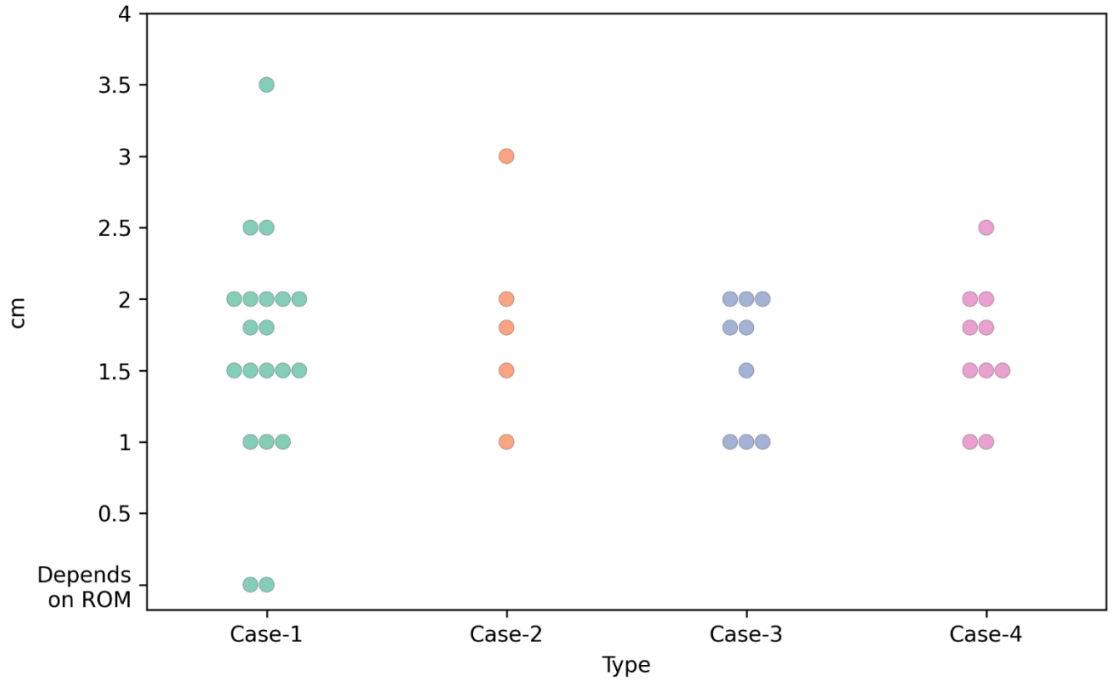


Figure 5.5

Toe Spring Recommended for Case-1, Case-2, Case-3 and Case-4 (Scatter Plot)

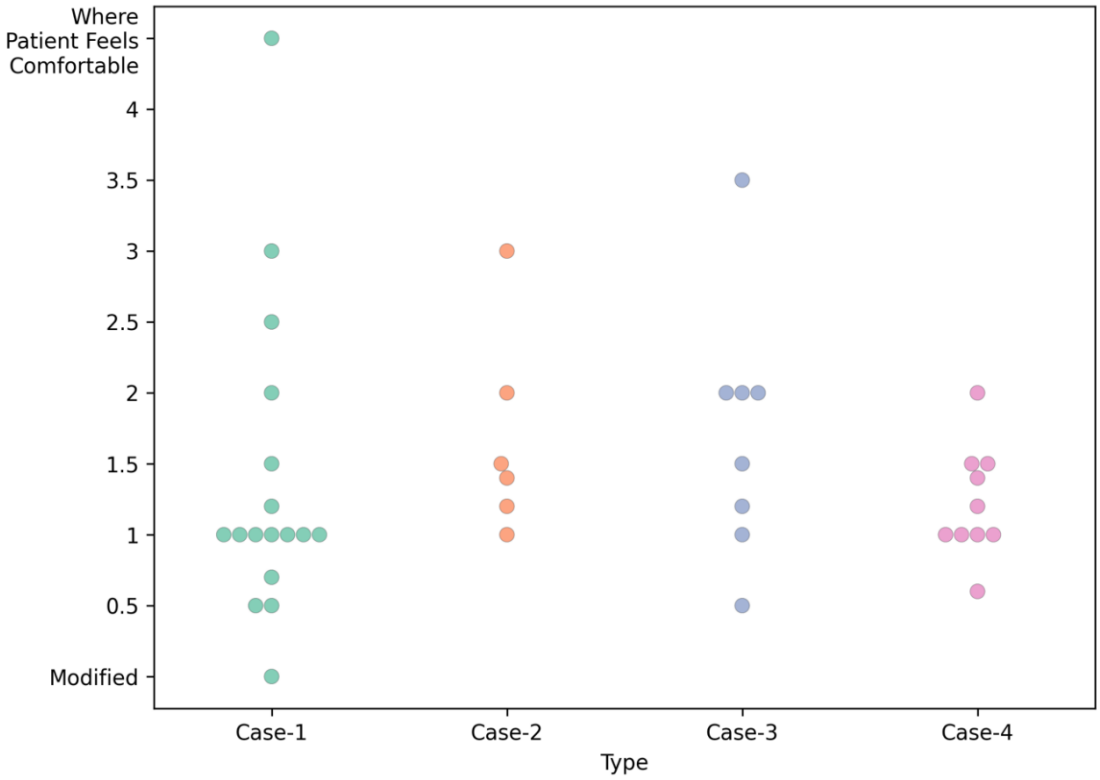


Table 5.1

Heel counter design recommended for Case-1, Case-2, Case-3 and Case-4

Parameters for footwear features	Case-1		Case-2		Case-3		Case-4	
	Description	**n**	**Description**	**n**	**Description**	**n**	**Description**	**n**
Heel counter type	Standard	12	Standard	2	Medial extended and reinforced	2	Medial/ lateral extended	1
	Extended medial	1	M & L elongated	1	Standard	2	Standard	6
	Lateral extended	1	Reinforced		Medial extended	2		
	Medial/lateral extended, reinforced	1	Reinforced extended medial/lateral	1	Extended medial& lateral	1		
	Medial extended	1	Lateral extended + reinforced	2	Medial Reinforced	1		
	Standard medial	1			Extended	1		

5.2.5 Opening and fastening

The variation in recommendations for opening and fastening for each case is displayed in Figure 5.6. Additional suggested types of fastening are outlined in Table 5.2 and material recommendations in Tables 5.3-5.6.

Figure 5.6

Type of Opening and Fastening Recommended for Case-1, Case-2, Case-3 and Case-4 (Spider Web Graph)

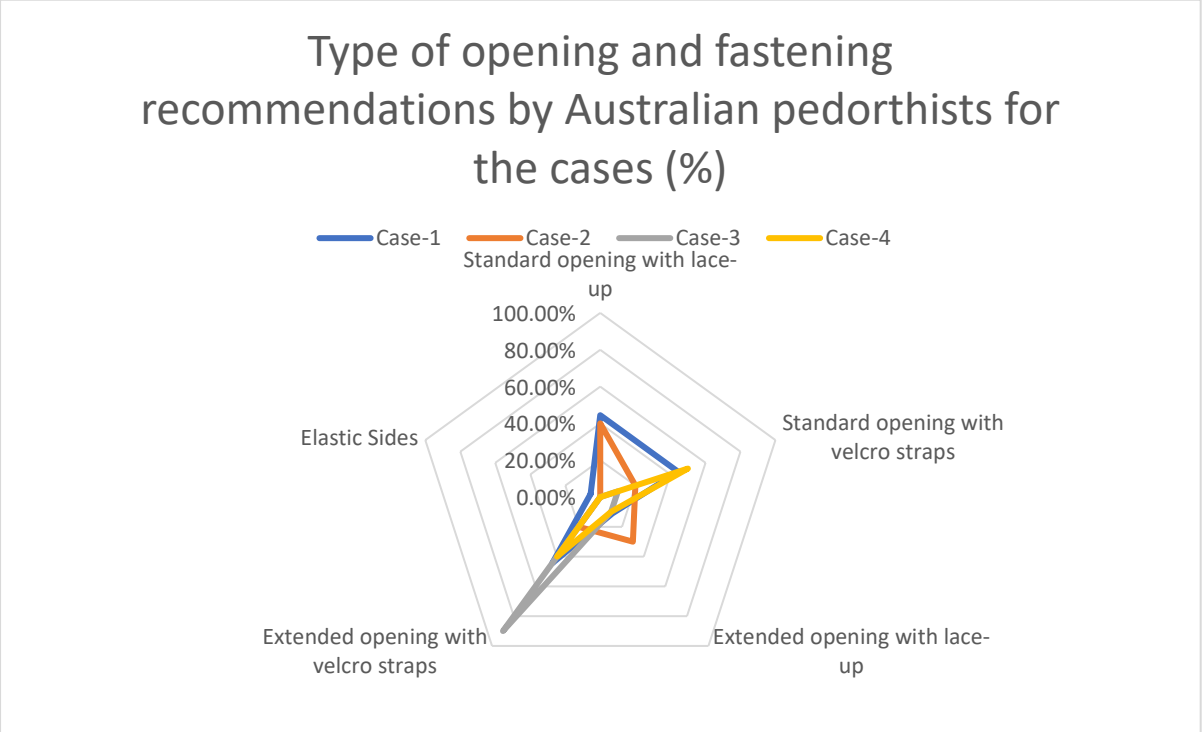


Table 5.2

Additional types of opening and fastening recommended for Case-1, Case-2, Case-3 and Case-4.

Parameters for footwear features	Case-1		Case-2		Case-3		Case-4	
	Description	**n**	**Description**	**n**	**Description**	**n**	**Description**	**n**
Type of opening and fastening	Neoprene padded topline	1	As an alternative to only lace-up	1	Medial zip	1	Forward opening	1
					Forward opening to aid easy access for the rigid flat foot into the shoes	1	Velcro selected due to RA may affect the hands	1

Table 5.3

Upper materials recommended for Case-1, Case-2, Case-3 and Case-4

Type of materials for the upper component	Case-1		Case-2		Case-3		Case-4	
	Description	**n**	**Description**	**n**	**Description**	**n**	**Description**	**n**
Upper	Leather	7	Combination of leather and fabric (breathable, if possible, like Gore-Tex)	1	Leather	8	Stretchable leather, neoprene, material	1
	Soft leather	3	Soft but durable Leather	3	Leather/ neoprene	1	Lycra stretch/leather combo	1
	Neoprene/ stretchable/ Lycra	1	Leather	11	Soft leather	1	Leather	2
	Neoprene & leather plug in the vamp	1					Soft leather	4
							Leather/neoprene	3

Table 5.4

Lining materials recommended for Case-1, Case-2, Case-3 and Case-4

Type of materials for the upper component	Case-1		Case-2		Case-3		Case-4	
	Description	**n**	**Description**	**n**	**Description**	**n**	**Description**	**n**
Lining	Leather	7	Leather	1	Leather	4	Soft leather with no seams in the toe area	3
	Diabetic lining Airnet	1	Leather Calf medium-weight	1	Leather/ neoprene	1	Stretchable leather, neoprene, material	2
	Soft non-leather	1	Diabetic lining Airnet	1	Leather seamless	1	Standard with the footwear	1
	Moisture wicking	1	Leather/ plastazote combination	1	Diabetic lining	1	Diabetic, non-seams	1
	Kangaroo leather	1	Antibacterial lining	1	Air net antibacterial lining	1	No seems soft non-leather	1
	Diabetes-friendly, non-leather	1	Diabetes-friendly, non-leather	1	Diabetes-friendly, non-leather	1	Leather/ synthetic	1
			Soft, no seams non-leather	1	No leather, no seams	1		
			Seamless leather	1				
			Synthetic	1				

Table 5.5

Padding between the upper and lining recommended for Case-1, Case-2, Case-3 and Case-4

Type of materials for the upper component	Case-1		Case-2		Case-3		Case-4	
	Description	**n**	**Description**	**n**	**Description**	**n**	**Description**	**n**
Padding between the upper and lining	Mole foam	1	As they come in prefab shoes	1	Plastazote	1	Plastazote	1
	Padded top line	1	0.2 cm foam forefoot	1	0.2 cm Topy Cellolite	1	Foam	1
	Collar and tongue	1	Plastazote	2	Latex/foam	1	Collar padding	1
	Latex	1	Collar & tongue	1	Tongue	1		
	Foam	1	Foam	1	Soft Urethane for the collar and tongue areas	2		
	Around the topline	1			Collar padding, tongue	1		
					0.3 cm	1		

Table 5.6

Upper reinforcement materials recommended for Case-1, Case-2, Case-3, Case-4

Type of materials for the upper component	Case-1		Case-2		Case-3		Case-4	
	Description	**n**	**Description**	**n**	**Description**	**n**	**Description**	**n**
Reinforcements	Stiff toe box to ensure depth	1	Anti-tear material	1	Shield tongue	1	Tape	1
	Toes	1	Tape	1	Tape	1		
	EVA	1	Counter	1	Extended M/L reinforced	1		
	The custom-made orthotic insert to offload plantar pressures	1	Strong toe cap	1	Tongue reinforcement	1		
	Buttress if required	1	Lateral buttress /bilateral		Reinforce the tongue and vamp amputated side	1		
	Anti-tear	1			1.8mm Rhenoflex heel stiffener	1		
	Non-extra	1						
	Good heel counter	1						

5.2.6 Other modifications

Footwear modification is a common recommendation for the cases, and the most common recommendation is a semi-rigid rocker sole design for Case-1 (n=10) and Case-4 (n=8), followed by a rigid rocker for Case-1 (n=6) and Case-4 (n=1). A rigid rocker sole design is also the most recommended for Case-2 (n=7) and Case-3 (n=9), and a buttress (n=6) and (n=4) for them, respectively. Re-lasting or widening (n=4) are also recommended for Case-1 as she has HAV that needs extra room on the right foot. For Case-2 and Case-3, the extra

room required is incorporated within the custom-made footwear design. Other footwear modifications include a stiffened outsole, toe-off rocker, deflection under the hallux, and re-lasting to accommodate the HAV and flared outsole. Figures 5.6, 5.7, and Tables 5.2 - 5.7 present the details of the above footwear parameters for all the cases.

Figure 5.7

Type of Footwear Modification Recommended for Case-1, Case-2, Case-3 and Case-4 (Spider Web Graph)

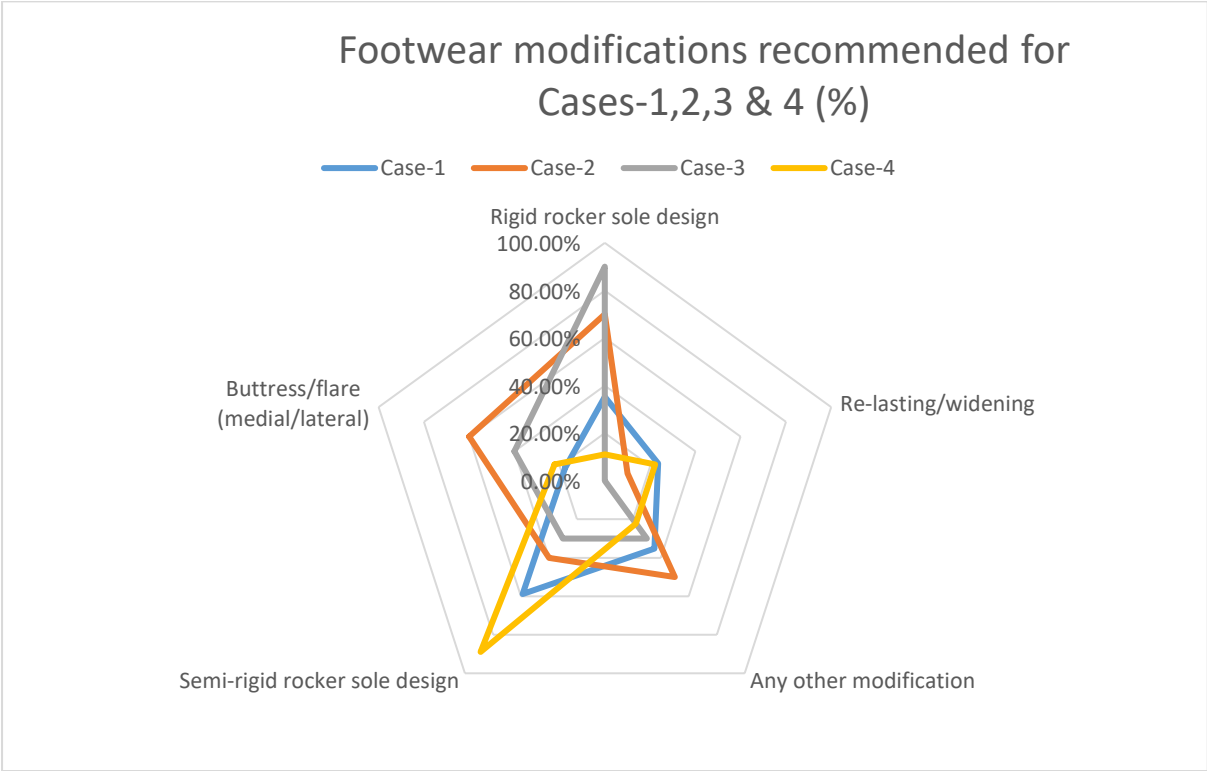


Table 5.7

Other types of footwear modification recommended for Case-1, Case-2, Case-3, Case-4

Type of footwear modification	Case-1		Case-2		Case-3		Case-4	
	Description	**n**	**Description**	**n**	**Description**	**n**	**Description**	**n**
Type of footwear modification	It depends on gait & stability	2	Possibly, depending on gait		Medial (R&L)	3	M/L flares bilaterally	1
	If required	1	Lateral flare	3	Medial flares bi-laterally	1	Buttress if needed	1
	Flared outsole	1	Lateral buttress on insole component	2	Rocker: left is rigid, right is semi-rigid	1	Stretch toe box to accommodate overriding digits	1
	Toe off rocker	1	Flare	1	Rigid rocker for the left	1		
	Offloading excavation for the hallux (can be in either shoe or orthosis or both)	1	Carbon fibre stiff sole (R)	2	The device is custom-made	1		
	Stiffened sole	1	Stretch or reblock upper at left 5th MPJ	1				
	Forefoot required widening to accommodate HAV	1						

5.2.7 Rocker sole design parameters

There was a common agreement on rocker sole apex position parameters and variations in apex angle parameters with greater variations in rocker angle parameters recommendations among the pedorthists. The reason for the variations is due to participants' stability, the

orientation of the metatarsal heads and the bony prominences such as region of interest to offload the plantar pressure.

Apex position recommendations for the cases vary in interpretation by the pedorthist, and the most common recommendations are at 55-60% of the length of the shoe for the cases, respectively. At 70% length ,the apex position is the second most recommendations for the cases, and 1cm proximal to the MTHs are common recommendations for all cases. Some pedorthists also recommended performing in-shoe pressure analysis to determine the apex position.

Apex angle recommendations range from 50-97 degrees, and this is mostly dependent on the alignment of the 1^{st} and 5^{th} MTHs. The most common recommendations are between 80-95 degrees for the apex angle.

Rocker angle recommendations vary between 10 to 30 degrees, and the most common recommendations are 10-12 degrees and 15 degrees for all cases. The participant's balance and in-shoe pressure mapping have also been recommended to determine the rocker angle.

The detailed descriptions and recommendations on the rocker apex position, apex angle and rocker angle are presented in Table 5.8 and Figures 5.8 – 5.9.

Table 5.8

Apex position design parameters recommended for Case-1, Case-2, Case-3 and Case-4

Rocker sole design parameters	Case-1		Case-2		Case-3		Case-4	
	Description	**n**	**Description**	**n**	**Description**	**n**	**Description**	**n**
Apex position	10 %	1	2 cm behind the previous ulceration site (% depends on the length of his foot)	1	2 cm behind 1st MPJ R)	1	It depends on the position of the 1st and 5th MPJ - probably 3 cm behind the joint line	1
	70%	2	Proximal to MTHs, approximately 1 cm, equal 2/3 (70%) from heel to forefoot	2	Proximal to MTHs, approximately 1 cm, equal 2/3 (70%) from heel to forefoot	1	Proximal to MTHs, approximately 1 cm, equal 2/3 (70%) from heel to forefoot	1
	2 cm behind MTHs 1-5 (R&L) depends on where the patient feels stable	1	50 %, and proximal to the past ulcer site	1	55-60%	3	60%	1
	Proximal to MTHs, approximately 1 cm, equal 2/3 (70%) from heel to forefoot	1	55-60%	3	1 cm proximal to MPTJ	1	55-60 %	3
	I would not recommend a rocker sole on this, but these are typically my normal setup – angles of 60	1	1 cm proximal from MPJ	1	60-65%	1	52%	1
	55-60 %	5	52%	2	Proximal to stump on the amputated side	1	60-70%	1
	Posterior to the met-heads	1	Based on the foot angle	1	40% or 50% on the amputated side, depending on the stump	1	Based F-scan data	1
	Relevant to the abduction of gait	1			Based on needs	1		

Figure 5.8

Apex Angle Recommended for Case-1, Case-2, Case-3 and Case-4 (Scatter Plot)

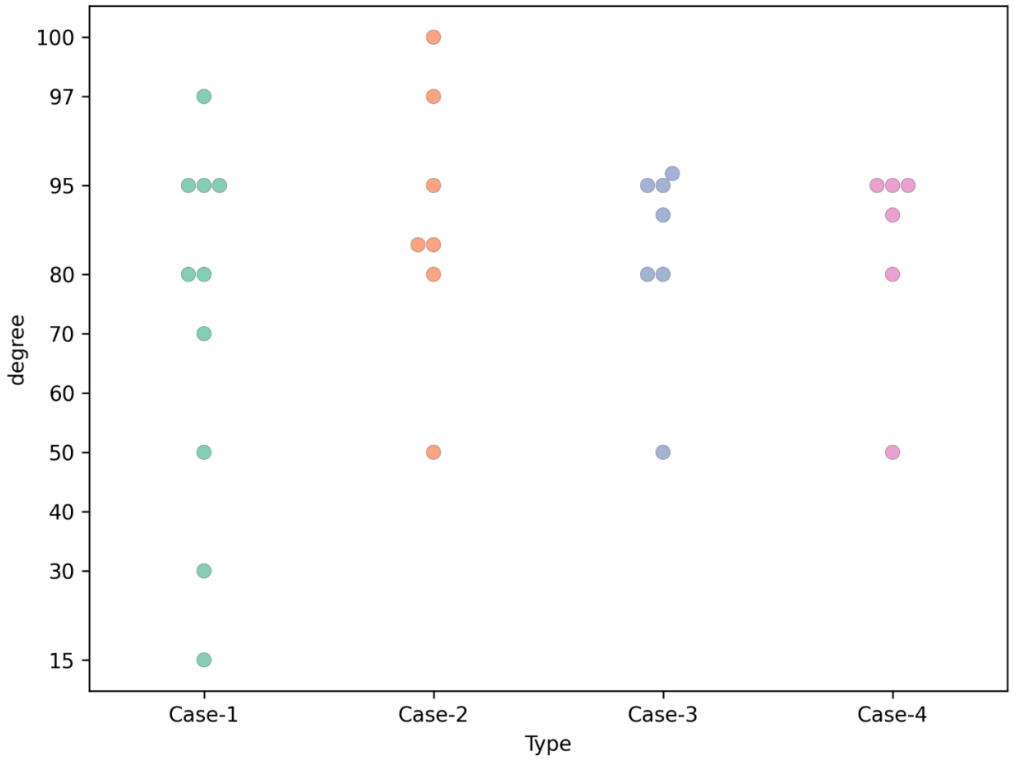
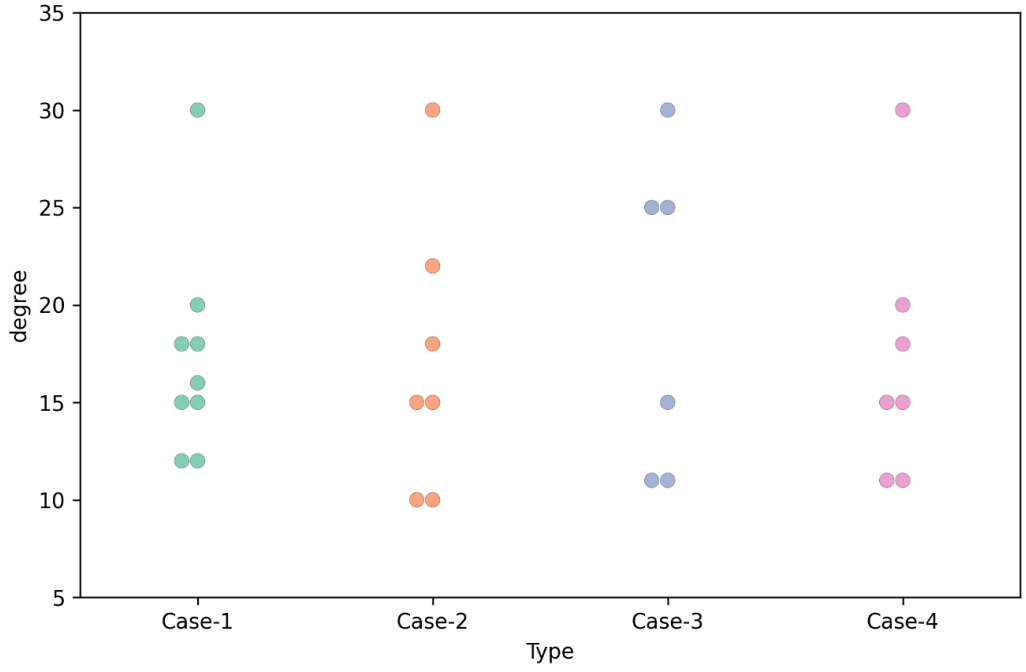


Figure 5.9

Rocker Angle Recommended for Case-1, Case-2, Case-3 and Case-4 (Scatter Plot)



5.2.8 Sole materials and characteristics:

There was a high level of consistency between the pedorthists around recommendations of shoe materials and characteristics for outsole, midsole and heel but there were some levels of disagreement around sole and wedge materials recommendations. More variation for cases 1 and 4 than for cases 2 and 3.

EVA was the most recommended midsole material for all cases by the pedorthists, and the shore value of the recommended EVA ranged from 35 to 80. Mid-range density (35-45 Shore A) EVA is the most preferred by the pedorthists when it comes to the midsole materials selection.

Non-slip rubber is the most preferred outer sole material by the pedorthists for the cases, and hard-wearing EVA and cellosoft rubber are the other recommended outsole materials by the pedorthists. Heel materials recommendations have similar choices as the outer soles.

Sole and wedge are common recommendations for the cases by the pedorthists, and a combination of EVA wedge and non-slip rubber or Topy outer layers are the most common preferences by the pedorthists when it comes to the sole design. Tables 5.9 - 5.12 present more detailed descriptions of the midsole, outer sole, heel, sole and wedge materials that are recommended by the pedorthists for the cases.

Table 5.9

Midsole materials recommended for footwear bottom construction of shoes for Case-1, Case-2, Case-3 and Case-4

Materials recommended for footwear bottom	Case-1		Case-2		Case-3		Case-4	
	Description	**n**	**Description**	**n**	**Description**	**n**	**Description**	**n**
Midsole	EVA, softer for cushion	1	EVA shore A40-45	3	EVA shore A45	3	EVA shore A40	2
	EVA	2	EVA Shore A80	3	Mid-density EVA generic brand	1	Low-density EVA generic brand	1
	EVA Shore A80	1	EVA	3	EVA 80 shore	4	EVA	2
	EVA Shore A45	3					EVA Shore A60	1
	EVA Shore A60	1					EVA Shore A35	3
	PU or EVA Shore A35-45	1						
	EVA (Shore A~40)	1						
	EVA or PU firm	1						

Table 5.10

Outsole materialrecommended for the bottom construction of shoes for Case-1, Case-2, Case-3, Case-4.

Materials recommend-ed for footwear bottom	Case-1		Case-2		Case-3		Case-4	
	Description	**n**	**Description**	**n**	**Description**	**n**	**Description**	**n**
Outsole	High wear rubber	1	Commando Soles	1	Rubber or EVA non-slip	1	EVA non-slip	1
	EVA	1	One-piece full-length Vibram trekking flat sole Full length	1	0.6 cm cellosoft Topy	1	0.3 cm Topy cellosoft	1
	Cellosoft Topy	1	Rubber	1	Rubber carbon fibre plates	1	Rubber/EVA	1
	Rubber/ Topy	1	Grippie Vibram Tank	1	Topy Cellotop	1	Vibram Clivia	1
	Non slip Vibram Clivia	1	Vibram Clivia Non slip	1	Topy Crock	1	Light anti-slip	2
	Rubber with an anti-slip profile	1	Durable rubber for bush	1	Rubber, non-slip	2	0.4 cm rugged	1
	Cellotop (~50D shore)	1	Strong profile for bushwalking	1	0.6 cm rugged	1		
	An anti-slip, active person	1	0.6 cm rugged	1				
	0.4 cm rubber rugged	1						

Table 5.11

Heel materials recommended for bottom construction of shoes for Case-1, Case-2, Case-3, Case-4

Materials recommend-ed for footwear bottom	Case-1		Case-2		Case-3		Case-4	
	Description	**n**	**Description**	**n**	**Description**	**n**	**Description**	**n**
Heel	EVA	1	3.5 cm	1	0.6 cm cellosoft	1	0.6 cm cellosoft	1
	Rubber or EVA depends on the activity levels of the patient	1	One-piece full-length Vibram trekking flat sole Full length	1	Rubber	1	Rubber	1
	Mid-density EVA	1	Rubber	1	Vibram Tank	1	Vibram Tank	1
	Rubber	1	Wedge	1				
	Topy Winter	1	Topy Winter	1				
	Full wedge heel preferred	1						

Table 5.12

Sole & Wedge materials recommended for bottom construction of shoes for Case-1, Case-2, Case-3, Case-4

Materials recommend-ed for footwear bottom	Case-1		Case-2		Case-3		Case-4	
	Description	**n**	**Description**	**n**	**Description**	**n**	**Description**	**n**
Sole & Wedge	EVA	1	Vibram pre-formed hiking long soles	1	EVA or rubber non-slip	3	EVA with non-slip sole	1
	Rubber or EVA depends on the activity levels of the patient	1	Rubber	1	EVA Vibram	1	Vibram	2
	EVA Vibram shore A60	2	EVA	1	Rubber	1	928 wedges, EVA	1
	Mid-density EVA generic	1	EVA wedge Shore A65 + full rubber (Vibram)	1	EVA	1		
	Rubber /Topy	1	Preferred heel sole wedge	1	Vibram	1		
	EVA, Shore A45	3	Vibram	1	Wedge, 924	1		
	Non-slip top	1	928 wedge, EVA 400	1				
	Vibram	1						

5.2.9 Insole characteristics

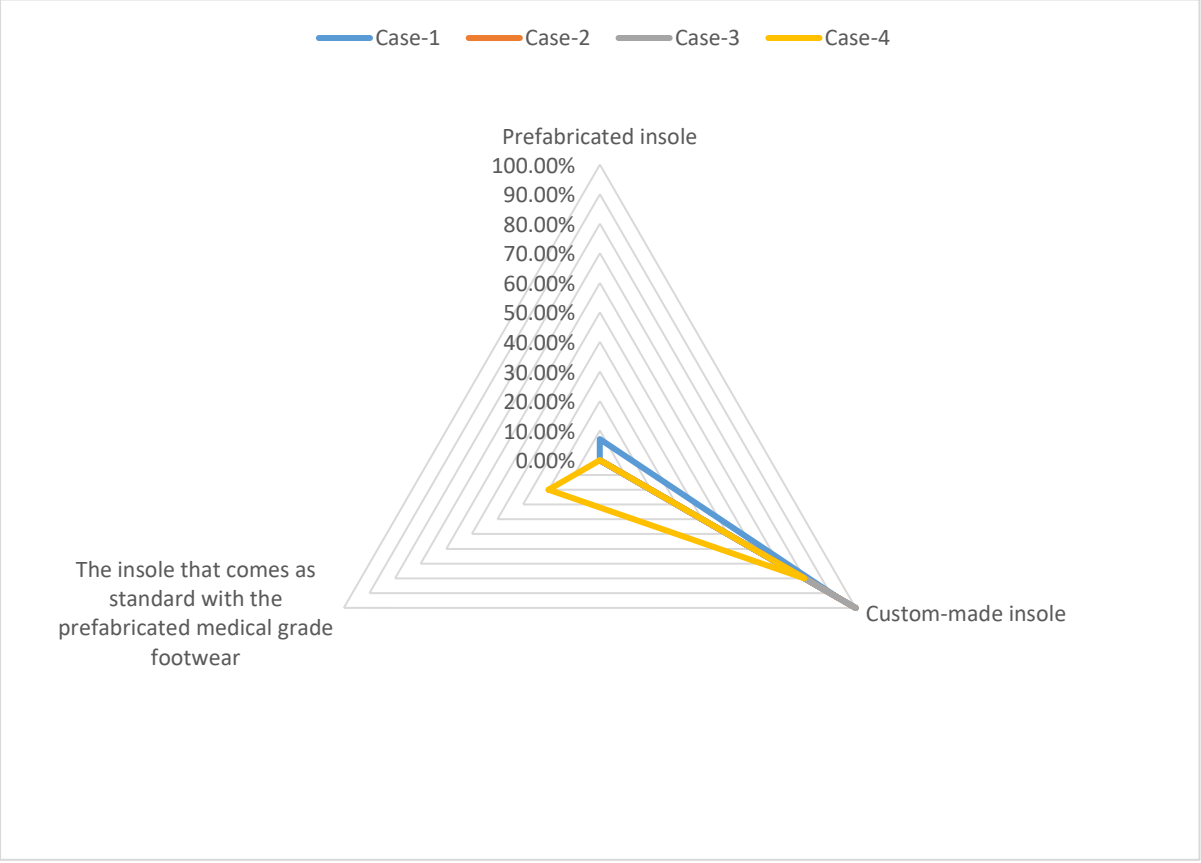
There is consistency in recommendations for insole type for the cases, with some variations in case 4. There are somevariations in recommending insole materials type by the pedorthist. There are more variations in recommendations for cases 1 and 4 and fewer variations in cases 2 and 3 when it comes to insole material recommendations.

5.2.10 Insole type

Three different types of insoles were recommended by the pedorthists for the cases, including prefabricated insoles, custom-made insoles and the insoles that come with prefabricated medical-grade footwear. Among them, the custom-made insoles are the predominant recommendations for all the cases (n= 13, 10, 10, 8 for each case), and in some cases, this is the only recommendation.. Figure 5.11 describes the type of insole recommendations for the cases by the pedorthists.

Figure 5.10

Type of Insole Recommendations for Case-1, Case-2, Case-3, and Case-4 (Spider Web Graph)



5.2.11 Casting method

Casting method recommendations also vary in pedorthists' choices, and the most preferred casting methods are non-weight-bearing casting followed by semi-weight-bearing casting.

The full-weight-bearing casting method is the least recommended casting method (n=1) by the pedorthists. Tables 5.13 describe the various casting methods and recommendations for the cases by the pedorthists.

Table 5.13

Casting method for making insoles for Case-1, Case-2, Case-3 and Case-4

Casting Methods	Case-1		Case-2		Case-3		Case-4	
	%	n	%	N	%	n	%	n
Non-weight-bearing	50.00%	7	50.00%	5	50.00%	5	66.67%	6
Semi-weight-bearing	42.86%	6	50.00%	5	40.00%	4	33.33%	3
Full-weight-bearing	7.14%	1	0.00%	0	10.00%	1	0.00%	0
	100%	14	100%	10	100%	10	100%	9

5.2.12 Insole materials

Insole design involves decisions on various materials used for different layers with various densities and hardness of materials based on the requirements and cases. EVA of various thicknesses and hardness is the most common recommendation for insole design as the base layer. The insole thickness recommendation is 0.5 to 1.5 cm, and the shore value is between 35 to 65 shore A. Table 5.14 presents the detailed recommendations on insole base layer material, thickness and hardness.

Table 5.14

Insole base materials recommended for Case-1, Case-2, Case-3, Case-4

Insole/ Orthoses design materials	Case-1		Case-2		Case-3		Case-4	
	Description	**n**	**Description**	**n**	**Description**	**n**	**Description**	**n**
Insole base material and thickness in cm	EVA 1.5 cm	2	EVA 1.5 cm	2	EVA Shore A35-40	2	EVA shore A30	1
	Heat moulded Relux	1	Heat moulded Relux	1	Tri-laminate/ cork 1.5cm	1	Tri-laminate/ cork 1.5cm	1
	Qform 0.14 cm from heel to metatarsal heads line	1	Qform 0.14 cm from heel to metatarsal heads		High-density EVA Generic	1	Qform 0.14 cm	1
	EVA 1 cm	1	EVA shore A35-40	1	0.6 cm Thermocork X 2	1	EVA 0.5 cm	1
	EVA Cork Shore A65	1	O.3 cm	1	0.3 cm	1	EVA Cork Shore A45	1
	EVA shore A35-40	2	EVA 1 cm	1	EVA 1 cm	1	EVA shore A35	1
	EVA 3/4 length	1	EVA Cork Shore A65	1	EVA shore A45 - 50	1	3/4 length EVA	1
			EVA 3/4 length		Hard EVA 3/4 length	1	EVA 1.5 cm ground to zero at peak	1
					EVA 1.5 cm ground to zero at the apex	1		

Medium-density EVA (Shore 30-35A), PPT or Poron, Qform are the commonly recommended mid-layer materials for insole design. The recommended thickness of PPT or Poron is between 0.3-0.6 cm, and other recommended materials are XRD Poron, cellolite and dual-density Urethane. Table 5.15 presents a detailed description of mid-layer materials for the insole design for the cases.

Table 5.15

Insole mid-layer materials recommended for Case-1, Case-2, Case-3, Case-4

Insole/ Orthoses design materials	Case-1		Case-2		Case-3		Case-4	
	Description	**n**	**Description**	**n**	**Description**	**n**	**Description**	**n**
Insole mid-layer material and thickness in cm	PPT 0.3-0.6 cm	1	PPT 0.3-0.6 cm	1	EVA shore A35 and PPT (Poron)	1	EVA shore A30	1
	Q-form	1	Q-form	1	Tri-laminate PPT/Poron/ Plastazote	1	0.3cm dual-density Urethane	1
	Mid-density EVA full-length	1	Mid-density EVA full-length	1	6mm Poron	1	Poron + layer of EVA Shore A30	1
	0.3 cm Poron blue	1	0.3 cm Poron blue	1	0.6 cm EVA 220	1	Poron / PPT	1
	Dual-density Urethane 0.5 cm	1	0.3 cm	1	0.3 cm	1	0.5 cm Poron	1
	0.3 cm slow-release Poron	1	Dual-density Urethane 0.5 cm	1	Dual-density Urethane	1	65 celolite, 0.6 cm	1
	Shore A35 0.6cm and Poron / PPT 0.6 cm	1	3mm slow-release Poron	1	Slow-release Poron, EVA Shore A35	1		
	0.6 cm Poron	1	Shore 35 0.6 cm and poron / ppt 0.6 cm	1	EVA shore A35 and PPT / Poron	1		
	0.6 cm XRD Poron	1	0.6 cm Poron	1	0.5 cm Poron	1		
			0.6 cm XRD Poron	1	0.6 cm XRD Poron	1		

A number of materials were recommended as insole top covers by pedorthists. The most commonly used top covers were 0.3-0.6 cm thick, softer density EVA (Shore 20A) and 0.2-0.6 cm thick Plastazote. Supersoft Poron and smooth, shiny leather are were recommended by some pedorthists. The insole top cover materials recommendations are described in Table

5.16, and Table 5.17 illustrates any additional information provided by the pedorthists for the insole design.

Table 5.16

Insole top cover design materials recommended for Case-1, Case-2, Case-3, Case-4

Insole/ Orthoses design materials	Case-1		Case-2		Case-3		Case-4	
	Description	**n**	**Description**	**n**	**Description**	**n**	**Description**	**n**
Insole top cover material and thickness in cm	EVA 0.3-0.6 cm	1	EVA 0.3-0.6 cm	1	EVA shore A20, 0.3-0.6 cm	1	EVA shore A20 0.3-0.4 cm	1
	EVA 0.45 cm	1	EVA 0.45 cm	1	Tri-laminate is complete	1	Tri-laminate	1
	0.4 cm cellolite with Smooth, shiny leather full length 0.1cm	1	0.4 cm cellolite with smooth, shinny leather full length 0.1 cm	1	Smooth, shiny leather 0.1cm	1	0.6 cm Super soft Poron with smooth, shinny leather cover	1
	0.6cm Plastazote	1	0.6cm Plastazote	1	0.6cm Plastazote	1	EVA Perf A35 0.175 cm thickness	1
	Plastazote	1	0.2cm	1	0.2cm	1	0.2cm, EVA Shore A20	1
	0.3 cm Luna lastic, Shore A25	1	Plastazote	1	EVA Marilon Perf	1	0.3cm shore A20 EVA	1
	0.4 cm EVA shore A20	1	0.3 cm Luna lastic, Shore A25	1	EVA Shore A22	1	0.3 cm Plastazote	1
		1	0.4 cm EVA shore 20	1	0.4 cm EVA shore 20	1	0.2cm Plastazote	1
	0.2cm Plastazote	1	0.3cm Plastazote	1	0.5cm Plastazote	1		
			0.2 cm Plastazote	1	0.2 cm Plastazote	1		

Table 5.17

Insole design materials (additional information) recommended for Case-1, Case-2, Case-3, Case-4.

Additional information on insole materials	Case-1		Case-2		Case-3		Case-4	
	Description	**n**	**Description**	**n**	**Descript-ion**	**n**	**Description**	**n**
Additional information on insole materials	Full-length carbon plate for right with a prostheses toe spacer for missing hallux	1	Possibly cork inlays	1	Sanded thin at distal toes	1	Low-density EVA base to match the insole shape - no thickness	1
	0.6 cm EVA Shore A45 as middle layer lateral buttress, 1 cm support proximal cuboid by caving into the mould, 12 cm high buttress on lateral side bi-lateral	1	Full-length carbon plate for right with a prostheses toe spacer for missing hallux	1	Prosthetic element EVA shore A35	1	Dr Comfort gel insole with mods	1
			0.6 cm EVA Shore A45 as middle layer lateral buttress, 1 cm support proximal cuboid by caving into the mould, 12 cm high buttress on lateral side bi-lateral	1			Add to the bottom of the provided insole soft EVA and sand ding to grind out high-pressure points	1
							Soft prosthetic element shore A15 or less	1

Additional arch support to increase the contact area and to offload was recommended by some pedorthists. Common materials for the additional arch support re Slow-release Poron, and medium-density EVA. The recommended thickness was between 0.5-1 cm. Table 5.18 outlines the details for each case.

Table 5.18

Additional arch support design and modification features for Case-1, Case-2, Case-3 and Case-4

Other insole/ Orthoses design/ modification features	**Case-1**		**Case-2**		**Case-3**		**Case-4**	
	Description	**n**	**Description**	**n**	**Description**	**n**	**Description**	**n**
Additional arch support	Slow-release PPT 0.6 cm	1	Possibly	1	As the cast was taken, it should not need additional arch support	1	EVA shore A30, 1cm	1
	Cast from the foot, it should not need it	1	1 cm	1	as required	1	6 mm taken out of the mould	1
	As required	1	0.5 cm EVA	1	0.5 cm	1	0.6 cm EVA shore A35	1
	0.2 cm EVA	1	0.5 cm	1				
	0.6 cm	1						
	plus 1 cm	1						

Pedorthists commonly recommended a metatarsal dome between 0.3-0.6 cm thick, with 0.6 cm thickness being the predominantly recommended thickness, and the suggested materials are Poron or PPT. The positioning of the metatarsal dome was recommended proximal to the MTHs. Table 5.19 provides more information on the recommended metatarsal dome by the pedorthists.

Table 5.19

Metatarsal dome design and modification features for Case-1, Case-2, Case-3 and Case-4

Other insole/ Orthoses design/modification features	Case-1		Case-2		Case-3		Case-4	
	Description	**n**	**Description**	**n**	**Description**	**n**	**Description**	**n**
Metatarsal dome	Pre-1st and 5th MPJ - PPT - 0.6cm	1	PPT, behind 3rd MTH (L), 0.6 cm	1	Rt 1st MPJ. 0.6 cm PPT	1	0.6 cm PPT slow-release (Poron)	1
	0.4 cm proximal from MTH	1	220 EVA 0.6cm distal 3rd MTH left	1	0.6 cm Poron MD proximal to amputation site on L	1	Right pre met 0.6 cm Poron.	1
	Poron met done 0.6 cm	1	Poron Metdome	1			0.6 cm Poron MD R proximal 2nd MTH	1
	0.4 cm, proximal MTHs	1	0.5 cm met dome; proximal MTHs	1			0.4 cm taken out of the mould	1
	plus 0.8 cm	1	1 cm	1			0.6 cm Poron	1
	0.5 cm Poron	1	0.3-0.4 cm	1			0.3-0.4 cm	1

Pedorthists also recommended metatarsal bars for the cases, and common materials for the bars are EVA with 0.3-0.8 cm thickness and medium density and Poron with 0.6 cm thickness. More information is provided in Table 5.20.

Table 5.20

Metatarsal bar design and modification features for Case-1, Case-2, Case-3 and Case-4

Other insole/ Orthoses design/modification features	Case-1		Case-2		Case-3		Case-4	
	Description	**n**	**Description**	**n**	**Description**	**n**	**Description**	**n**
Metatarsal bar	EVA 0.3-0.6 cm behind metatarsal heads	1	EVA behind the metatarsal heads, min 0.6 cm	1			Possibly	1
	Proximal 1 cm approx., from the angle of the 1st to the 5th	1	EVA, depending on how he feels about offloading	1			Left 0.6 cm Poron pre MTHs #1-5	1
	0.8 cm	1	Pre # 3, #1, #5 met bilateral Mid density EVA 0.8 cm	1			0.6 cm Poron MB proximal L 4th-5th	1
	0.4 cm, prox MTHs	1	220 EVA 0.6 cm + proximal 1st-5th met heads	1				
	0.5 cm EVA Shore A35	1	0.4 cm proximal from MTHs	1				
			0.8 cm met bar; prox MTHs	1				

Pedorthists also recommended a metatarsal pad when indicated by the condition for the cases, and commonly preferred materials are Poron with 0.3-0.4 cm thickness. More information is provided in Table 5.21. The pedorthists have provided a number of additional information on insole design and modification, and the details are presented in Tables 5.22-5.23.

Table 5.21

Metatarsal pad design and modification features for Case-1, Case-2, Case-3 and Case-4

Other insole/ orthoses design/modification features	Case-1		Case-2		Case-3		Case-4	
	Description	**n**	**Description**	**n**	**Description**	**n**	**Description**	**n**
Metatarsal pad	As per In-shoe pressure mapping	1	Not recommend-ed	1	0.3 cm Poron blue proximal to 1st met head R/F	1	Not recommend-ed	1
	0.3 cm urethane	1			0.3 cm	1		
	0.3-0.4 cm				0.3-0.4 cm	1		

Table 5.22

Other insoles (orthoses) design and modification features (Local cushioning) for Case-1, Case-2, Case-3 and Case-4

Other insole/ Orthoses design/modification features	Case-1		Case-2		Case-3		Case-4	
	Description	**n**	**Description**	**n**	**Description**	**n**	**Description**	**n**
Local cushioning by removal of materials and adding cushion	Excavation in areas where high plantar pressure is present	1	Excavation under previous ulceration site	1	Plantar aspect and stump face – 0.6 cm Super soft Poron	1	Remove hard materials and replace them with slow-release Poron, under the boney proms bilaterally	1
	Qform to have a shape dropout at the right hallux	1	Left #3 MPJ, right #1 MPJ	1	Removal of approx. 0.3 cm under 1st R met and replaced with 0.3 cm Poron blue	1	SLR Poron at bony prominence	1
	Under 1st and 5th Urethane 0.3 cm	1	Slow release Urethane 3mm	1	Additional Poron	1	SLR Poron	1
	Offload 1st + 5th MTP, by adding to mould	1	0.5 cm offload under 5^{th}, 3rd MPJs by adding to the mould on the left side	1	0.6 cm SR Poron	1		
	Slow-release Poron 0.3-0.6 cm in the area of the closed ulcer	1	0.6 cm slow-release Poron	1				
	At ulcer site slow-release Poron 0.6 cm	1						

Table 5.23

Additional information on insoles design and modification features for Case-1, Case-2, Case-3 and Case-4

Other insole/ Orthoses design/modification features	Case-1		Case-2		Case-3		Case-4	
	Description	**n**	**Description**	**n**	**Description**	**n**	**Description**	**n**
Additional information on insole design / modification features	Excavation for hallux where ulcer has occurred	1	Prostheses toe spacer for missing R hallux	1	Medial buttress (R&L)	1	Toe filler poron/ plastazote	1
	Trial & test pressure	1	The depths and density of materials used will depend on supporting feet and controlling function	1	Left is a partial foot orthosis wrapping over the stump up to the dorsal midfoot - with a carbon plate. Right, no carbon plate	1	small prostheses spacer fitted to the left for missing digits.	1
	Right carbon plate or Qform to be full length (reduce, to reduce hallux plantar pressure in gait.	1			Carbon fibre plate	1	Mods based on F-scan	1
	A custom-made foot orthosis.	1			Prosthesis element on the amputated side	1		
	Reassessing high-pressure points	1			Prosthetic element, with the anterior shield to take the load away from the stump on amputated site	1		
	In-shoe pressure mapping to measure the effectiveness of the offloading (all is relative)	1			Toe filler left	1		
					All modifications based on F-scan findings	1		

5.2.13 Addressing adherence

Common challenges related to adherence described by the pedorthists in the survey were the appearance of the footwear, weight and profile, insole material and thickness that determine the depth of the footwear and adapting to shoe and insole modifications. Pedorthists reportedly apply and recommend various techniques to overcome adherence-related challenges in their practice.

Some common strategies are designing person-centric footwear, explaining the benefit of wearing the footwear that can reduce the risk of further complications, and footwear designed for specific intended use such as outdoor and indoor use, bushwalking and such. Cultural and gender-specific footwear design, intended use of the footwear, and engaging the client and family or friends in design-related decision-making with evidence from clinical assessment and plantar pressure-related data are some key techniques that the pedorthists apply, as reported by some pedorthists in the open text sections. A suitable fastening system, easy donning and doffing, instructions on the wearing-in process, review appointments to monitor adherence and outcome, necessary adjustments and referring back to referring podiatrist or multidisciplinary team, and advising on suitable fund options are also some approaches that pedorthists apply to increase adherence of the clients. More detailed information on pedorthists' common practice and adherence-related challenges and overcome techniques are presented in Figures 5.11 and 5.12. The total number of pedorthists who responded to Cases 1, 2, 3 and 4 are n=19, 11, 10 and 10.

Figure 5.11

Common Challenges with Footwear and Insole Recommendations for Case-1, Case-2, Case-3 and Case-4 (Spider Web Graph)

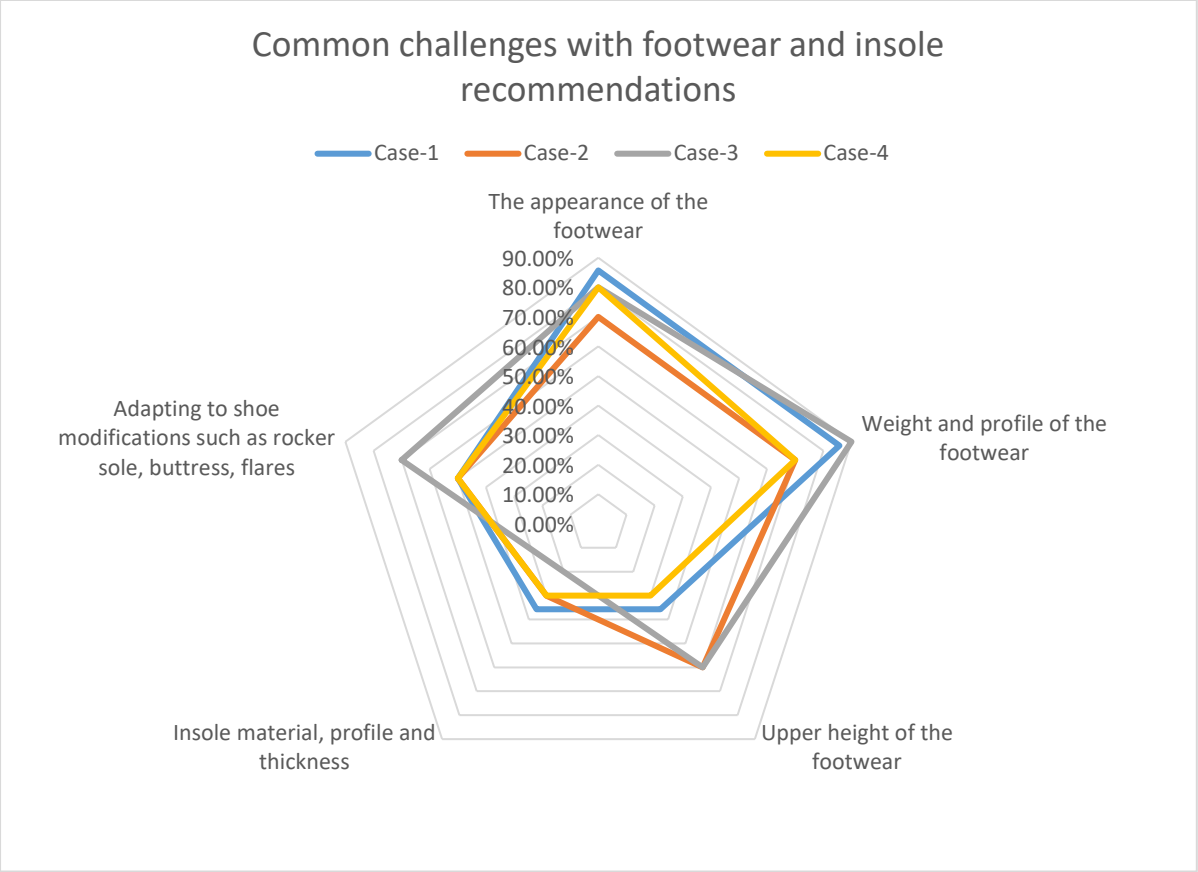
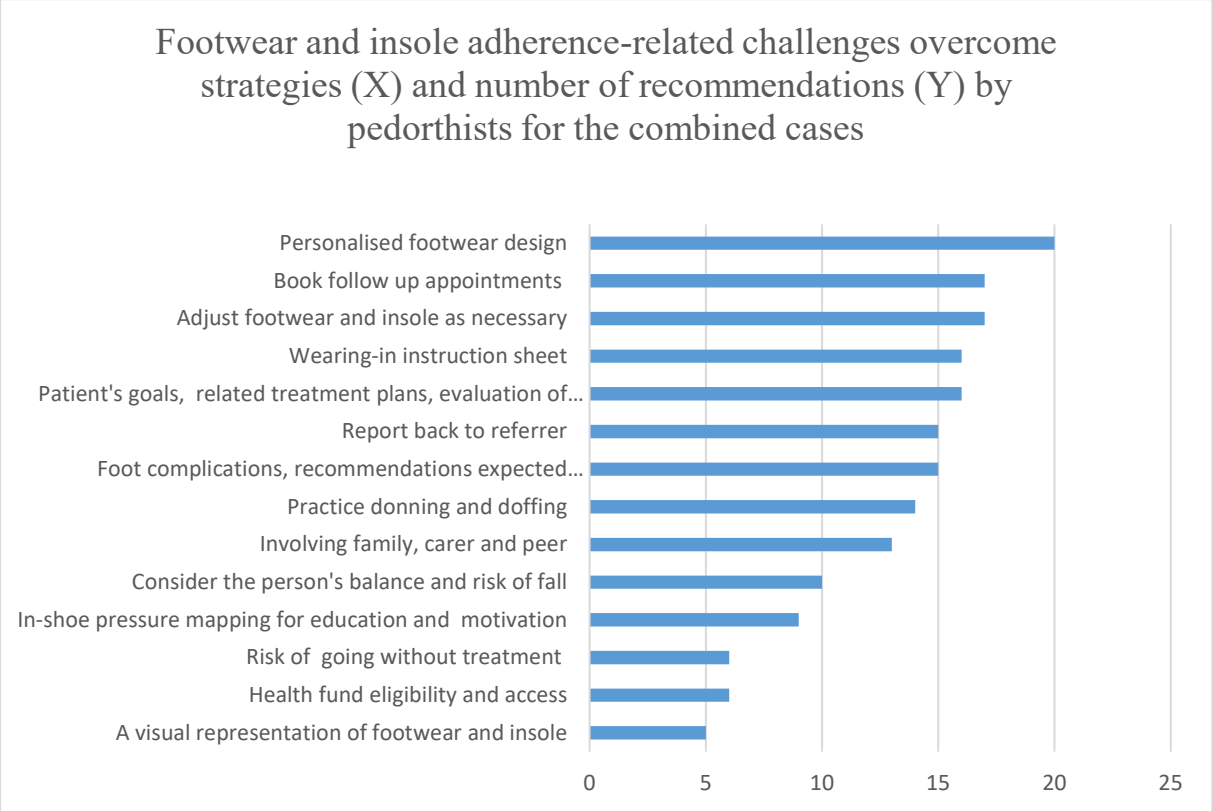


Figure 5.12

Footwear and Insole Adherence-Related Challenges Overcome Strategies by Pedorthists for the Combined Case (Bar Chart)

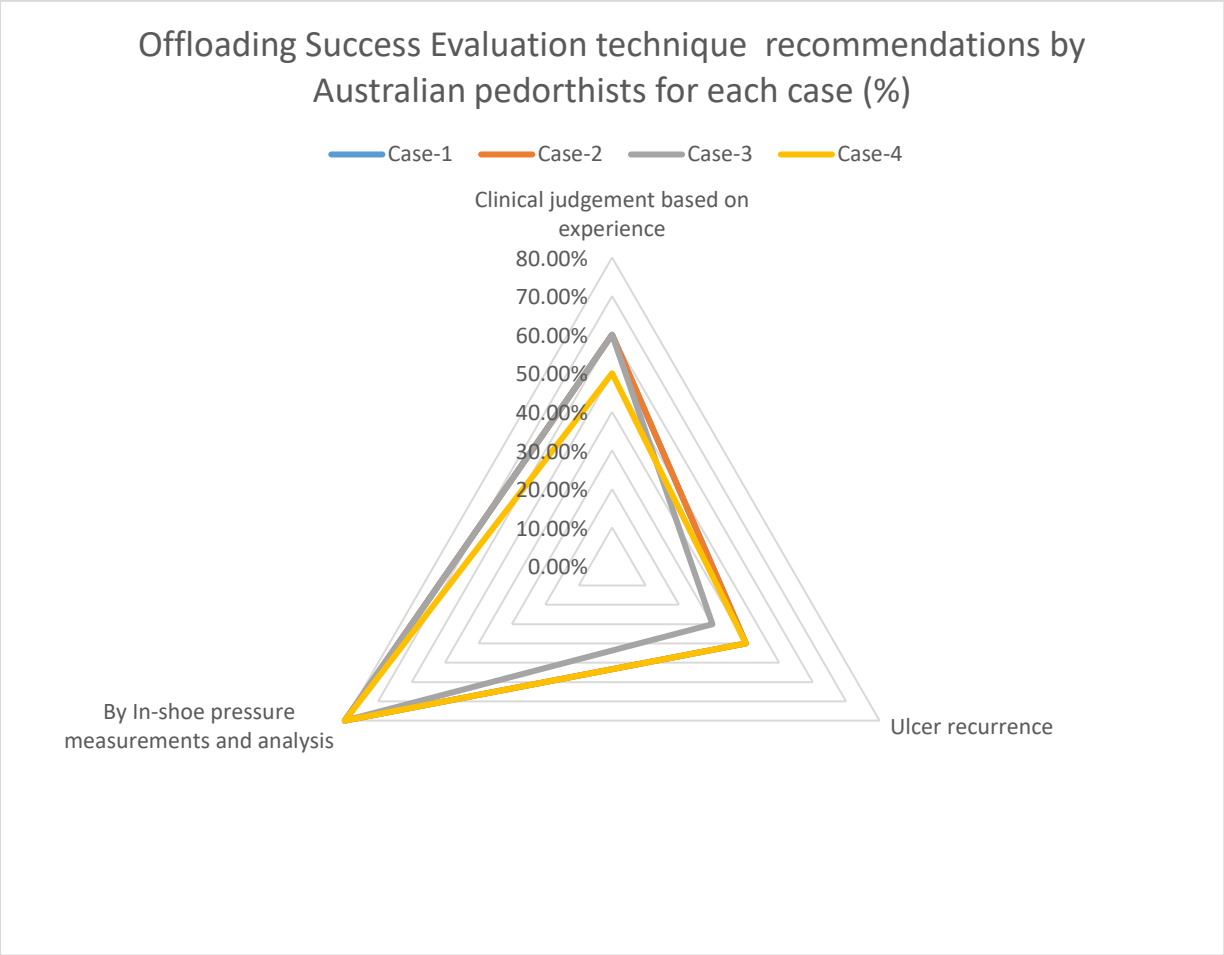


5.2.14 Evaluating the Plantar Pressure Offloading Success

Pedorthists use three different approaches to evaluate the offloading success of the prescribed devices: clinical judgements based on experience, recurrence of ulcers and in-shoe pressure mapping and analysis. In-shoe pressure analysis is the most commonly used method to evaluate pressure offloading success (n=11, 8, 8, 8), followed by clinical judgment (n=5, 6, 6, 5) and ulcer recurrence (n=5, 4, 3, 4) for each case. Detailed information for assessing the offloading success of the prescribed devices is presented in Figure 5.13.

Figure 5.13

Offloading Success Evaluation Techniques (Spider Web Graph)



The results from this Australian pedorthists survey have been used to inform current practices to test in the series of N-of-trials (chapter six) and built a knowledge base to recommend the footwear and insole prescription algorithms in chapter seven.

5.3 Discussion

The purpose of this study was to compare prescribing practices of Australian pedorthists when given four 'typical' patients at risk of diabetic neuropathic forefoot ulceration, to identify consistencies of patterns or differences in prescribing, and to examine whether there is agreement around the types of prescribing.

Complexity level and general assessment of the cases:

Case-1:The biomechanical factors in this case are simpler than subsequent cases, requiring less skill and technical knowledge to address , Hence, the response rate is highest for this case, and the recommendations in footwear type, upper height, heel height, and toe spring have the greatest consensus compared with other cases.

Case-2: This case is relatively complex in biomechanical aspects, and pedorthists with the qualifications of C Ped and C Ped CM were able to handle this case. Variations in footwear type recommendation are observed here, and that continues for other features such as upper height, heel height, rocker sole profile and insole design characteristics. The intended activity and lifestyle of the participant would influence the recommendations.

Case-3: This case is relatively complex in biomechanical nature, and pedorthists with the qualifications of C Ped and C Ped CM were able to handle this case. Case-3 also shows similar variations patterns to Case-2 except for the common consensus on custom-made footwear but variations in other footwear and insole parameters.

Case-4: This case is relatively complex biomechanically, and pedorthists with the qualifications of C Ped CM were able to handle this case. The main reasons are the over-riding digits that often require fully custom-made orthopedic boots, and only the C Ped CMs have the skill set to handle the case. The possible variations in footwear type recommendations also may vary due to age and gender-specific preferences on aesthetics, and custom-made footwear options could have been considered a barrier to adherence as the participant was a female.

This study has shown that for the most biomechanically simple patient(Case-1), there was a reasonable amount of consistency in prescribing footwear type, upper height, rocker profile, insole type and other insole design characteristics. The heel height and toe spring recommendations vary between respondents for Case-1. This could be what brand and style of footwear they could offer from the prefabricated medical grade footwear with modification, and the rocker sole modification would also re-define heel height based on

individual pedorthist's and patient's preferences, in-shoe pressure analysis data and balance issues.

For more complex cases such as (Cases 2, 3 and 4), there was a great deal of variation in prescribing approaches. This may be due to the different skill levels of the pedorthists to handle those cases and scope of practice (Pedorthic Association of Australia, 2019), available options of footwear type supply in their practices and variation in material supply for manufacture and modifying insoles, health fund availability, patient's preferences and intended activity. In Australia, pedorthists registered with APRB with three different skill levels (Pedorthic Association of Australia, 2019).

The survey allowed the participants to answer Case-related questions that were comfortable for them to answer and relevant to their regular scope of practice. Best practice (Ahmed et al., 2020; van Netten, Lazzarini, et al., 2018) would suggest that pedorthists recommend prefabricated medical grade footwear with modifications for the less complex cases such as Case-1 and custom-made footwear for the more complex cases such as Case-2 to Case-4. Similarly, based on existing practice guidelines (Kaminski et al., 2021; van Netten, Lazzarini, et al., 2018a), participants were expected to recommend custom-made insoles (foot orthotics) for all Cases (Ahmed et al., 2020; van Netten, Lazzarini, et al., 2018).

Ideally, in-shoe pressure mapping systems would be used to evaluate offloading success rather than clinical judgement and waiting on recurring ulcers (Ahmed et al., 2020; van Netten, Lazzarini, et al., 2018). However, variations were anticipated due to the different skill levels of the participating pedorthists, the scope of practice and available clinical and device-specific resources, the patient's preferences and suitability with the intended use, and available funds for therapy.

These results show limited consensus in prescribing practices, particularly as cases become more complex, although some features could be standardised in prescribing footwear (Bus, Zwaferink, et al., 2020). For example, a person with diabetes, neuropathy and a regular foot structure and no to minor foot deformity could be prescribed prefabricated medical grade footwear and additional modification for increased deformity level, and fully custom-made footwear for a complex foot structure and deformation. This approach is within the guidelines of DFA guidelines (van Netten, Lazzarini, et al., 2018) recommendations. A custom-made insole can be commonly recommended for a person with diabetes, neuropathy, and any foot

complications. One of the problems is that there are a lot of variations in prescribing practices but little evidence to support one approach over another. This research has explored the pathways to tighten up the variations in an evidence-based way.

All these variations in prescribing patterns, such as footwear and insole type, design and modification features, could be explored and standardised more for each case through a person-centric design approach. Hence, the variations were tested in a series of Trials to have a precise prescription for each individual for the foot pathology, comorbidity, intended activity, mobility status and personal preferences.

Overall, the purpose of this chapter was to identify variations in prescribing practices. Table 5.24 shows the extent of variations in consensus by Australian pedorthists in prescribing footwear and insole design and modification when they see various typical cases.

Footwear type

Whether it is custom-made or a prefabricated medical grade (Pedorthic footwear) footwear with or without modifications to be recommended, it is guided by foot pathology, foot structure, comorbidity and patient preferences. The variations are within the evidence in the literature (Ahmed et al., 2020; van Netten, Lazzarini, et al., 2018), and pedorthists follow the best practice statement as seen in the case responses.

Footwear upper height

There is a common practice of recommending higher upper for reducing plantar forefoot pressure, although there is a lack of scientific evidence for the influence of higher upper vs. low-cut shoes in the efficacy of plantar pressure reduction (Ahmed et al., 2020) but the higher upper may reduce shear forces inside the shoe at the forefoot by increasing contact area around the ankle (Praet & Louwerens, 2003). The upper height recommendation is based on foot pathology, comorbidity and mostly on the patient's preferences. The evidence in the literature is weak for upper recommendations (Ahmed et al., 2020), but pedorthists tend to make recommendations for ankle-high or even higher upper design for the complex foot when the patient agrees, and this approach is supported by the best practice statement (van Netten, Lazzarini, et al., 2018). For low complexity and when there is no pathological

indication for a higher-cut upper design, pedorthists commonly recommend a low-cut shoe, as seen in case 1.

Heel counter

Heel counter design is predominantly decided by the pedorthists based on foot pathology, and it is less influenced by the patient's choice as it is invisible, does not affect the appearance of the footwear, and the patient is more motivated by the comfort and ease of walking (van Netten, Lazzarini, et al., 2018)

Heel height and toe spring

Evidence for the above two design parameters is very limited in the literature (Ahmed et al., 2020). However, these are very important parameters for footwear design and influence the pressure offloading capacity and balance of the patient (Bus, Zwaferink, et al., 2020). For the prefabricated medical-grade footwear range, the heel height and the toe spring are guided by the footwear manufacturer's specification on the shoe last, and pedorthists sometimes modify them as per the foot and lower limb assessment and in-shoe plantar pressure data, also assessing the balance of the patient. Pedorthists use foot assessment outcomes, patient preferences, and balance to determine heel height and the toe spring as reported for the relevant cases. Hence, the recommendations on the heel height and toe spring represent such a variation.

Rocker profile

Apex position and apex angle are guided by the orientations of the MTHs (Ahmed et al., 2020; Bus, Zwaferink, et al., 2020). The variations in recommendations are generally due to offloading requirements, the target MTH, the patient's balance (Bus, Zwaferink, et al., 2020) and aesthetics requirements (Ahmed et al., 2020). The same factors also guide rocker angle recommendations, and the recommendations are within the range recommended in the best practice statements (Ahmed et al., 2020; van Netten, Lazzarini, et al., 2018).

Insole type

Custom-made insoles are the most common recommendation by the pedorthists for all cases with the least variations, and it is consistent with the evidence (Ahmed et al., 2020).

Casting method

The variations in the casting method for insole design are within two types of casting methods, and it is also within the range of variations in the literature (Ahmed et al., 2020). However, recent evidence recommends non-weight-bearing casting methods and digital optimisation of the cast for increased contact area and optimum offloading (Telfer et al., 2017).

Insole design characteristics

Variations in recommendation for these features are observed among the practitioners and the variations are for the metatarsal additions in the form of a metatarsal pad, bar or dome and their position thickness and materials (Ahmed et al., 2020). These features are also guided by the anatomical, biomechanical (Bus, Zwaferink, et al., 2020) and patients' feedback on comfortability and preferences (Ahmed et al., 2020).

Table 5.24

Summary of consensus on footwear and insole design and modification prescribing by Australian pedorthists

Legend	
>75% agreement	50-75% agreement
10-50% agreement	<10% agreement

Footwear and insole design and modification features		Agreements on recommendations by the pedorthists			
		Case-1	Case-2	Case-3	Case-4
Footwear type	Custom-made pedorthic footwear				
	Prefabricated pedorthic footwear				
	Prefabricated pedorthic footwear with modification				
Footwear upper height	Low cut				
	High cut/Bottine				
	Extra high cut				
Heel counter	Standard				
	Extended Med/Lat				
Heel height	1-2 cm				
	2.1-3 cm				
	3.1-3.5 cm				
Toe spring	0.5-1 cm				
	1.1-1.5 cm				
	1.6-2 cm				
	2.1-3 cm				
	3.1-3.5 cm				
Rocker profile	No rocker				
	Apex position at 50-60%				
	Apex position at 61-70%				
	Apex angle 80°-94°				
	Apex angle 95°-97°				
	Rocker angle 10°-15°				
	Rocker angle 16°-20°				
	Rocker angle 21°-25°				
Insole type	Prefabricated				
	Custom-made				
Casting method	Non-weight-bearing				
	Semi-weight-bearing				
	Full-weight-bearing				
Metatarsal additions	MLA increase 0.1-0.5 cm				
	MLA increase 0.6-1 cm				
	Metatarsal addition 0.5-0.8 cm				
	Location 0.4-1 cm prox MTHs				
Insole modification	Removal of hard material				
	Local cushioning				
	Replacement of top cover				

Table 5.25

Summary of evidence on footwear and insole design and modification prescribing by Australian pedorthists

Intervention	Treatment goal	Strength of evidence	Current pedorthic practice
Footwear type and upper height	Protect the foot Accommodation for a specific activity Aesthetics Plantar pressure reduction	Good evidence for footwear-type recommendations Limited evidence for upper height Patient preference plays an important part Cost is an important determinant	Wide variations in practice based on upper type, upper height and upper material.
Heel height	Reduce forefoot plantar pressure Increase propulsion Minimise the risk of falling Aesthetics	Good evidence for plantar pressure offloading efficacy and influence on balance	Variations in practice according to pedorthists' choices on heel height selection for individual cases. There is sufficient evidence to recommend heel height between 1-2 cm for optimum forefoot plantar pressure offloading
Toe Spring	Reduce forefoot plantar pressure Increase propulsion Minimise the risk of falling Aesthetics	Good evidence for plantar pressure offloading efficacy and influence on balance	Variations in practice according to pedorthists' choices on toe spring height selection for individual cases. Common agreement on 0.5-1.5 cm toe spring for the individual cases
Rocker Profile	Reduce forefoot plantar pressure Increase propulsion Minimise the risk of falling Aesthetics	Strong evidence for plantar pressure offloading efficacy and influence on balance	Variations in practice according to pedorthists' choices on rocker apex position and rocker angle selection for individual cases. Common agreement on apex position at 50-60% length of the shoe, rocker apex angle between 95°-97°, rocker angle 10°-15° for the individual cases.
Insole type and insole casting methods	Increase the base of contact and cushion under the foot Reduce forefoot plantar pressure Reduce mechanical pressure and stress on the foot plantar tissue	Strong evidence for plantar pressure offloading efficacy and influence on comfort level	Common agreement on insole type and variations in practice according to pedorthists' choices on casting methods where non-weight bearing and semi-weight bearing casting methods are most popular choices by the pedorthists.
Insole modification	Reduce peak plantar pressure Reduce mechanical pressure and stress on the foot plantar tissue Increase comfort level	Strong evidence for plantar pressure offloading efficacy and influence on comfort level	Common presentation in practice according to pedorthists' choices on the removal of hard material and adding local cushioning, variations in choices of topcover replacements.

5.4 Limitations of this study

One limitation of this study was the small sample size. Each case had between 19 and 10 respondents, perhaps in part due to the length of the survey. However, pedorthics is a new and growing profession in Australia, and the number of registered pedorthists in Australia is very low. The response rate was reasonable overall and resulted in many variations in prescription represented. As the purpose of this study was to understand variations in current practice, this study helped to achieve this within the existing Pedorthic workforce.

Another limitation is that in the survey format, standardised cases were used, which may limit to what extent it reflects real practice. As the cases were standardised and there was no face-to-face consultation with a real person, some of the person-centric information could have been missing that could influence prescription. Furthermore, all persons with diabetes accessing pedorthics services are complex psychosocial factors that interact with chronic disease. We are limited in the ability in this format to explore all these aspects. However, cases were developed using audit data and reviewed by clinicians to mitigate this and ensure to whatever extent possible that all possible information was provided in the cases to be able to make an optimal treatment decision by the pedorthists.

5.5 Conclusion

Based on these survey results, there is a high level of variation and little consensus around the best way to treat patients with diabetes and neuropathy for forefoot plantar ulceration prevention. Some of this variation is warranted due to the different skill levels of the pedorthists and patients' treatment goals, health fund availability and adherence-related matters, which further justifies the need for this study.

Some standard parameters for footwear design for some patients include prefabricated footwear with or without modification for low to moderate complexity and custom-made footwear for higher complexity cases. Custom-made insoles should be recommended for all levels of complexity for people with diabetes and neuropathy (Ahmed et al., 2020; Kaminski et al., 2022). The design and modification features of all these devices need to be tailored for

individuals based on their pathology, comorbidity, mobility status, intended activity and lifestyle.

No one size fits all, but with an effective sample size and person-centric study design, there is the potential to standardise this further (Catalfamo et al., 2008).

CHAPTER 6 | Study 4 – A Series Of N-Of-1 Trials

This chapter presents the methods, findings, discussion, and conclusion of the series of N-of-1 trials (study 4). The purpose of this study was to explore the specific design and modification features of footwear and insole that reduce plantar forefoot pressure and increase adherence in people with diabetes and neuropathy. Two different footwear concepts and three insoles concepts were also tested in this study. This study was built on the findings of Studies 1, 2 and 3, and the research protocol was published in the Trials Journal. The publication coverage is attached in Appendix 5, and the open-access publication link is below.

> *"Ahmed S, Butterworth P, Barwick A, Sharma A, Hasan MZ, Nancarrow S. Footwear and insole design parameters to prevent occurrence and recurrence of neuropathic plantar forefoot ulcers in patients with diabetes: a series of N-of-1 trial study protocol. Trials. 2022 Dec 16;23(1):1017. doi: 10.1186/s13063-022-06968-5. PMID: 36527100; PMCID: PMC9755781."*

Based on the previous studies, two shoe concepts and three insole concepts were taken forward into a series of N-of-1 trials. Although 21 participants were targeted for inclusion in the study, due to the Covid-19 restrictions in New South Wales, Australia, the public hospital outpatient department visits were very restricted. In the end, it was possible to recruit 12 participants.

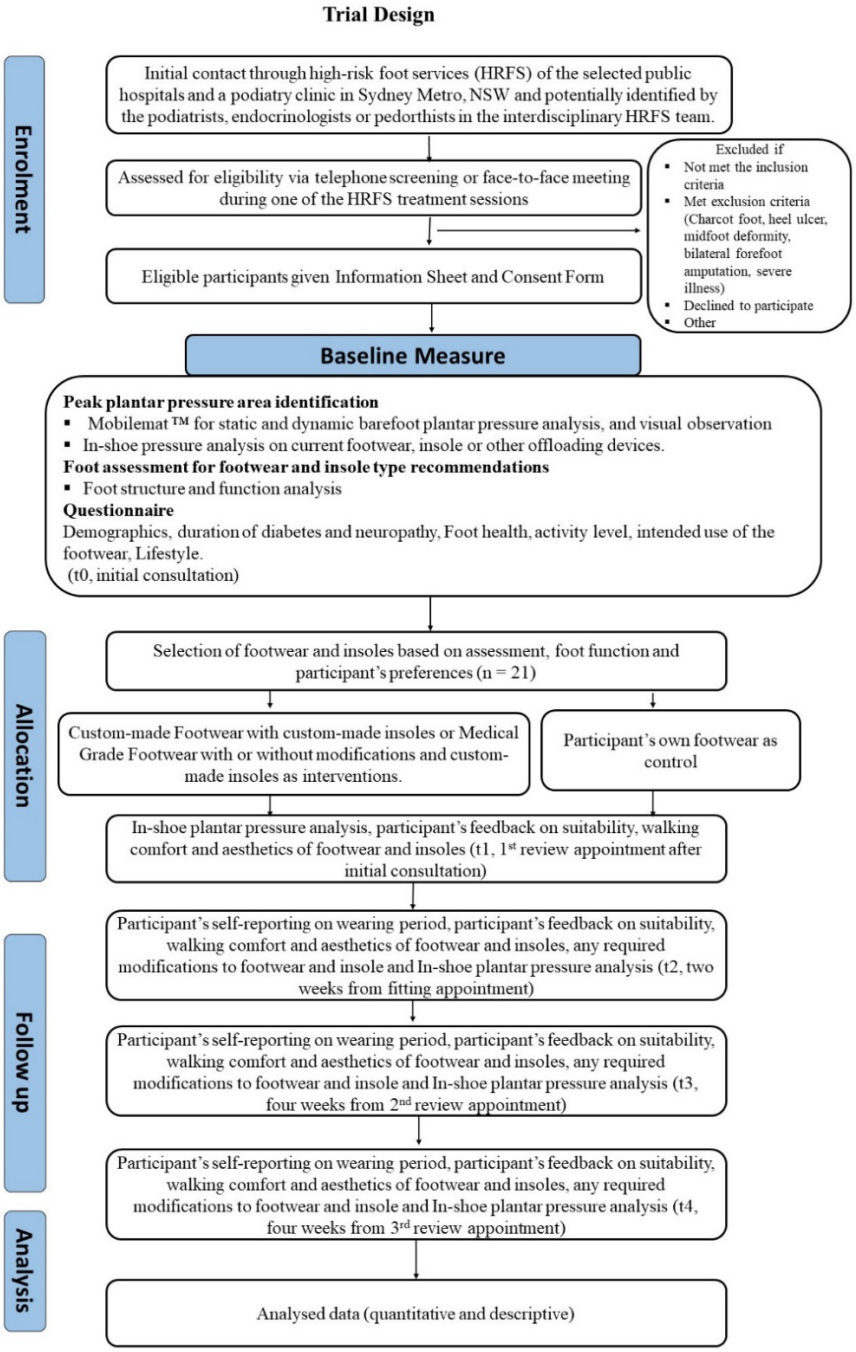
The intervention footwear and insole concepts are described at the beginning to outline their characteristics and design basics and give context to the rest of the chapter. The demographic-related information, such as baseline information and main foot morphology, comorbidity, footwear-related preferences, and health fund information of patients of the N-of-1 trials, are presented. Following this, the impact of footwear and insole modification on plantar pressure reduction, adherence, and satisfaction are presented. The information has been presented in tables, figures, and graphs as they fit and analysed contextually in the relevant sections.

These findings are interpreted and placed in the context of previous literature, and the implications for plantar pressure measurement, personalised design, environmental considerations, and multidisciplinary care are outlined. The study's limitations are explored, followed by the conclusions drawn from this series of N-of-1 trials.

6.1 Methods

Figure 6.1

Trial Design Flow for the Series of N-of-1 Trials



6.1.1 Sample

Patients from the high-risk foot clinics of two major public hospitals and affiliated community clinics in Sydney (Nepean Hospital from the Western Sydney area, St Vincent's Hospital Sydney from the Eastern suburbs of Sydney) and a private podiatry clinic (Western Sydney area) were selected to participate in the study. Although the clinics were chosen carefully for convenience, the Eastern and Western parts of the Sydney area consist of a diverse sociodemographic population. Previous studies (Haines & Gaines, 1999; March et al., 1994; Nikles et al., 2011; Sniehotta et al., 2012) have recruited 10 to 25 participants to generate a series of N-of-trials for this trial. This was expected to help create a series of N-of-1 trials for more robust statistical data analysis. The study design flowchart is presented in Figure 6.1.

This study took place between May 2021 and April 2022, which was during the peak of the COVID-19 outbreak and involved severe practice restrictions in all healthcare facilities in Australia. This affected access to patients and sampling.

The sample selection was undertaken using pragmatic sampling. Covid-19 restrictions for outpatients' visits, mandatory vaccination, and a polymerase chain reaction (PCR) test conducted within 72 hours of the clinic visit requirements policy were in place during the study. Hence, the recruitment of potential participants and their ongoing availability were highly prioritised before selection. The participants were recruited from the group of adult participants (≥18 years) with T1DM or T2DM, peripheral neuropathy and a recently healed plantar forefoot ulcer. Eligibility criteria included at least one or more forefoot deformities such as claw or hammer toes, cross-over toes, hallux valgus, hallux amputation, limited joint mobility, pes planus or pes cavus and bony prominences at metatarsal heads. Each participant had a prescription for orthopedic footwear and custom-made insoles.

Exclusion criteria were bilateral amputation (proximal to the trans-metatarsal joint), Charcot foot, active or healed heel ulcers, midfoot deformities, the use of a walking aid for offloading the foot, having a severe illness (determined by clinicians as meaning the individual that participant may not survive the study period), and limitations of the participant to follow the study instructions. Eligible participants were identified by the referrer podiatrists, the researcher and the endocrinologists of the multidisciplinary high-risk foot care team and

considered the potential regular clinic attendance for the study as per the schedule. Then the potential participants were asked if they would be interested in participating in the study. Those who agreed were given the participant information sheet (PIS) and the consent form (CF). Written consent from each participant was received before participating in the study. The sample of the PIS and CF are included in the ethics application documents, also in Appendices 3 and 4, respectively.

6.1.2 Sample size calculation

The sample size was calculated to be 21 for this trial based on the calculation undertaken by Nikles et al. (2011) for proposed aggregated N-of-1 trials:

For a conventional RCT, the sample size required to detect a difference in the effect of 8 on the FACIT-F fatigue subscale between MPH and placebo with a 5% significance level and 80% power, using a two-sided test, is 33 per treatment group. Allowing for 30% attrition raises the sample required to 47 per group or 94 overall. Using the same information, assuming no period effect or treatment time interaction, a computer simulation of size N 5 10 000 in SAS (SAS Institute Inc., Cary, NC, USA) was used to model the required sample size for the equivalent aggregated N-of-1 design. If 60% of recruited participants completed the first cycle, 50% completed the first two cycles, and 45% completed all three cycles, then 21 participants would be needed to satisfy the same significance and power requirements. (Nikles et al., 2011, p. 479)

In the end, it was possible to recruit 12 participants only due to COVID-19-related restrictions and the deadline for the study completion. In this study, the participants act as their own controls, and hence, the overall sample size is less important than intra-subjects tests and data.

6.1.3 Interventions

Instrumentation

The primary outcome of this study is in-shoe plantar pressure below the recommended pressure threshold. In-shoe plantar pressure was measured by using the F-Scan® system by Tekscan® Inc, USA, which captures plantar pressure data in kPa.

Barefoot pressure was measured by using a Mobilemat™ standard pressure mat to measure barefoot static and dynamic pressure in kPa.

Once the participants signed the CFs, they were booked for the initial appointment (t0) and provided options selection for footwear design and style. Footwear type (custom-made or prefabricated) was primarily discussed between the referrer podiatrist and the participants during the recruitment process and further confirmed with the researcher at t0. The decision on footwear type was based on the participant's foot structure, their preferences and intended activities, and fund availability or access to funds. The details on footwear styles and colors, and fastening systems were decided following assessment and discussion with the participant by the researcher. For insoles, fully custom-made insoles following heat moulding methods were by default offered for the group of participants who were recommended fully custom-made footwear, and the participants recommended for prefabricated medical grade footwear had the choice on selecting a heat moduled or 3D printed custom insoles to fit into their prefabricated medical-grade footwear.

Footwear

Every participant received one of two types of footwear - either fully custom-made or prefabricated with extra depth and width and, therefore, with the capacity to accommodate a custom-made insole. The need for fully custom-made and prefabricated extra depth and width footwear was determined by the clinical requirements of the participant based on the assessment of the referring and prescribing clinicians. When foot structure was deemed to be accommodated in an extra depth and width prefabricated medical grade footwear, the participant was recommended for that, and when the foot structure was too complex for the above footwear type, fully custom-made footwear was considered and requested by the referring podiatrist. Participant preference regarding style was also considered to adhere to the use of footwear. Custom-made orthopedic footwear was made from custom-made shoe Last, based on a 3D foot and leg scan. The 3D foot scans were made using an iPad and structure sensor through a DTScanner 3D human body scanning app with the aid of DTROM by Pedi-Wiz Digital Technology, Australia.

Insole

Each participant received fully custom-made insoles. Custom-made insoles were made from either a 3D scan of a foam impression box or a positive or negative cast. The foam impression was taken at a non-weight-bearing position. The foam impression box was 3D scanned by using the Dt Scanner app.

Socks

Participants were provided with appropriate socks that were diabetes-feet-friendly, seamless and non-constraint around the leg or calf.

The referring podiatrists and the prescribing pedorthist (the researcher) had more than four years of post-qualification experience. Custom-made footwear was made by central fabrication companies (Foot Balance Technology Bd Ltd, Dhaka, Bangladesh, and Choose Your Shoes, Heythuysen, the Netherlands) as per the prescription and digital foot and foam impression box scan files provided by the pedorthist. The prefabricated medical grade footwear range was selected from the available stock range of Fooot Balance Technology Pty Ltd, Sydney, Australia brands (Orthofeet Inc, NJ, USA, Mt Emey, CA, USA and Lucro by Schein Orthopedics, Germany). Shoe modifications were made under the direct supervision of each pedorthist by an orthopedic shoe technician (Maurice Hollands) with over 15 years of experience in modifying orthopedic footwear.

The initial assessment session (t0) consisted of recording a health history, measuring plantar pressures during barefoot standing and walking, in-shoe pressure mapping in the baseline (control) footwear and insole, and taking foam impressions of the feet. Footwear style was selected, and sizing was determined for the prefabricated orthopedic footwear for those participants for whom the footwear was recommended. A 3D foot scan for the fully custom-made orthopedic footwear and a foam impression box scan for custom-made insoles for all types of footwear were also undertaken at this stage. The scanning was made by using an iPad, structure sensor and DtSacnner 3D human body scanning software.

Figure 6.2

DTScanner App and DT ROM Device for 3D Scanning of the Foot and Leg, by Pedi-Wiz Digital Technology Pty Ltd, Australia.

The health history included recording any lower-extremity amputations, prior ulcers, deformities, current hyperkeratosis or pre-ulcerative lesion, skin conditions, and self-reported activity level. Neuropathy and other comorbidity-related data were recorded using the referral form completed by the podiatrist.

Plantar pressure during barefoot walking was measured using a Mobilemat™ pressure platform with one sensels/cm² (Tekscan®). Participants' barefoot plantar pressures were obtained when stepping directly onto the centre of the pressure platform with a specific foot with continued walking. Only the first step of each trial was recorded, and any partial step of the contralateral foot was excluded. A trial was considered successful only if the entire foot contacted the pressure platform. Six successful trials were collected for each foot at each time point, and these were averaged (Bus & de Lange, 2005).

In-shoe plantar pressure was measured using F-Scan® wireless system by (Tekscan®), Boston, USA. The F-Scan® sensors have four sensels/cm² (Ahmed et al., 2020) and can be cut to the shape of the insoles. The sensors were placed on top of the insole, and the

participants wore socks during the measurements. Participants wore the new shoes and orthotics and walked around for at least five minutes to get used to them and to have more reliable in-shoe pressure data (Catalfamo et al., 2008). Walk calibration of the sensors was done by using the participant's body weight. The data was recorded for 12 seconds while the participant was walking toward a straight line at a comfortable and regular walking speed. Participants were walking in various walkways, such as in the hospital clinic's corridor and on the footpath for the private podiatry clinic participants, to record the in-shoe pressure data. The reason for following this protocol is to use real-life and realistic approaches as much as possible that would replicate what happens in an actual clinic situation.

F-Scan® Research software version 7.5 was used for data recording and analysis. The first and last steps were excluded during the data analysis, and the average of the total steps was calculated.

The timing of plantar pressure readings and data collection is crucial for understanding the progression of the study. To clarify this timeline:

T0 (Initial Appointment): At the initial appointment (T0), barefoot static and dynamic pressure analysis, as well as in-shoe pressure analysis on the baseline footwear, were conducted. This initial assessment served as a baseline measurement to understand the participants' plantar pressure patterns before any intervention.

T1 (2nd appointment): The intervention footwear and insole design were decided upon at T0, and at the second appointment (T1), these intervention components were fitted to the participants. This marks the initiation of the intervention phase.

Rounds of Modifications: Over subsequent appointments (T1-T4), a maximum of three rounds of modifications were carried out on the footwear and insoles. The goal of these modifications was to achieve an acceptable plantar pressure offloading threshold for each participant.

Patient Satisfaction and Adherence: At each appointment (T1-T4), data related to patient satisfaction and adherence were captured. This included information about how participants perceived and experienced the intervention.

6.1.4 Protocol and footwear and insole concepts

Footwear design and modification

Custom-made footwear was designed based on recommendations provided by DFA guidelines regarding footwear for people with diabetes (van Netten, Lazzarini, et al., 2018) and any specific recommendations resulting from the literature review (Ahmed et al., 2020) and survey study (Study 3). Footwear modifications were informed by data from the in-shoe pressure analysis (Arts et al., 2015), and multiple modifications were carried out until the desired pressure value was achieved. Many different types of footwear and insoles have been proposed in this study. The type of footwear recommendations were guided by the participant's foot structure, the complexity of device design for optimum pressure offloading, and the preferences of the referrer and participant, including consideration of health fund contributions and participant budget.

Insole design and modification

Custom-made insoles were commonly used in this study, and construction methods and material choices for these depended on the participant's footwear type and history of using custom-made insoles. Custom-made footwear could only be made using conventional heat-moulded insoles with multiple layers of cushion (Bus, Zwaferink, et al., 2020), and prefabricated medical-grade footwear could only consist of conventional heat moulded insoles (Ahmed et al., 2020; Zwaferink et al., 2020) or digitally optimised, 3D printed insoles (Telfer et al., 2017). Digitally optimised and 3D printed insoles were considered to explore the efficacy of this new concept against conventional heat moulded insoles when the participant already had the latter type of insoles and was willing to try the new insole concepts. The cost variation among the types of insoles was at a minimum.

Two footwear concepts and three insole concepts were used in this study, and the concepts were adopted from an earlier study conducted in the Netherlands (Zwaferink et al., 2020). The design concepts were adopted from the above-mentioned study as there were inconsistencies and variations in footwear and insole design in our Study 3. Hence, the design concepts were adapted based on current practices in Australia (Study 3) and earlier literature review (Ahmed et al., 2020).

Shoe A

Shoe-A comprises a fully custom-made shoe that is made from a 3D scan of the foot, and computer-aided design (CAD) software is used to design the shoe last. Then, the shoe last is either milled by using a computer-aided manufacturing (CAM) system out of timber or 3D printed from a suitable filament.

Shoe-AA includes a custom-made insole (Insole-A) that uses a CAD-based design by optimising the shape from barefoot pressure data and the evidence-based considered in Study 1 (Ahmed et al., 2020) and Study 3 (pedorthists' survey). The evidence-based was consistently followed for all footwear and insole concepts which were guided by studies 1 (Ahmed et al., 2020) and 3.

Insole A

The manufacturing process for the Insole-A was undertaken using a conventional heat moulded method by adding multiple layers of materials, including Plastazote ®, Poron ® and EVA base. Plastazote ® top layer thickness was 3 to 5mm, Poron ® layer thickness was 6 to 10mm with dual density, and the base was mid to high-density EVA, with measurements guided by participant body weight. The Insole-A was heat moulded over the custom-made shoe last for Shoe-A and became part of Shoe-A.

Shoe B

Shoe-B was a prefabricated extra depth and width medical-grade footwear modified for pressure optimisation in the ROI and increased postural stability of the participant. The Shoe-Bs were from the brands Orthofeet (USA), Apis (USA) and Lucro by Schein (Germany). Common modifications included a rocker sole, reinforced rocker sole, medial or lateral buttress, and re-lasting or widening the shoes to accommodate the width of the modification. Shoe-B group participants had two different types of insole concepts, Insole-B and Insole-C.

Insole B

The Insole-B was designed from the 3D scan file of the semi-weight bearing foam impression box using CAD software, with the shape optimised from the barefoot plantar pressure data and researcher input. Then, the insole base was 3D printed either in full-length or ¾ length

from thermoplastic polyurethane (TPU) filament with multi-density region options. A slicer software was used to create multi-density within the same insole base. To hand finish, a soft or medium-density EVA top cover and Poron mid-layer were attached to the 3D-printed insole base. When a metatarsal dome or bar was prescribed, this was 3D printed with the base of the insole.

Insole C

Insole-C was made using a positive plaster cast of the foot from the semi-weight bearing foam impression box, a heat moulded medium-harder density EVA base, Poron mid-layer and soft to medium density EVA top cover. A metdome or metatarsal bar was prescribed as necessary based on the barefoot plantar pressure data.

All footwear concepts underwent a series of modifications following the in-shoe plantar pressure analysis and participants' feedback on the suitability and ease of walking in order to tailor the shoe to the needs of individual participants. Rocker sole modifications and re-configurations were the most common modifications. The rocker apex position (10-20 mm behind the MTH's), and rocker angle (12-20 degrees) were determined based on the plantar pressure data and participant feedback. Adding medial or lateral wedges, stiffening the outsole and adding a hallux rigidus rocker were other common footwear modifications. The researcher prescribed all footwear modifications, and these were implemented by the same orthopedic shoe technician who has over 15 years of experience.

Additionally, all insole concepts underwent a series of modifications, which included adjusting the height of the medial longitudinal arch (MLA), deflection under the bony prominence or ROI by removing harder materials and adding cushioning, replacing the top cover with a different density top cover, adjusting height or position of the metatarsal dome or bar, and Morton's extension.

Figure 6.3

Shoe-A with Insole-A

Figure 6.4

Shoe-B

Figure 6.5

Insole-B, 3D Printed Shell

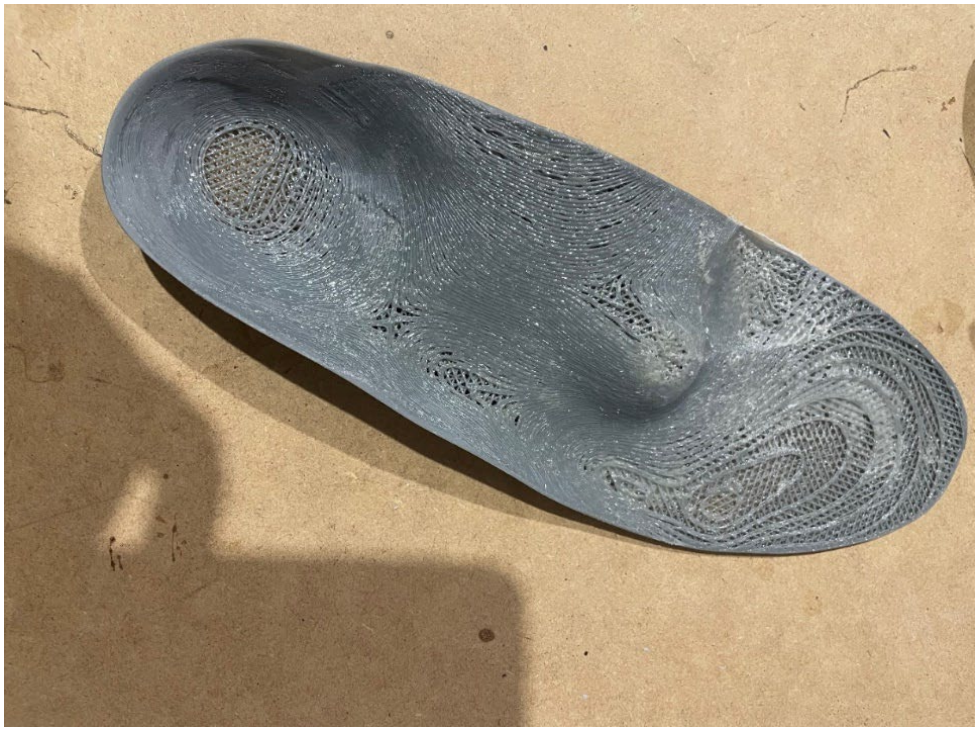
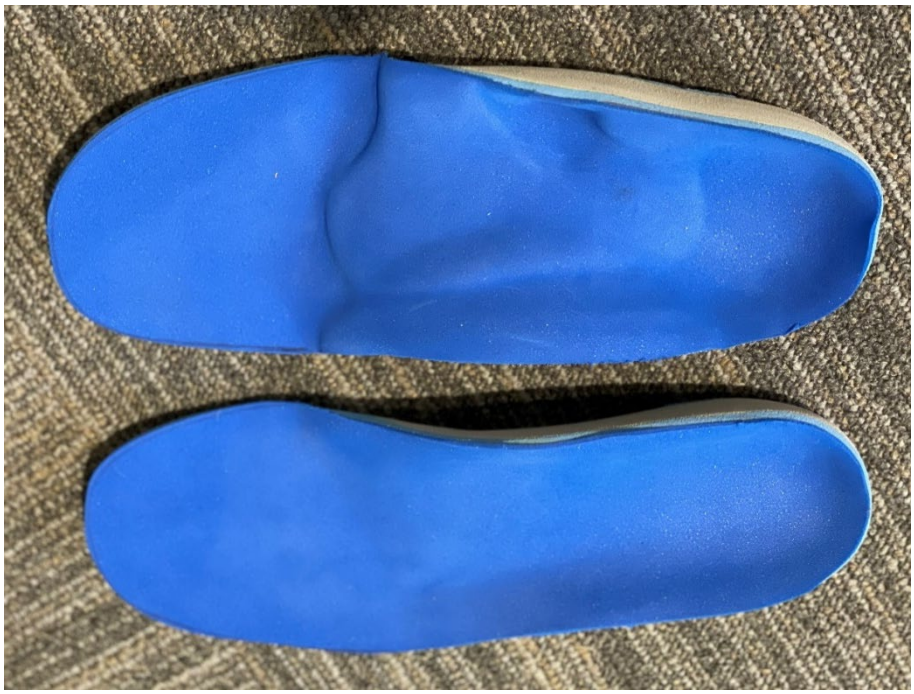


Figure 6.6

Insole-B, Hand Finished with Top Cover

Figure 6.7

Insole – C



6.1.5 Summary of the footwear and insoles used in this study

This study has used two main types of footwear and three insoles as interventions for the participants. Table 6.1 outlines the components and concepts used in the study here for reference.

Table 6.1

Summary of design and manufacturing components for the evidence-based footwear and insole concepts used in the trials.

	BASELINE SHOE	**SHOE-A + INSOLE-A**	**SHOE-B + INSOLE-B**	**SHOE-B + INSOLE-C**
BAREFOOT PRESSURE DATA	n/a	MobileMat ™ pressure mat by Tekscan ®	MobileMat ™ pressure mat by Tekscan ®	MobileMat ™ pressure mat by Tekscan ®
FOOT SHAPE DATA	n/a	3D scan of feet, Semi-weight-bearing foam impression cast and digital shape modification for insole	Semi-weight-bearing foam impression cast and 3D scan of the cast and digital shape modification for insole	Semi-weight-bearing foam impression cast and manual shape modification for insole

Table 6.1

Summary of design and manufacturing components for the evidence-based footwear and insole concepts used in the trials (Continued).

	BASELINE SHOE	**SHOE-A + INSOLE-A**	**SHOE-B + INSOLE-B**	**SHOE-B + INSOLE-C**
SHOE DESIGN	Various prefabricated footwear	Scientific evidence-base	Scientific evidence-base	Scientific evidence-base
MANUFACTURING	Various traditional mass produced	CAD-CAM design last, Heat moulding method for insoles	Prefabricated medical grade footwear (Orthofeet by Orthofeet Inc. NJ, USA, Mt Emey by Apis Footwear, CA, USA, Lucro by Schein Orthopedics, Germany) with modifications, Insole with CAD and 3D printed TPU base with Poron mid-layers and EVA top cover	Prefabricated medical grade footwear with modifications, insole with positive plaster cast and heat moulded conventional manufacturing method. Medium to harder grade EVA base with Poron mid-layers and soft to medium EVA top cover
EVALUATION	In-shoe plantar pressure analysis by F-Scan system	In-shoe plantar pressure analysis by F-Scan system	In-shoe plantar pressure analysis by F-Scan system	In-shoe plantar pressure analysis by F-Scan system
MODIFICATION	N/A	If indicated	If indicated	If indicated

6.1.6 Outcomes

The primary outcome of this study is peak plantar pressure reduction at the forefoot within the desired threshold of <200 kPa or a >30% reduction from baseline (Bus et al., 2011).

The secondary outcome of this study is participants' adherence to treatment and satisfaction with the intervention were also measured. The adherence includes participants reporting on suitability, likeliness to use, wearing period and overall satisfaction with the prescribed footwear and insoles. These were measured by the questionnaires for participant satisfaction on a Likert scale (Ulbrecht et al., 2014), based on self-reported wearing period over a certain period frame, and they were measured at T1-T4 for each participant. In this study, 16 hours/day was considered the standard weight-bearing period for the participants indoors and outdoors. The remaining 8 hours were considered as non-weight-bearing periods. Questions were derived from previous literature (Ulbrecht et al., 2014). To ensure that participants self-reporting adherence-related information is accurate, the following strategies were employed: structured questionnaire design, clear and specific questions, clear participant instruction and participant engagement.

6.1.7 Blinding

In this study, blinding was not used as blinding is recommended but not mandatory in _N-of-1 trial (Ahmed et al., 2022). Authentic blinding of participants and researchers applying the interventions is not possible with footwear interventions. In N-of-1 trials, generally, the results are presented to respective participants at the end of the trial. Considering the practicality and adherence-related matters, the participants were not blinded in this study. The clinician discussed the possible design principles with each participant for all cases for clear goals to achieve, and the potential bias was addressed by using referrer notes by ensuring the design protocol was within standard clinical practice, health fund assessment and fund approval was undertaken through a clinical advisors panel.

6.1.8 Data Collection

Plantar pressure data were collected by using F-Scan® Research Software version 7.5. and FootMat® Research Software version 7.10. The foot was grouped into ten anatomical regions for the convenience of data analysis and focused on the target regions: lateral and medial heel, metatarsal1, metatarsal2/3, metatarsal 4/5, hallux, toes 2/3, and toes 4/5 (Arts et al., 2015). All feet were grouped based on the type of forefoot deformity, such as claw/hammer

toe, hallux valgus and bony metatarsal heads. Participant self-reporting on the wearing period was also recorded.

6.1.9 Data Analysis

Barefoot static (standing) and dynamic (walking) data were collected during the initial assessment (t0) session and were averaged for each foot and region representing MTH1, MTH2, and lateral MTH (MTH3–5) were identified using FootMat® research software (version 7.10) analysis. The forefoot region with the highest peak pressure in kPa was considered the region of interest (ROI), whereas any remaining MTH or forefoot region was considered a non-ROI (Allan et al., 2022).

In-shoe pressure data were analysed using F-Scan® Research software (version 7.5). For each condition, all collected steps were averaged for each foot. Using the participant's own footwear (medical-grade or regular retail footwear or post-op shoes) with the inherent standard insole condition as the baseline, a mask was created that represented four regions of each foot: first MTH, second MTH, lateral MTH (MTH3–5), and midfoot. For each region, peak pressure and force-time integral were extracted.

6.1.10 Statistical analysis

Both descriptive and inferential statistical techniques were used in this research. In the descriptive analysis, participant characteristics and adherence (wearing time) based on participant satisfaction with the footwear and insoles were summarised. Under the statistical inference, a paired sample t-test was used to compare the significant difference in plantar pressure between the custom-made footwear and baseline and control footwear. Correlation analysis was used to investigate the relationship between satisfaction scores and left and right In-shoe (Reduce). The descriptive and inferential statistical analyses were performed using IBM SPSS Statistics (version 27), and the statistical significance was set at $p<0.05$ with a confidence limit of 95% in a two-tailed fashion.

6.1.11 Other information

Funding: There is no dedicated funding for this project; however, multiple stakeholders took part in this project for the research to occur. Nepean Hospital and St Vincent's Hospital in

Sydney assisted in recruiting participants from high-risk foot clinics. Foot Balance Technology (FBTech, Sydney based Pedorthic company owned by this researcher) took part in providing the footwear, insoles, and modification services, which were funded by Enable NSW, National Disability Insurance Schemes (NDIS), Department of Veterans Affairs (DVA), Private Health Insurance or by the participants themselves. The researcher used his own time to conduct the research. All the above facilities had the in-shoe plantar pressure measuring systems (F-Scan ® by Tekscan ®, USA), FootMat ® research software version 7.10, and the F-Scan ® research software version 7.5 for data analysis. FBTech provided funding for the sensors that were used for this trial.

Ethical considerations for N-of-1 trial: The ethical aspects of this research project have been approved by the Nepean Blue Mountains Local Health District (NBMLHD), the Human Research Ethics Committee (HREC) and the Southern Cross University HREC. The Approval numbers are 2020/ETH02250 and 2020/093, respectively.

Registration: This N-of-1 trial has been registered with the Australian New Zealand Clinical Trials Registry (ANZCTR), and the Registration number is ACTRN12620000699965p.

Protocol: Full trial protocol, which is approved by the respective HREC committee, can be accessed by communicating with the researcher.

Acknowledgement: Participating practitioners and relevant organisations for the survey and the participants in the N-of-1 trial and the related referring clinics.

6.2 Results

6.2.1 Demographic baseline characteristics and other related information

A total of 12 participants (11 male, 1 female) with a history of plantar forefoot ulceration, moderate to severe neuropathy and moderate to severe foot deformity were included in this series of N-of-1 trials. All participants had Type 2 Diabetes Mellitus (T2DM). Participants were recruited from two high-risk foot services of tertiary hospitals and one private podiatry clinic in Sydney, Australia, between June 2021 to May 2022. The mean age of the participants was 64 years, and SD was 10.96. The average BMI (Kg/m²) for the participants was 29, and SD was 6.55. Foot deformity[a] was primarily moderate (n=10) with some severe (n=2). The summary of the demographic information is provided in full detail in Table 6.2.

[a]Level of deformity: mild: pes planus, pes cavus, Hallux valgus, hallux limitus, hammer toes, and lesser toe amputation; moderate deformity: hallux rigidus, claw toes, Hallux or ray amputation, and prominent metatarsal heads; severe deformity: forefoot amputation, and pes equines.

Table 6.2

Participants' other characteristics and information related to footwear choices

Participant #, Gender, Age, Body weight	Main foot pathology	Co-morbidity	Person's mobility status	Treatment goals	Participant's preferences and intended activity during ulcer in remission	Family/partner /carer/peer preferences and influence on footwear selection	Fund options and if they influence therapy	Participants' desire for future footwear	Additional information
Participant 01, M 71 Y/O, 84 Kg	Rigid bil Cavus feet (R>L), bony prom R MTH 5, L 2nd clawed digit	Hyper-tension, PVD	Active and has good hand and feet dexterity	Protecting feet Forefoot plantar pressure reduction under the right 5th MTH base Increase adherence Increase aesthetics	Mobilising indoors and outdoors with comfort reduced callus, podiatry visits >5 weeks	The wife is supportive, participates and plays an influential role in footwear style selection and other therapies	Enable NSW funded, Yes	Prefers indoor footwear with similar offloading efficacy	Prefers custom-made footwear, but wife recommends prefab MGF to match her outfit while going out, and footwear type was decided upon that
Participant 02, M 53 Y/O, 134 Kg	Rigid bil flat feet, thick callus under the IPJ's (R>L)	Hyper-tension, PVD, obesity, swelling feet	Active and has good hand and feet dexterity	Protecting feet Forefoot plantar pressure reduction Increase adherence Increase aesthetics	At work on feet >10 hrs/day/5 days/wk walking on a wet and slippery floor, with comfort, reduced callus, podiatry visit >6 weeks.	Lives with family, wife attends appointments with him and prefers participant to make footwear choices that suit his workplace, accepts healthcare professionals' recommendations	Privately funded, Yes	Prefers indoor footwear with similar offloading efficacy	Muslim faith, prays regularly, and that requires bending of the Right Hallux where the IPJ ulcer location is. Advised to explore praying option in a chair seating position due to illness and that influenced rate of callus building with concurrent footwear therapy
Participant 03, M 74 Y/O, 84 Kg	Transmet amputation R, bony prominence 1st MTH 1 R and L MTH 4	Hyper-tension, moderately severe CKD, retinopathy	Moderately active and has good dexterity in hands	Protecting feet Forefoot plantar pressure reduction Increase adherence Increase balance while mobilising	Mobilising indoors and outdoors with comfort, improved balance, no foot ulcers, reducing callus build-up rate and podiatry visit at >6 weeks	Lives alone and relies on healthcare professionals' recommendations on therapy	Enable NSW funded, Yes	Prefers indoor and other styles of outdoor footwear with similar offloading efficacy	Uses a walking stick in the Right hand to maintain balance outdoors and in unknown indoor places

Table 6.2

Participants' other characteristics and information related to footwear choices (Continued)

Participant #, Gender, Age, Body weight	Main foot pathology	Co-morbidity	Person's mobility status	Treatment goals	Participant's preferences and intended activity during ulcer in remission	Family/partner/carer/peer preferences and influence on footwear selection	Fund options and if they influence therapy	Participants' desire for future footwear	Additional information
Participant 04, F 63 Y/O, 87 Kg	Flexible flat feet, dorsiflexed R Hallux with LJM, amputation of R 3rd digit,	Hyper-tension, PAD, swelling feet	Active and has good hand and feet dexterity	Protecting feet Forefoot plantar pressure reduction Increase adherence Increase aesthetics	Mobilising indoors and outdoors with comfort, improved balance, reduced callus, podiatry visit >6 weeks	Lives with family and makes self-decision on her therapy and footwear choices	Enable NSW funded, Yes	Prefers indoor and other styles of outdoor footwear with similar offloading efficacy	Prefers sandal or Mary-jane design footwear and is very concerned about the appearance of the footwear. Did not prefer custom-made footwear in fear of the appearance of them although the fund was available and R foot structure suggested custom-made footwear
Participant 05, M 47 Y/O, 110 Kg	Rigid bil Cavus feet, bony proms bil MTHs 1, 5, amputation of 2nd, 3rd digits on the R	PVD, obesity	Active and has good hand and feet dexterity	Protecting feet Forefoot plantar pressure reduction Increase adherence Increase aesthetics Increase social image	At work on feet >10 hrs/day/6 days/wk., with comfort, improved balance, reduced callus, podiatry visit >6 weeks	Lives alone and makes self-decision on his therapy and footwear choices, and accepts healthcare professionals' recommendations	Privately funded, Yes	Prefers indoor and other styles of outdoor footwear (custom-made) with similar or more offloading efficacy	Would prefer a custom-made ankle boot if access to a health fund was available. His Right foot deformity suggests requirements for additional cushioning to slow down callus build-up and a podiatry visit
Participant 06, M 72 Y/O, 110 Kg	Rigid bil flat feet, thick callus under the IPJ's (R>L)	Hyper-tension, PVD, obesity, swelling feet	Moderately active and has good dexterity in hands and feet. Struggles to reach to the toes	Protecting feet Forefoot plantar pressure reduction Increase adherence Increase aesthetics and walking comfort	Mobilising indoors and outdoors with comfort, improved balance, reduced callus, podiatry visit >8 weeks	Lives alone and makes self-decision on his therapy and footwear choices, and accepts healthcare professionals' recommendations	Enable NSW funded, Yes	Prefers indoor and other styles of outdoor footwear with similar offloading efficacy	Participant prefers to have lowered heel footwear (5mm heel height) as this was the most comfortable position for him and improved balance while walking and standing

Table 6.2

Participants' other characteristics and information related to footwear choices (Continued)

Participant #, Gender, Age, Body weight	Main foot pathology	Co-morbidity	Person's mobility status	Treatment goals	Participant's preferences and intended activity during ulcer in remission	Family/partner/ carer/peer preferences and influence on footwear selection	Fund options and if they influence therapy	Participants' desire for future footwear	Additional information
Participant 07, M 68 Y/O, 104 Kg	Rigid bil flat feet, hallux limitus, thick callus under the IPJ's (L>R), moderate clawing digits and moderate LJM of ankle bil	Nephro-pathy	Active and has good hand and feet dexterity	Protecting feet Forefoot plantar pressure reduction Increase adherence Increase aesthetics and walking comfort, ease of use	Mobilising indoors and outdoors with comfort, improved balance, reduced callus, podiatry visit >8 weeks	Lives with a partner and makes self-decision on his therapy and footwear choices, and accepts healthcare professionals' recommendations	Enable NSW funded, Yes	Prefers indoor and other styles of outdoor footwear with similar offloading efficacy	Participants preferred to have sandals or more open-type footwear but agreed to wear closed-in, low-cut athletic appearance footwear
Participant 08, M 47 Y/O, 125 Kg	Rigid bil Cavus feet, bony proms bil MTHs 1, 5, moderate claw digits bil	Hyper-tension, obesity, swelling feet	Active and has good hand and feet dexterity. Struggles to reach to the toes	Protecting feet Forefoot plantar pressure reduction Increase adherence Increase aesthetics and device suitable for use at work	Mobilising indoors and outdoors with comfort, improved balance, reducing callus, podiatry visit >6 weeks	Lives alone and makes self-decision on his therapy and footwear choices, and accepts healthcare professionals' recommendations	Enable NSW funded, Yes	Prefers indoor and other styles of outdoor footwear with similar offloading efficacy	Prefers to get a job and suitable footwear specific to the job requirements and concerned about re-ulceration if the job requires increased physical activity and weight-bearing periods
Participant 09, M 68 Y/O, 94 Kg	Rigid bil Cavus feet, bony proms bil MTHs 1 (R>L), 5, moderate claw digits bil	Hypertens ion, PAD, swelling feet	Active and has good hand and feet dexterity	Protecting feet Forefoot plantar pressure reduction Increase adherence Increase aesthetics and walking comfort, ease of use Reduce shear	Mobilising indoors and outdoors with comfort, playing musical instruments at events, improved balance, reduced callus, podiatry visit >6 weeks	Lives with a partner and makes self-decision on his therapy and footwear choices, and accepts healthcare professionals' recommendations	Enable NSW funded, Yes	Desired a fully custom-made ankle boot and requested the referrer to recommend custom footwear in future that resembles his other footwear style	His foot structure and cushion requirements suggest custom-made footwear, but the referrer suggested trying on MGF first during the fund application process and after the follow-up, agreed to suggest custom footwear in future

Table 6.2

Participants' other characteristics and information related to footwear choices (Continued)

Participant #, Gender, Age, Body weight	Main foot pathology	Comorbidity	Person's mobility status	Treatment goals	Participant's preferences and intended activity during ulcer in remission	Family/partner /carer/peer preferences and influence on footwear selection	Fund options and if they influence therapy	Participants' desire for future footwear	Additional information
Participant 10, M 77 Y/O, 75 Kg	Rigid bil Cavus feet, severe bony proms R MTH 3, 2nd R digit amputation, sever claw digits bil (R>L), over-riding 3rd digit R	Hypertension PAD	Active and engaged in various social activities and has good hand dexterity	Protecting feet Forefoot plantar pressure reduction Increase adherence Increase aesthetics Increase social image	Mobilising indoors and outdoors with comfort, improved balance, reduced callus, podiatry visit >6 weeks	Lives with a partner and makes self-decision on his therapy and footwear choices, and accepts healthcare professionals' recommendations	Privately and co-funded by a peer, Yes	Participant desired fully custom-made indoor footwear and other styles of outdoor ankle boot style footwear.	Strongly desires custom-made footwear to suit his outfit and lifestyle after the initial pair was successful in pressure offloading and attracted lots of positive comments on shoe appearance from his friends at the club. Health fund access inability makes a choice harder as the first pair of custom footwear was co-funded by a peer.
Participant 11, M 72 Y/O, 85 Kg	Flexible flat feet, Hallux limitus L, bony prom L MTH 1, hyper-keratosis L IPJ plantar	Hypertension	Active and has good hand and feet dexterity	Protecting feet Forefoot plantar pressure reduction Increase adherence Increase aesthetics	Mobilising indoors and outdoors with comfort, improved balance, reduced callus, podiatry visit >8 weeks	Lives with family and makes self-decision on his therapy and footwear choices, and accepts healthcare professionals' recommendations	Enable NSW funded, Yes	Prefers indoor and other styles of outdoor footwear with similar offloading efficacy	Overall, happy with the appearance of MGF and receiving regular podiatry care to maintain foot health and ulcer remission periods. Well-educated on personal health requirements

Table 6.2

Participants' other characteristics and information related to footwear choices (Continued)

Participant #, Gender, Age, Body weight	Main foot pathology	Comorbidity	Person's mobility status	Treatment goals	Participant's preferences and intended activity during ulcer in remission	Family/partner /carer/peer preferences and influence on footwear selection	Fund options and if they influence therapy	Participants' desire for future footwear	Additional information
Participant 12, M 52 Y/O, 98 Kg	Rigid bil Cavus feet, bony proms bil MTHs 2-4, moderate claw digits bil	Hypertension Nephronpathy Retinopathy PAD, swelling feet	Active and has good hand and feet dexterity. Struggles to reach to the toes	Protecting feet Forefoot plantar pressure reduction Increase adherence Increase aesthetics, ease of use Suitable for use at work	Mobilising indoors and outdoors with comfort, improved balance, reduced callus, podiatry visit >7 weeks	Lives alone and makes self-decision on his therapy and footwear choices, and accepts healthcare professionals' recommendations	Enable NSW funded, Yes	Prefers indoor and other styles of outdoor footwear with similar offloading efficacy	Prefers to get a job and suitable footwear specific to the job requirements and concerned about re-ulceration if the job requires increased physical activity and weight-bearing periods. Can feel the forefoot pain if callus is built and access to regular podiatry care and pedorthic reviews to maintain the footcare and footwear suitability

The questions for the above table were derived from the standard clinical practice protocol in the high-risk foot services and allied healthcare facilities, literature review and expert input.

6.2.3 Barefoot static and dynamic plantar pressure

The barefoot static and dynamic plantar pressure magnitudes vary for the same foot in the same participant, and the ROI also varies in most cases. Barefoot pressure analysis shows that most participants' weight bears on the heel. The peak plantar pressure area is the heel during the barefoot static phase, but the peak pressure area shifts towards the forefoot during the dynamic phase of the gait.

Table 6.3 demonstrates the identified primary ROI with pressure magnitude for each participant during static standing and dynamic gait. The barefoot static and dynamic plantar pressure were measured at the baseline (T0) for each participant to guide the insole design. The barefoot static pressure (mean 200.08, SD 61.923) and dynamic pressure (mean 299.42, SD 94.554) for the left foot and the right foot static pressure (mean 182.58, SD 80.890), and dynamic pressure (mean 297.42, SD 108.717) are not consistent across all the participants. Although measured with different devices, at a 5% level of significance, there is a statistically significant difference between the left barefoot static peak pressure (kPa) and left barefoot dynamic peak pressure (kPa) (p-value = 0.002), and the dynamic pressure is higher as expected. In addition, there is also a statistically significant difference between the right barefoot static peak pressure (kPa) and right barefoot dynamic peak pressure (kPa) (p-value < 0.001), and the dynamic pressure is higher at a 5% level of significance.

In this analysis, it was considered the possibility of conducting Bonferroni correction, but it was decided to take a trade-off approach due to the increased risk of Type II errors (false negative) because it makes it more challenging to declare statistical significance.

In this specific case, it was carefully considered the trade-offs between Type I and Type II errors, the context of the research, and the research objectives.

Table 6.3

ROI and barefoot static and dynamic plantar pressure in all participants

Participants	Left Barefoot Static peak pressure (ROI)	Left Barefoot Dynamic peak pressure (ROI)	Left Barefoot Static peak pressure (kPa)	Left Barefoot Dynamic peak pressure (kPa)	Right Barefoot Static peak pressure (ROI)	Right Barefoot Dynamic peak pressure (ROI)	Right Barefoot Static peak pressure (kPa)	Right Barefoot Dynamic peak pressure (kPa)
1	MTH 3	MTH 3	165	272	MTH 5	MTH 5	114	168
2	Lateral Midfoot	Hallux	190	262	Lateral Midfoot	Hallux	126	322
3	Heel	MTH 1	337	205	Heel	MTH 1	343	344
4	Heel	MTH 1	144	238	Heel	Hallux	165	308
5	Heel	MTH 3	223	374	MTH 1	MTH 1	269	467
6	Heel	MTH 3	215	314	Heel	Hallux	94	364
7	Heel	MTH 1	224	353	MTH 2-3	MTH 2-3	168	257
8	Heel	Heel	262	326	Heel	MTH 1	259	424
9	Heel	MTH 1	161	365	MTH 1	MTH 1	246	270
10	Heel	Heel	91	91	Heel	Heel	91	55
11	Heel	Hallux	182	335	Heel	MTH 1	119	295
12	Heel	MTH 2-3	207	458	Heel	MTH 2-3	197	295

6.2.4 Footwear and insole design and modifications effect on in-shoe plantar pressure

A series of modifications to the footwear and insole for each participant was performed, and the maximum series of modifications was three rounds until a satisfactory in-shoe plantar pressure reduction was achieved. Some modifications increased the peak plantar pressure at the ROIs of the feet as participants' balance, preferences and acceptance of appearance on the modified footwear were given priority. That resulted in increased in-shoe plantar pressure at the ROIs in some phases of the modifications, and Tables 6.5 and 6.6 describe those modifications for the relevant events that influenced in-shoe plantar pressure reduction. Then further objective modifications reduced the peak plantar pressure at the subsequent ROIs. Table 6.4 represents the rate of in-shoe plantar pressure reduction following each round of footwear and insole modification. Most participants (n=10) footwear and insole modification show improvement well above the pressure threshold of >30% reduction from the baseline footwear except for participants 03 and 05, but their baseline footwear and insoles were already offloading effective.

Table 6.4

In-shoe peak plantar pressures (kPa) per region (of interest) for their intervention footwear at t0, t1, t2 and t3 for both limbs.

Study participants	Footwear and insole concepts	Left (ROI) in-shoe	Right (ROI) in-shoe	kPa_baseline_left	kPa_t1_left	kPa_t2_left	kPa_t3_left	% Change t0 to t3 left	kPa_baseline_right	kPa_t1_right	kPa_t2_right	kPa_t3_right	% Change t0 to t3 right
01	Shoe-B + Insole-C	MTH 2-3	MTH 5	589	342	352	352	-40%	335	148	106	103	-69.25%
02	Shoe-B + Insole-C	Hallux	Hallux	417	374	315	306	-27%	736	558	476	452	-38.60%
03	Shoe-A + Insole-A	MTH 4-5	MTH 1	275	289	243	257	-6.60%	429	589	310	341	-20.50%
04	Shoe-B + Insole-C	Hallux	Hallux	417	361	315	211	-49.40%	736	533	376	227	-69%
05	Shoe-B + Insole-C	MTH 1	MTH 1	954	1007	684	482	-49.48%	447	744	613	431	-3.50%
06	Shoe-A + Insole-A	Hallux	Hallux	513	985	804	342	-33.33%	739	775	677	439	-40.59%
07	Shoe-B + Insole-B	Hallux	MTH 2-3	487	245	210	198	-59.34%	389	253	215	206	-47%
08	Shoe-B + Insole-B	Hallux	MTH 1	433	417	333	238	-45%	778	594	513	317	-59.25%
09	Shoe-B + Insole-B	MTH 1	MTH 1	246	374	207	140	-43%	444	432	389	246	-44.60%
10	Shoe-A + Insole-A	MTH 2-3	MTH 2-3	222	235	209	186	-16.20%	248	236	211	161	-35%
11	Shoe-B + Insole-C	Hallux	Hallux	539	457	396	314	-41.74%	375	308	257	230	-38.66%
12	Shoe-B + Insole-B	MTH 2-3	MTH 2-3	757	689	438	365	-51.80%	912	677	512	315	-65.46%

Table 6.5

Series of modifications on footwear and insoles

Participant	Shoe + Insole concepts	T1		T2		T3	
		Shoe modification	**Insole modification**	**Shoe modification**	**Insole modification**	**Shoe modification**	**Insole modification**
Participant 01	Shoe-B+Insole-C	4mm Lateral wedge on the right, Lateral Buttress on the Right, Rigid forefoot rocker on both	9mm Arch pad shaped to the required profile and create a deflection under the Right MTH 5	4mm Lateral wedge on the right, adjusting the Lateral Buttress on the right to match the additional wedge	Adding a 6mm EVA arch cookie under the lateral midfoot on the right, 5mm behind the MTH 5	Deflection in the midsole under the Right MTH 5	2mm Soft EVA top cover to the Right insole
Participant 02	Shoe-B+Insole-C	4mm medial wedge on the Right, Rigid forefoot rocker bilaterally	4mm Morton's extension under the Right MTH 1	Re-lasting, another 2mm medial wedge on the right, Rigid forefoot rocker on both with a hard-wearing heavy-duty outsole	Adding a total of 7mm Morton's extension under the MTH 1 on the Right	Deflection in the midsole under the Right MTH 1 and reinforced the rocker profile by full-length carbon fibre plate, hard wearing heavy-duty outsole	Adding a 2mm medium Soft EVA top cover to the Right insole
Participant 03	Shoe-A+Insole-A	4mm medial wedge on the right, Rigid forefoot rocker on both	Adding a 4mm Medial arch pad increase	Lowering the heel height to 5mm to create a relatively reduced heel rocker and increase the angle of the forefoot rocker	6mm Poron Blue Metatarsal Dome 5mm behind the Right MTH 1	Reducing the forefoot rocker to 12 degrees to improve balance	Adding a 2mm medium Soft EVA top cover to the Right insole

Table 6.5

Series of modifications on footwear and insoles (Continued)

Participant	Shoe + Insole concepts	T1		T2		T3	
		Shoe modification	**Insole modification**	**Shoe modification**	**Insole modification**	**Shoe modification**	**Insole modification**
Participant 04	Shoe-B+Insole-C	4mm medial wedge and Rigid forefoot rocker on both	NA	Re-lasting forefoot and 2mm medial wedge on the Right, rigid forefoot rocker bilateral with a thinner profile outsole for aesthetics.	2mm Morton's extension under the MTH 1 on the Right	Deflection in the midsole under the Halluxes and reinforced the rocker profile by full-length carbon fibre plate. Lowered bilateral heel by 5mm. Lace to double velcros conversion for convenience.	NA
Participant 05	Shoe-B+Insole-C	MGF without rocker sole design as participant wanted to try this first.	6mm height Metdome on the Right	Rigid forefoot rocker bilateral, Apex position 15mm behind the MTH's	3mm extra deflection under the Right MTH 1 and 4mm MLA increase bilaterally	Increase stiffness and rcoker angle (20 degrees) at the forefoot, both shoes.	NA
Participant 06	Shoe-A+Insole-A	Without any modification as participants wanted to try them first as it is	NA	Rigid forefoot rocker bilaterally	5mm Morton's extension bilaterally	Stiffened rocker and reposition the apex, deflection in the midsoles under the Halluxes, bilateral 4mm medial wedges and lowering the heel height by 5mm.	NA

Table 6.5

Series of modifications on footwear and insoles (Continued)

Participant	Shoe + Insole concepts	T1		T2		T3	
		Shoe modification	Insole modification	Shoe modification	Insole modification	Shoe modification	Insole modification
Participant 07	Shoe-B+Insole-B	4mm medial midfoot wedge on the Left, Bilateral rigid forefoot rocker.	5mm increase in the MLA as part of the base design	Lowered the heel by 5mm on both shoes and added 2mm extra medial wedge on the Left midfoot, ending right behind the MTH 1	NA	Deflection in the midsole under the Halluxes on the Left and reinforced the rocker profile by full-length rigid EVA midsole.	NA
Participant 08	Shoe-B+Insole-B	Rocker sole (15 degrees rocker angle)	5mm MLA increase on both insoles	Adding rigid forefoot rocker sole bilaterally	7mm thick medium-soft Met Pads 6mm behind the MTHs, 5mm MLA increase bilaterally	Stiffened and rocker angle (20 degrees) at the forefoot, bilateral. Reposition apex on the Right shoe by 15mm behind the MTH 1 and Lowering heel height by 5mm bilateral, 4mm medial wedge on the Left midfoot and deflection under the Hallux.	2mm medium-soft EVA top cover on both insoles
Participant 09	Shoe-B+Insole-B	Lucro classic standard boot without further modification	Adding 6mm MLA increase on both insoles and 6mm metatarsal domes, 3mm Blue Poron layer cushion, 2mm Soft EVA top cover	Repositioning the rocker Apex at 15mm behind the MTHs	NA	Removal of EVA from the midsole under the MTH 1 bilaterally and filling with Blue Poron to improve offloading and added forefoot rocker	NA

Table 6.5

Series of modifications on footwear and insoles (Continued)

Participant	Shoe + Insole concepts	T1		T2		T3	
		Shoe modification	Insole modification	Shoe modification	Insole modification	Shoe modification	Insole modification
Participant 10	Shoe-A+Insole-A	Custom boots without further modification	Adding 6mm MLA increase on both insoles	Repositioning the rocker apex at 15mm behind the MTHs	Creating deflection and adding cushion materials (Blue Poron) under the MTH 2-3 on the right	Lowering the heel height by 5mm bilaterally and re-align the forefoot rocker	6mm Metatarsal Bar on the Right insole, 5mm behind the MTH 2-3
Participant 11	Shoe-B+Insole-C	Forefoot rocker bilaterally	NA	4mm medial wedge at the midfoot of both shoes	6mm thick Poron metatarsal dome, 5mm behind the MTH	Lowering the heel height by 5mm on both and re-align the forefoot rocker, keeping the same rocker profile and creating deflection under the Hallux in the midsole bilaterally	NA
Participant 12	Shoe-B+Insole-B	MGF without rocker sole design as the participant wanted to try this first.	NA	Bilateral rigid forefoot rocker and lowering the heel height by 5mm.	Bilateral 6mm Metatarsal Dome, 9mm behind the MTH's	Increased stiffness and rocker angle (20 degrees) at both shoes' forefoot.	5mm MLA increase, 6mm Metatarsal dome, 6m behind the MTHs bilaterally.

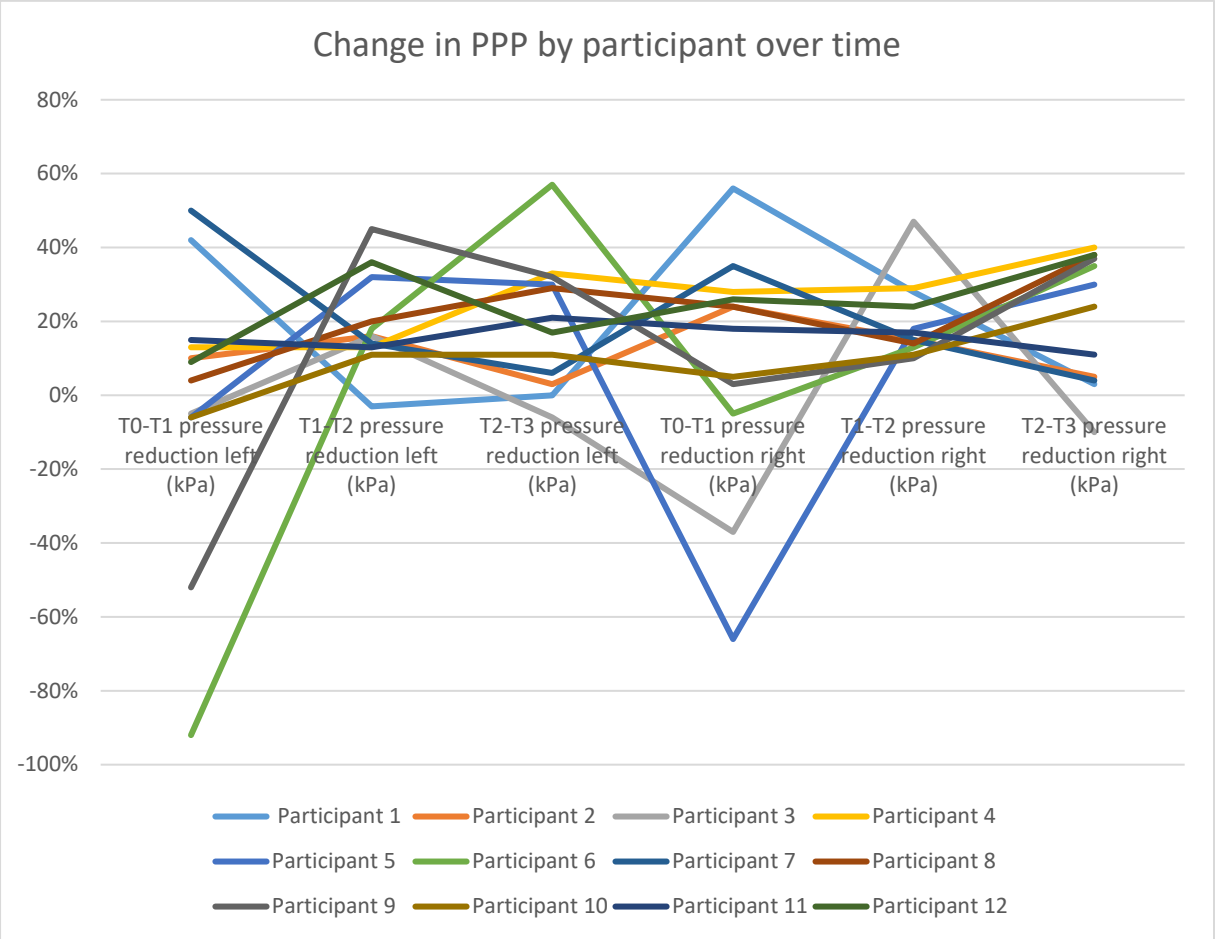
Table 6.6

In-shoe plantar pressure reduction rate following various modifications on footwear and insoles

Study participants	Footwear and insole concepts	Left (ROI) in-shoe	Right (ROI) in-shoe	T0-T1 pressure reduction left (kPa)	T1-T2 pressure reduction left (kPa)	T2-T3 pressure reduction left (kPa)	T0-T1 pressure reduction right (kPa)	T1-T2 pressure reduction right (kPa)	T2-T3 pressure reduction right (kPa)
01	Shoe-B + Insole-C	MTH 2-3	MTH 5	42%	-3%	0%	56%	28%	3%
02	Shoe-B + Insole-C	Hallux	Hallux	10%	16%	3%	24%	15%	5%
03	Shoe-A + Insole-A	MTH 4-5	MTH 1	-5%	16%	-6%	-37%	47%	-10%
04	Shoe-B + Insole-C	Hallux	Hallux	13%	13%	33%	28%	29%	40%
05	Shoe-B + Insole-C	MTH 1	MTH 1	-6%	32%	30%	-66%	18%	30%
06	Shoe-A + Insole-A	Hallux	Hallux	-92%	18%	57%	-5%	13%	35%
07	Shoe-B + Insole-B	Hallux	MTH 2-3	50%	14%	6%	35%	15%	4%
08	Shoe-B + Insole-B	Hallux	MTH 1	4%	20%	29%	24%	14%	38%
09	Shoe-B + Insole-B	MTH 1	MTH 1	-52%	45%	32%	3%	10%	37%
10	Shoe-A + Insole-A	MTH 2-3	MTH 2-3	-6%	11%	11%	5%	11%	24%
11	Shoe-B + Insole-C	Hallux	Hallux	15%	13%	21%	18%	17%	11%
12	Shoe-B + Insole-B	MTH 2-3	MTH 2-3	9%	36%	17%	26%	24%	38%

Figure 6.8

In-shoe plantar pressure reduction rate over a period of time following various modifications on footwear and insoles



The above table and figure (Table 6.6 and Figure 6.8) show that the changes in PPP are significant in some participants as per the desired pressure threshold (>30% reduction or <200 kPa) when compared with the baseline measurements (control, participants's own footwear). They are also statistically significant as presented in section 6.2.5 below. As per Table 6.4, the changes are within >30% reduction parameters for the participants 1-6, 8,11-12 and <200 kPa for the participants 7, 9-10 for the left foot. The changes are within >30% reduction parameters for the participants 2-9 and 11-12 and <200 kPa for the participants 1 and 10 for the right foot. The reason for such variations is due to some participants wanting to try the intervention footwear and insoles without significant modifications with the goal of PPP offloading until they try them first. Then, at the subsequent appointments, further

modifications to the footwear and insoles were performed, and PPP was reduced to the desired level in all participants' footwear. For example, participant 6 had biomechanically complex feet and the ROI is under the Hallux. Participant preferred a lower heel and thin profile sole and insole that was not adequate to create the offloading efficacy through the rocker and insoles. That showed significant increase in plantar pressure (-92%) from the base line at T1. Then further modifications were done to reduce the plantar pressure to come closer to the desired threshold and still it was 5% less than the control, where the control was custom-made orthopedic footwear and insoles. Tables 6.2 and 6.5 provide the details of the relevant information (participant-specific and footwear and insole design-specific) relating to the PPP reduction rate at the ROIs for each participant.

6.2.5: Summary of all footwear and insole concepts' efficacy in plantar pressure reduction (T0-T3)

All types of footwear and insole modifications helped to reduce peak plantar pressure but the sole modifications (rocker apex position and rocker angle, medial or lateral wedges, heel height adjustments and sole rigidity) were more effective in plantar pressure reduction.

All footwear and insole concepts went through up to three iterative modifications that were applied objectively (guided by in-shoe PP analysis) based on main foot pathology, comorbidity and participants' preferences that show success in offloading compared to the baseline footwear and the final modified version of the intervention footwear (double-sided $p<.001$). The in-shoe plantar pressure data were compared with baseline footwear and insole (T0) and the final round modifications of intervention footwear and insole at T3. The statistical analysis and significance of the in-shoe plantar pressure reduction success of each footwear and insole concept, when compared with the baseline footwear and insole, are presented below.

Shoe A+Insole A:

Mean Difference: 116.667

SD (Standard Deviation): 104.410

95% CI (Confidence Interval): Between 7.095 and 226.238

t-value (Test Statistics): 2.737

df (Degrees of Freedom): 5

p-value: < 0.05 (indicating statistical significance)

The paired sample t-test compares the mean difference in peak plantar pressure before and after using Shoe A+Insole A. The mean difference of 116.667 indicates the average change in peak plantar pressure. The t-value of 2.737 is a standardized score that measures how many standard deviations the mean difference is from zero. The degrees of freedom (df) are 5 in this case. The p-value of < 0.05 suggests that the observed reduction in peak plantar pressure is statistically significant, meaning it is unlikely to have occurred by random chance.

Shoe B+Insole B:

Mean Difference: 302.625

SD (Standard Deviation): 167.082

95% CI (Confidence Interval): Between 162.941 and 442.309

t-value (Test Statistics): 5.123

df (Degrees of Freedom): 7

p-value: < 0.001 (indicating statistical significance)

Similar to Shoe A+Insole A, the paired sample t-test for Shoe B+Insole B compares the mean difference in peak plantar pressure before and after intervention. The large mean difference, tight confidence interval, high t-value, and low p-value all indicate that the reduction in peak plantar pressure is statistically significant.

Shoe B+Insole C:

Mean Difference: 243.700

SD (Standard Deviation): 151.026

95% CI (Confidence Interval): Between 135.662 and 351.738

t-value (Test Statistics): 5.103

df (Degrees of Freedom): 9

p-value: < 0.001 (indicating statistical significance)

The paired sample t-test for Shoe B+Insole C follows the same logic. The mean difference, confidence interval, t-value, and p-value collectively suggest a statistically significant reduction in peak plantar pressure.

In summary, these paired t-tests assess whether the observed changes in peak plantar pressure are likely due to the interventions (Shoe A+Insole A, Shoe B+Insole B, and Shoe B+Insole C) rather than random variation. The statistical significance, indicated by the p-values, supports the conclusion that the interventions have a significant impact on reducing peak plantar pressure.

6.2.6 Adherence

Adherence was measured by the self-reported wearing period by the participants and their answers on satisfaction and ease of use on the Likert scale. Some participants had low adherence at the beginning, and that increased over the period of time and towards the end of the trials, all participants had high adherence.

Field notes and Table 6.2 revealed several factors influencing adherence and how they were addressed. Adherence of the participants to the footwear was self-reported, and adherence (amount of time participants spent in the shoes during specific activities) to the footwear and insole.

The adherence score percentage was high (over 80% for the majority of cases, n=7, over 70% for n=4 and above 60%, n=1) for their intended use and activity, considering the three main activities the participants were engaged in daily. The activity scores were multiplied by 2 hours, and 16 hours/day was considered the standard weight-bearing period for the participants indoors and outdoors. Table 6.7 and Figure 6.9 describes the detailed adherence-related information for each participant from each appointment.

A number of individual factors impacted patient adherence to wearing the shoes. In standard clinical trials, these kinds of attributes are rarely considered; however, the N-of-1 study allowed us to understand person-specific issues that influence adherence, such as religious practices, etc.

Person-specific activities that can influence adherence

In this study, participant 02 is from the Muslim faith and regularly practising prayers (salat) in the standard way that requires sitting on the flexed right knee and dorsiflexed Hallux for a couple of minutes each time (Nazish & Kalra, 2018; Reza et al., 2002) and at least 16 occasions per day. This position increases peak plantar pressure in the isolated location of the right Hallux. He was advised to seek alternative permitted postural options to perform the prayer and sit on a chair to perform the whole prayer (Ahmad et al., 2018) was adopted by the participant. There was remarkable improvement in callus building at the ROI with the adapted praying posture and the regular use of modified medical-grade footwear with custom insoles despite a PP of 452 kPa. This participant also reported that culturally, he is hesitant to take outdoor shoes indoors at home and also while he visits relatives. The details are provided in Table 6.2.

In our study, participant 03 used a walking aid to improve balance due to severe neuropathy and transmet amputation (TMA) on the right and a further comprehensive plantar pressure assessment was performed objectively to explore the influence of a walking aid on PP

offloading. Both in-shoe and barefoot static and dynamic PP assessments were done without the walking aid, with the walking aid on the right hand and on the left hand. All three types of PP assessment showed a similar trend in pressure offloading when the walking aid was used on the right-hand side. The ROI was the right MTH 1, and that area was showing reduced PP compared to the PP without the walking aid (27% reduction in in-shoe and 52% reduction at barefoot dynamic pressure). When the walking aid was used on the left-hand side, the PP was increased at the ROI when compared with the PP without the walking aid (increased in-shoe PP by 32%).

Family, spouse support and social environment influence adherence.

There is a positive and significant relationship between family, social support and adherence in people with diabetes (Miller & DiMatteo, 2013). Many participants in this series of N-of-1 trials reported that their foot conditions made them depressed and were concerned about how other people looked at them due to their illness. Some also reported their concern about the appearance of the footwear and how other people see them. Supportive and cooperative views in the family and social environment can bring significant positive health outcomes through increased adherence (Miller & DiMatteo, 2013). Participant 10 in our study was given an athletic design custom-made ankle-high boots with mesh vamp and leather quarters. The soles were the trainer's soles in white color, and the appearance was contemporary, semi-casual looking that suited well the participant's lifestyle and intention of use. He had positive feedback from his club mates, which made him very confident in himself and encouraged him to wear them as much as possible. During every appointment, he reported how good they looked and how comfortable they were walking in, with improved balance and relieving pain. He was also sharing his story with other patients in the waiting room of the outpatient department. These led to positive adherence and health outcomes for him.

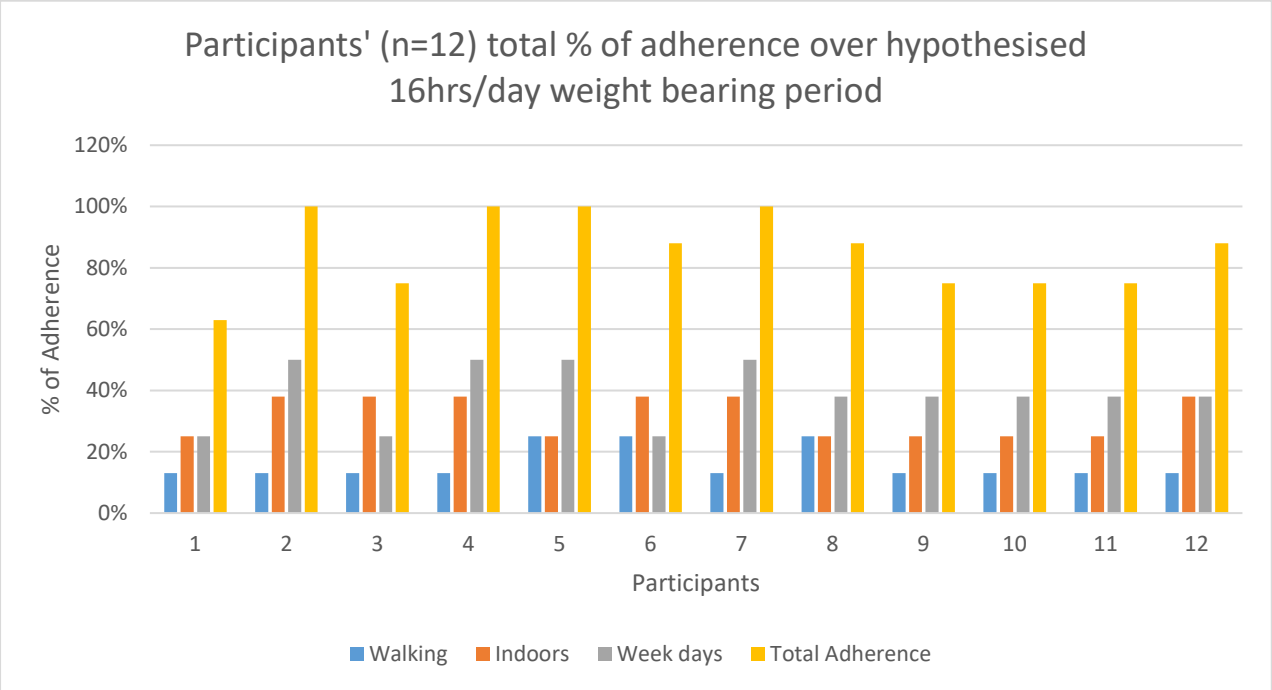
Health funds availability and influence on adherence

Health fund availability and influence on recommendations are commonly seen in clinical practice. In this series of N-of-1 trials, participants 02, 05, and 10 were given footwear options that were influenced by the fund availability and participant's affordability, referrer's recommendations on footwear type, and that demonstrated a potential limitation in foot structure accommodation without significant modification of the prefabricated medical-grade

footwear. Those participants were more willing to get fully custom-made footwear if they were available within their self-funded budget or the referrer's recommended budget with the health fund.

Figure 6.9

Participants' total % of adherence during weight-bearing activities



6.2.7 Participants' satisfaction with the prescribed footwear and insole

Participants' satisfaction score on each question which was recorded at each appointment (t1-t4), shows consistency in satisfaction score items in most cases. There have been some occasions where the satisfaction was lower in t2 or t3 such as Participant 3 reported lower satisfaction at t2 with the questionnaire on balance while using the footwear which correlated with modifications at the earlier appointment for PPP reduction. With neceassry adjustments, the satisfaction score went higher at t3. The similar trends were noted for participants 4 and 9. The satisfaction level increased towards the end of the trials. Generally, satisfaction was higher among the participants with their footwear and insole (90-100%, n=8, 70-80%, n=3, 40-50%, n=1). The questions report the satisfaction scores into two categories positive and

adverse outcomes. The positive outcomes were the appearance, usability, comfortability, fit, ease of walking, and overall perception of the footwear and insoles. The negative or adverse outcomes are unappealing or poor appearance, poor balance, increased weight and being too high from the ground.

Tables 6.7, 6.8 and Figures 6.9-6.12 describe detailed information about the participants' satisfaction.

Table 6.7

Participant's average satisfaction score across T1-T4

PARTICIPANTS	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10
1	5	5	1	1	5	5	1	2	5	5
2	4	5	1	3	4	5	3	4	5	4
3	5	5	1	1	5	5	1	1	5	5
4	4	2	4	1	5	5	1	4	5	5
5	5	5	3	1	5	5	1	1	5	5
6	5	5	1	1	5	5	2	1	5	5
7	5	5	1	4	4	5	2	4	5	5
8	5	5	1	1	5	5	3	4	5	5
9	4	4	4	3	4	5	3	4	4	4
10	5	5	1	1	5	5	1	1	5	5
11	5	5	1	1	5	4	1	1	5	5
12	5	5	1	1	5	5	3	2	5	5

SCORES	Questions details	
STRONGLY AGREE = 5	Q1. I really like the way these shoes look.	Q6. These shoes fit like a glove.
SOMEWHAT AGREE = 4	Q2. I can wear these shoes anywhere	Q7. These shoes are too heavy.
NEITHER AGREE OR DISAGREE = 3	Q3. I worry about what others think when I wear these shoes	Q8. These shoes make me feel too high from the ground.
SOMEWHAT DISAGREE =2	Q4. These shoes have made my balance worse.	Q9. These shoes are really easy to walk in.
STRONGLY DISAGREE =1	Q5. These shoes are very comfortable	Q10. Overall these are great shoes.

The data presented in Table 6.4 are the average sores of each timepoint to keep the information succinct and additional information of the questions details and scoring systems are described at the bottom of the Table.

Figure 6.10

Participants' single summary satisfaction score at each appointment

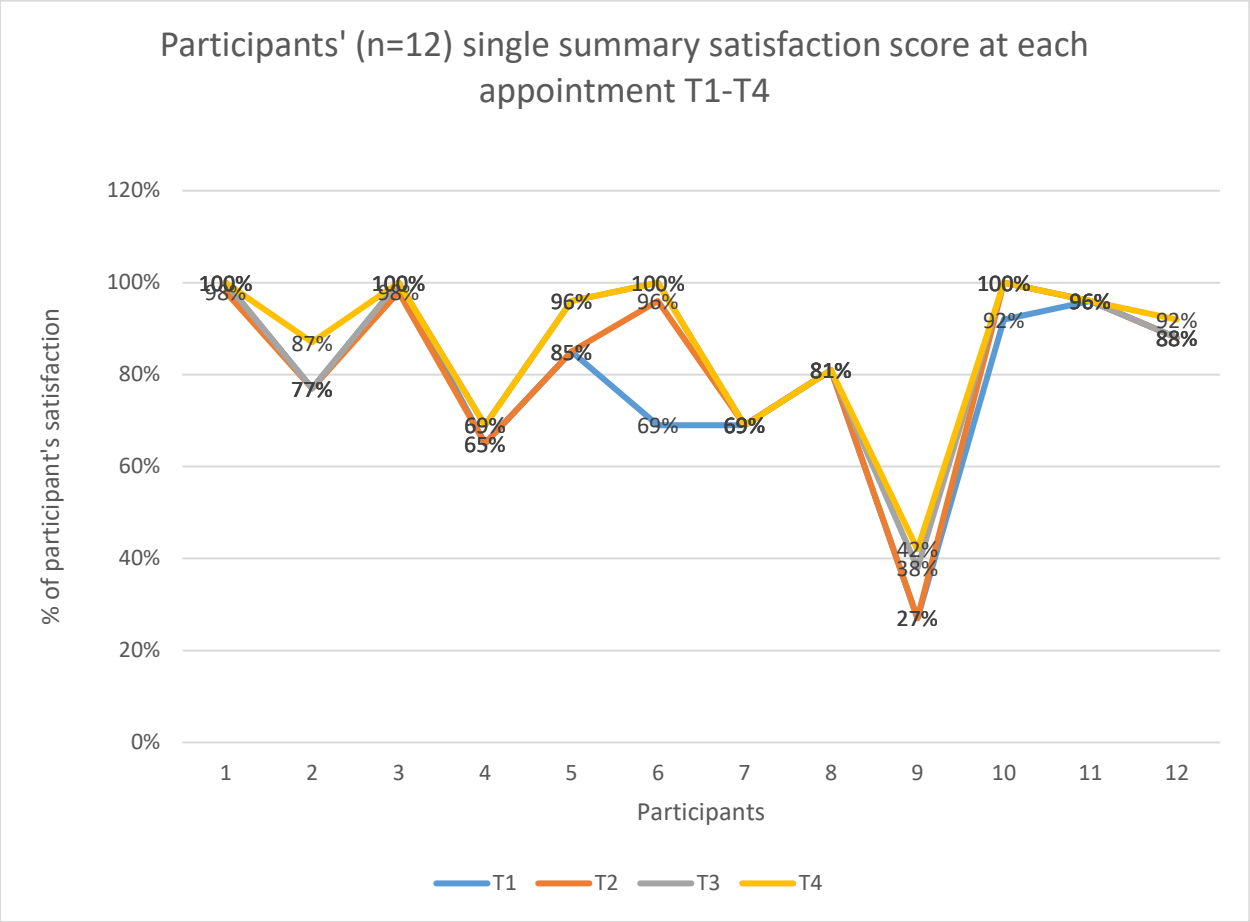
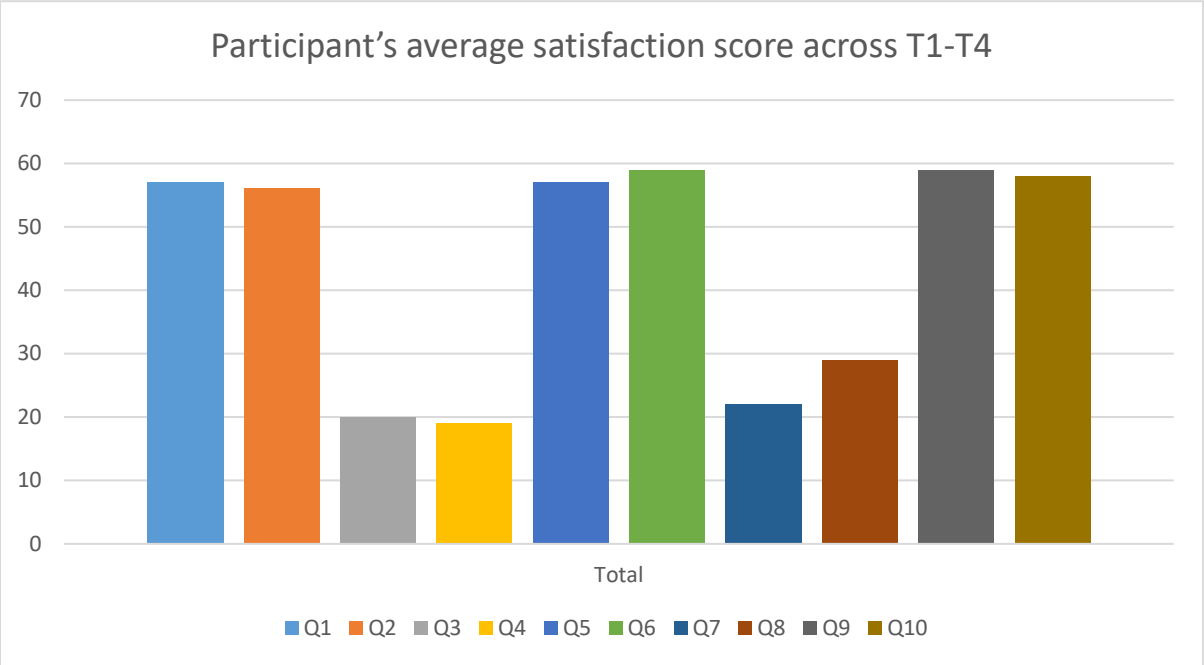


Figure 6.11

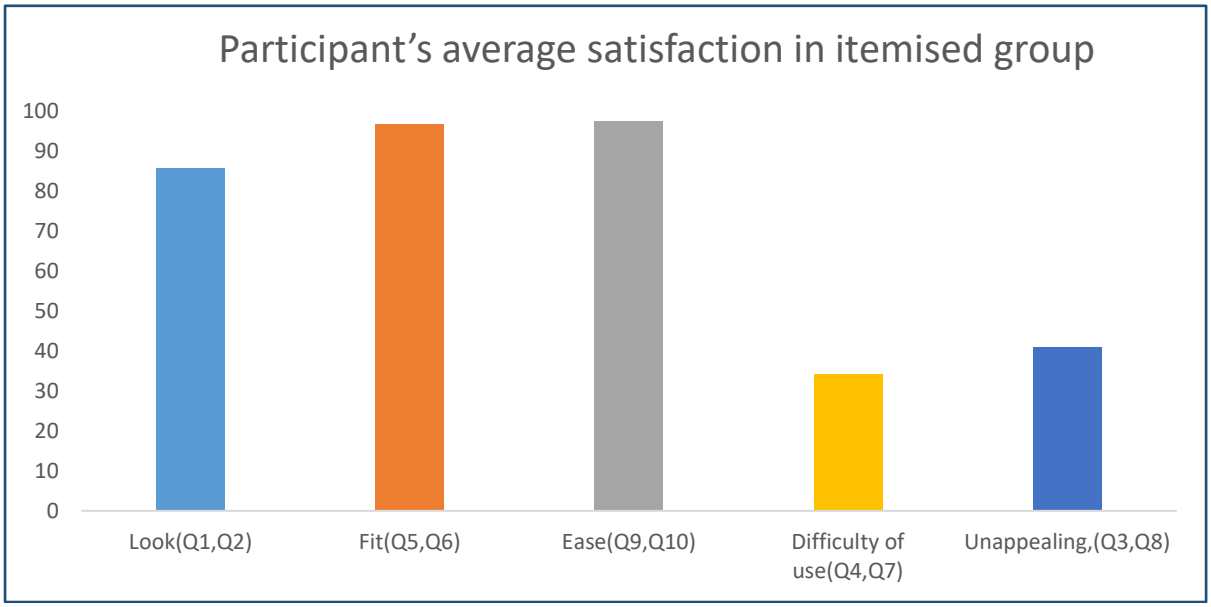
Participants' average satisfaction scores across T1-T4



In the above bar graph, the positive satisfaction outcomes scored high and fitting, and ease of walking scored the highest, followed by appearance, usability and overall perceptions of the footwear. The adverse effects are scoring low, where the feeling of being too high from the ground was the most reported negative outcome, followed by weight, poor balance and appearance.

Figure 6.12

Participants' average satisfaction in itemised group scores across T1-T4



6.2.8: Participants' satisfaction with in-shoe plantar pressure reduction

There is no association between a change in in-shoe plantar pressure and participants' satisfaction, as shown in Table 6.8. All the participants had moderate to severe neuropathy, and the plantar pressure reduction outcome did not influence satisfaction with the footwear and insoles. Ease of walking, appearance and improved balance were the most important factors for increasing satisfaction.

Table 6.8

Patient satisfaction score and the correlation with plantar pressure reduction

Correlations				
		Satisfaction Score (Positive)	Left In-shoe (Reduce)	Right In-shoe (Reduce)
Satisfaction Score (Positive)	Pearson Correlation	1	-.177	-.206
	Sig. (2-tailed)		.582	.521
	N	12	12	12

Correlations				
		Satisfaction Score (Negative)	Left In-shoe (Reduce)	Right In-shoe (Reduce)
Satisfaction Score (Negative)	Pearson Correlation	1	.455	.282
	Sig. (2-tailed)		.137	.374
	N	12	12	12

The data from this chapter of the results of a series of N-of-1 trials have been used to suggest the set of design principles in Chapter 7, and many of the recommendations are based on the findings from this series of trials.

6.3 Discussion

Context

All the participants in this study had Type-2 Diabetes Mellitus, and there were 12 participants in this series of N-of-1 trials. The population studied in these trials was representative of those with diabetes-related neuropathic foot complications. These usually occur from around 40 years of age, with increasing prevalence with age. Most of the participants were male in this study, which is consistent with the findings of other studies that diabetes-related foot complications are prevalent in male patients (Al-Rubeaan et al., 2015). The trend of participants' characteristics is reasonably representative of those found in Study 2 (clinical audit).

This is the first series of N-of-1 trials for footwear and insole intervention in people with diabetes. N-of-1 trials provide a technique to inform evidence-based treatment decisions for an individual participant. The most common methodological components of large clinical trials are used to measure treatment effectiveness in a single participant. These trials have practical and effective applications when circumstances preclude large-scale trials, such as investigations into rare diseases, comorbid conditions, or in participants using concurrent therapies (Vohra et al., 2015). The literature review shows that participant adherence is key for successful offloading initiatives for a diabetes-related neuropathic foot.

This study has shown that while a range of tailored treatment options is effective at reducing PP in the forefoot, the reduction in PP alone is not associated with patient satisfaction with treatment.

Satisfaction with footwear (likely to be a proxy for adherence to the footwear) was most strongly associated with fit, ease of use, and walking comfort.

Satisfaction influences adherence positively (Barbosa et al., 2012), and this study showed that if the participant was satisfied with the footwear and insoles at the beginning and if they experienced some problems due to poor balance, the weight of the shoes or inconvenience of donning and doffing, their adherence increased later once those issues were attended to and resolved. Adherence is also significantly associated with age and the duration of the illness

(Sweileh et al., 2011). In this study, all participants had the conditions for a longer period, which may explain why they were more persistent than many other people with the same conditions (Jarl et al., 2020; Waaijman et al., 2013). Personalised footwear design that is the participant's goal and intended activity oriented (Keukenkamp et al., 2022) and when the participant has a favourable social and family environment (Study 3), the adherence to footwear and insoles maximises.

Footwear is an integral part of clothing, and participant preference plays a vital role in footwear usage and client adherence to recommendations. Therefore, a person-centred study design that can recommend a precise prescription for personalised therapy or devices is very important. The N-of-1 trial is a unique trial that focuses on participant preferences and circumstances. This is also beneficial for personalised treatment decisions for participants with chronic conditions (Duan et al., 2013).

Patient adherence is important because it determines the outcome of the therapy (López-Moral et al., 2022) and is affected by fit, ease of use and walking comfort (Malki et al., 2023). The perceived value of footwear and insoles are also influencing factors for adherence in people with diabetes and neuropathy (Waaijman et al., 2013).

Patient satisfaction is important because it positively influences adherence (Barbosa et al., 2012) and is affected by aesthetics and perceived self-image in the social image (Waaijman et al., 2013).

The treatment goal of all of these studies was a reduction in peak plantar pressure of <200kPa or a 30% reduction from the control. The study showed that by using a range of different interventions, this was achieved to a greater or lesser extent with some variations as reported in sections 6.2.4 and 6.2.5The potential reasons for the variations are due to the baseline footwear type (offloading optimized shoes and orthotics), participants' preferences on intended activity and aesthetics, stability, intention to use them to start with to find out the comfort and stability prior to further modifications.

In addition, this trial has repeatability and direct application to individual participant treatment as the best-personalised treatment method (Duan et al., 2013). This trial method appeals to participants in generating feelings of being more involved and seeing accurate

feedback to responses (Nikles et al., 2011). This study had inclusion criteria that allowed to include participants with relatively more complex foot conditions than most other studies that have investigated footwear and insole design parameters (Ahmed et al., 2020) for people with diabetes and neuropathy. Hence, a variation is expected in findings and recommendations in footwear and insole design parameters and participants' adherence factors relating to their mobility and activity compared to other studies.

The results of this series of trials provide insights into plantar pressure measurement, insights into a personalised design, family and social environment and outlook on diabetes-related foot complications, cultural and religious rituals influence pressure offloading strategies, insights into adjunct / Multidisciplinary care, the impact of funding as described below.

Insights into plantar pressure measurement

This study found that the region of interest (ROI) or the peak plantar pressure area for the barefoot static and dynamic plantar pressure can be different, and it is consistent with other studies' findings (Chuter et al., 2021). Barefoot and in-shoe pressure values and ROIs are not the same for the same participant due to biomechanical and footwear design influences (Chuter et al., 2021). These findings suggest barefoot and in-shoe plantar pressure analysis for all participants with high-risk feet for an optimum outcome, which is also consistent with other studies' findings (Patry et al., 2013). Barefoot pressure analysis is only recommended when it is safe for the patient in terms of infection control and increased plantar pressure in barefoot conditions while performing the tests. The current guidelines on offloading threshold are generic and independent of the pressure measurement systems and technology around it (Bus, Armstrong, et al., 2016). However, the commonly available plantar pressure measurement systems and the sensors differ in thickness, flexibility, and sensor density (Ahmed et al., 2020), and it is not unlikely to have a different pressure reading for the same foot and footwear when a different system is used (Chevalier et al., 2010).

There was an unexpected finding in this study, and considered important to report. The role of a walking aid to reduce PP for the same hand side of the ROI needs to be considered in the treatment protocol for acute and remission phases. It shows positive outcomes for pressure reduction and balance improvement for patients with severe neuropathy and at risk of falls when used on the same side hand as the ROI.

Partial (Great Toe, GT) or TMA of the foot results in altered and increased plantar pressure on the amputation site (Ashry et al., 1997; Garbalosa et al., 1996) that requires a different offloading strategy with a different pressure threshold as the expected outcome to prevent further ulceration. The pressure threshold for the GT or TMA is not specified in the current guidelines (Ahmed et al., 2020). This series of N-of-1 trials shows that participant 03, with a transmetatarsal amputation on the right and having a PP under the MTH 1, was in remission with a PP of 341 kPa in his custom-made orthopedic boots with custom-made insoles. This participant used a walking aid on the right hand for maintaining his balance anytime he was mobilising, and pressure was increased on that ROI without the walking aid, and it increased further when used on the left hand. The same trend was followed in barefoot static and dynamic pressure analysis for the same participant.

Current guidelines recommend a <200 kPa PP or a 30% reduction of PP from the control footwear (4). However, participant 01, having a PP of 148 kPa under the MTH 5, needed to have a debridement of the callus every two weeks by the podiatrist; otherwise, it would lead to ulceration. A further reduction of PP to 103 kPa was able to ensure every four weeks debridement rather than every two weeks for the ROI on the right. The PP on the Left foot ROI was 352 kPa, and that did not cause any concern at any point in time for this participant. Participant 02, with a history of Hallux ulcer on the right with a BMI of 41.8 and being in an occupation that requires him to be on the feet for over 10 hours a day, was in remission with a PP value of 452 kPa and podiatry intervention for the debridement in every six weeks. The PP reduction from the baseline was over 40%; however, the PP is well above 200 kPa. This indicates that current guidelines may be insufficient as a threshold to encompass all possible variation and that the exact plantar pressure cutoff value is more person-specific and more accurate, and it is foot-specific (Chevalier et al., 2010) (Naemi et al., 2017). Hence, a comprehensive foot assessment (Naemi et al., 2017; Formosa et al., 2013), participant's lifestyle, and other adherence-related factors need to be taken into consideration with an objective plantar pressure analysis strategy to recommend footwear and insole design parameters and establish the minimum pressure threshold to keep that foot in remission (Chatzistergos et al., 2020) (Chatzistergos et al., 2015). Patients' comorbidity (Meloni et al., 2020; Meloni et al., 2018), tissue resistance, and plantar loading (Allan et al., 2022), skin properties and shear force (Jones et al., 2022) (van Netten, van Baal, et al., 2018; Yavuz et al., 2017) considerations are crucial for a comprehensive ulcer prevention strategy.

Insights into a personalised design

A personalised design approach is crucial for maximising the adherence of the participants. Adherence to the prescribed footwear and insole is an essential part of achieving the clinical outcome of optimum offloading and reducing the risk of foot ulceration and subsequent amputation (Botelho et al., 2022; Zhang et al., 2022). The recommended footwear needs to meet the criteria for the participant's intention of use, whether for outdoor use for walking, going shopping, medical appointments, social or religious events, occupational purposes or indoor use. In these populations, the indoor-specific footwear design and options consideration help to increase adherence and reduce the risk of ulcer occurrence and recurrence (Keukenkamp et al., 2022). In this series of N-of-1 trials, it was noted that most participants expressed the need for indoor footwear with a similar offloading capacity to the footwear and insole provided to them during the trial. Hence, it is recommended that footwear considerations cover all weight-bearing activities the patient would be taking in everyday life. This is also consistent with the finding of another recent study done in the Netherlands (Keukenkamp et al., 2021) in a similar patient group. Appropriate socks are also important to prescribe to this patient group for increased adherence and reduce the risk of issues caused by inappropriate socks (Ahmed et al., 2020; Kaminski et al., 2021).

Family and social environment and outlook on diabetes-related foot complications

A supportive partner or spouse helps enhance adherence and health outcomes and often influences treatment decisions (Miller & DiMatteo, 2013). The pedorthists' survey also describes various strategies the practitioners follow to overcome adherence-related challenges and increase adherence for improved clinical outcomes. As Study 3 (pedorthists' survey) reported, involving a spouse or partner is a key strategy most pedorthists follow during the consultation and footwear design planning phase. They often involve a supportive and engaging carer when the carer is the main point of contact for a patient.

Cultural and religious rituals influence pressure-offloading strategies.

Climate, cultural, and religious beliefs and practices influence footwear style and adherence (Ahmed et al., 2020; Jain, 2020; Jain et al., 2021). People who live in cooler climates are more likely to wear closed-in shoes, such as boots, and, from warmer climates, are more

likely to wear low-cut and minimal upper footwear styles, such as sandals or slides (Ahmed et al., 2020; DeMello, 2009). Some cultures do not allow wearing outdoor footwear indoors or wearing any footwear indoors at all (DeMello, 2009; Jain et al., 2021). Hence, culturally sensitive offloading strategy, patient education, and appropriate device design are essential. This study also found that religious rituals require a different offloading strategy and patient education.

Insights into adjunct / Multidisciplinary care

Regular reviews with podiatrists and pedorthists are a very important strategy to keep the foot in remission and reduce the risk of ulcer recurrence (Meloni et al., 2020). In this series of N-of-1 trials, the participants were under regular follow-up with the podiatry team either at the private clinic or at the high-risk foot clinic and the associated community clinic as part of their regular care and with a pedorthist for the ongoing offloading devices. None of them was ulcerated during that period of regular follow-up, although many of them had very high-risk feet. Hence, it is recommended that patients with high-risk foot need to be under a podiatry team either at the community health centres or private clinics for regular review and treatment as per the guidelines and pedorthic review every 12 weeks for the regular check-ups and maintenance of the footwear and insole to ensure the offloading efficacy all the time (NADC, 2018; Bus et al., 2013; Cheng et al., 2017; Jongebloed-Westra et al., 2021; López-Moral et al., 2022). On-time replacement of the footwear and insole that meets the patient's weight-bearing activities needs to be ensured for maximum adherence and the risk reduction of ulcer recurrence (Arts et al., 2015; Rizzo et al., 2012). A multidisciplinary approach to involving podiatrists and pedorthist in the care team for people with diabetes has complementing factors as confirmed by the scientific evidence (Ahmed et al., 2020; Botelho et al., 2022). For example, in research, the footwear assessment and evaluation tools are driven by the podiatry profession (Barton et al., 2009; Ellis et al., 2022), and the footwear design, manufacturing and modifications algorithms are pedorthic profession-driven approaches (Bus, Zwaferink, et al., 2020; Keukenkamp et al., 2021; Zwaferink et al., 2020). Both approaches can ensure the patients receive the most appropriate person-centric footwear and insoles that are effective in offloading, accommodation and fit for the purpose and intention of use by the patients (Ahmed et al., 2020; Botelho et al., 2022).

The impact of funding

There are various providers that provide funding for footwear and insoles for eligible patients (Kaminski et al., 2021). They include state government funds such as Enable HealthShare NSW and federal government schemes, including the National Disability Insurance Scheme (NDIS), Department of Veterans Affairs (DVA), Aged care package, Closing the GAP (for the Aboriginal and Torres Strait Islanders). Private health funds are available for patients who do not meet the eligibility criteria of any funding mentioned above. Access to health funds positively influences adherence to therapy (Priya et al., 2020), and this is supported by Study 3 (Australian pedorthist survey) and NADC HRFS service standards (NADC, 2018).

6.4 Limitations

A lower number of participants than the initial consideration of 21 participants. The study took place during COVID-19 restrictions, which meant that the hospital outpatients department's restriction on the maximum number of patients who could attend the clinics and the requirements of PCR tests and vaccination status of the participants were barriers to including the maximum number of participants. Four patients were unable to continue in the study because they were not vaccinated, and one participant dropped out due to ulceration while waiting for the 2nd consultation (t1) during the COVID-19 restrictions on OPD attendance.

A lower number of female participants limits the variations in adherence-related factors from female patients' perspectives, and studies (Jarl & Lundqvist, 2016) suggest that women have different expectations and resulting satisfaction levels from footwear. Although it was expected that women participants would be less than men, it was a lot less than anticipated as COVID-19-related restrictions influenced the lower number and other studies (Pang et al., 2021; Vogel et al., 2020) suggested a similar trend that female patients were more worried than men during the pandemic, and they preferred to use teleconferences for their foot care than attending the OPDs.

The outcome of satisfaction and adherence was not examined with a survey for quantification to be examined alongside the other outcomes. Rather it was carried out by a set of questionnaire derived *from previous literature* (Ulbrecht et al., 2014). Further research should evaluate satisfaction and experience with interventions in qualitative terms for a more robust analysis.

Because of the course of the study occurring during COVID-19-related restrictions, participation in the service from which participants were recruited was minimal from vulnerable groups such as Aboriginal and Torres Strait Islanders.

It is noted that for Shoe A + Insole A, the sample size is limited, with only 3 participants (numbers 3, 6, and 10). We recognised that with such a small sample size, the results should be interpreted with caution, and the statistical power to detect significant differences may be limited.

We acknowledge the limitation of generalisability due to the smaller sample size and the specific characteristics of our study population. It is clear that our findings primarily apply to individuals with similar demographic and clinical profiles.

We also emphasised the need for further research with larger and more diverse populations to validate and extend the applicability of our results to a broader range of individuals with diabetes and neuropathic plantar forefoot ulceration.

6.5 Conclusion

This is the first series of N-of-1 trials for footwear intervention for people with diabetes and neuropathy and at risk of plantar forefoot ulceration. This study has provided new insights into plantar pressure threshold for individual patients to ensure optimum offloading of the foot to prevent forefoot plantar ulceration. The plantar pressure cutoff threshold should be considered foot-specific, and other factors, such as minor or major foot amputation site and use of a walking aid, need to be considered for ulcer prevention management. Other interrelated factors such as comorbidity, mobility status, tissue biomechanics, plantar tissue stress, plantar loading, and shear force must be considered when planning for an optimum offloading strategy. Patient adherence is also integral to the foot ulcer prevention and

remission strategy. A personalised footwear and insole design that matches the goals and intention of use by the patient who finds them fit well, easy to use, and comfortable in walking can maximise the adherence. Adherence is influenced by family, spouse, friends, social environment, health funds availability, regular reviews, and follow-up with podiatrists and pedorthists, and other relevant health care professionals involved in their care.

Further studies need to explore the scope and effectiveness of those parameters to improve offloading and adherence for those population groups to keep the high-risk feet in remission and prevent avoidable amputation by helping the patients enjoy life towards overall health and emotional and social well-being.

CHAPTER 7 | Discussion

7.1 Overview of the chapter

This chapter synthesises the findings from the four studies in this thesis in the context of current evidence and examines the extent to which the studies were able to achieve the research aims and objectives. The study aims and objectives are presented, and then the key findings of each study in relation to the research aims are presented and synthesised into a set of design principles table to help guide the future prescription of footwear for people with neuropathic plantar forefoot ulcers in people with diabetes.

7.2 Thesis aims and objectives

Aims

The overall aim of this series of studies was to develop a set of design principles for footwear and insole design and modification prescriptions to prevent neuropathic plantar forefoot ulcers in people with diabetes.

Objectives

1. Collate and summarise the current literature on the effectiveness of footwear and insoles in reducing peak plantar pressures and preventing diabetes-related neuropathic forefoot ulceration. (Study 1)

2. a) Explore the population of patients who use pedorthic services. (Study 2)

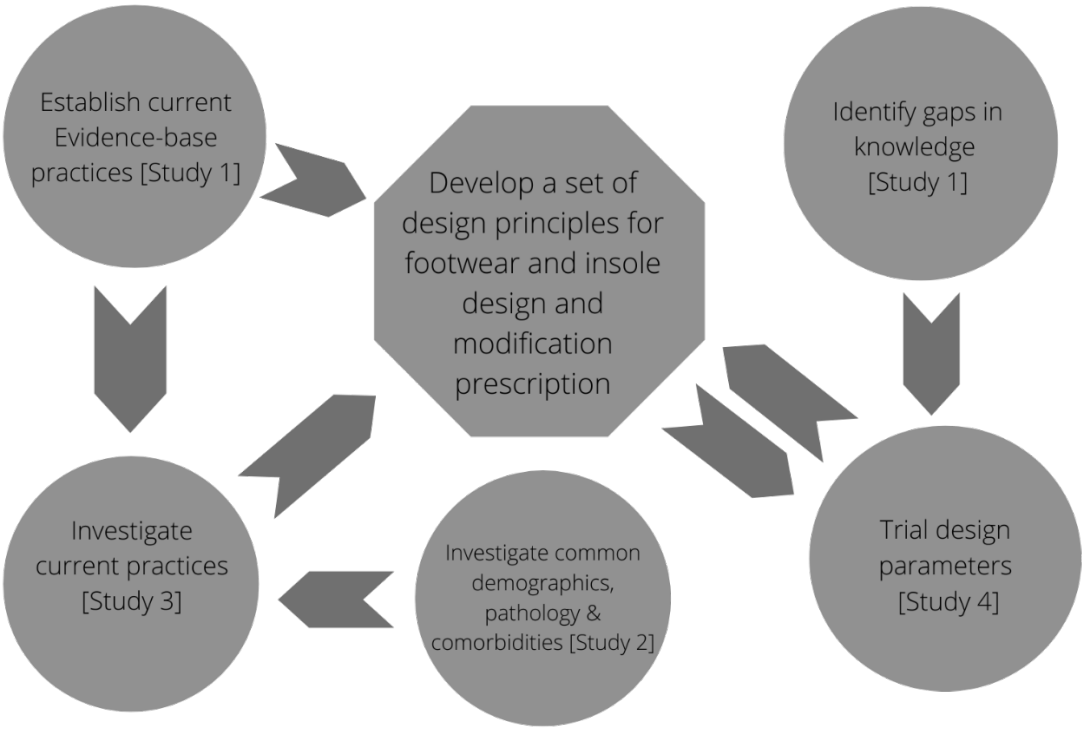
2. b) Explore current pedorthic practices in footwear prescription and manufacture (Study 3)

3. Examine footwear and the influence of features on plantar pressure, patient satisfaction, and adherence. (Study 4)

The research approach and development of the set of design principles are summarised in Figure 7.1 below.

Figure 7.1

Schematic of research approach and connections among studies



7.3 Summary of findings of the studies

To achieve these objectives, the following studies were undertaken:

7.3.1 Study 1: Systematic literature review

Twenty-five studies were reviewed systematicallyInvolved a total of 2063 participants. While methodological quality varied, there wasstrong evidence for rocker soles to reduce peak plantar pressure. Moderate evidence existed for custom insoles to offload forefoot plantar pressure. There was weak evidence that the insole contact area influenced plantar pressure. Footwear and insoles are complex interventions, and the outcome measure is still limited to PPP reduction and ulcer recurrence. Rocker soles, custom-made insoles with metatarsal

additions and a high degree of contact between the insole and foot reduce plantar pressures in a manner that may reduce ulcer occurrence.

Most studies rely on a reduction in PPP measures as an outcome as a proxy for the occurrence of ulceration. There is limited evidence to inform footwear and insole interventions and prescriptions in this population. Further high-quality studies in this field are required. Approaches to measuring patient adherence are lacking but play a vital role in the overall outcome of the treatment.

7.3.2 Study 2: Retrospective clinical audit

A retrospective clinical audit of a cohort of 70 patients at a suburban pedorthics clinic was undertaken to understand the pedorthists' patient profile, including sociodemographic, pathological, comorbidity-related, and other individual characteristics.

The mean age of participants was 64.69 (SD 11.78) years, ranging from 27 to 90 years old. They were more likely to be male (n=43 males (61.4%)). Australia was the birthplace of the highest number of participants (n=28) and the majority of the participants (n=42) were born outside of Australia. About 5.7% (n=4) were of Aboriginal or Torres Strait Islander origin.

The mean duration of diabetes among the participants was 14.09 years (SD 6.58). The mean duration of neuropathy was 8.56 (SD 4.16) years.

Approximately 47% (n=33) of participants had HAV; 39% (n=27) participants had hammertoe and cavus foot conditions, and 33% (n=23) of participants had clawed toes. Common foot pathologies among the participants were bony prominence at 71% (n=50), rigid flat foot, and limited joint mobility (LJM) (53%, n=37). Hyperkeratosis was the most common condition in the participant group; everyone (n=70) had this condition. Of previous foot pathology, about half (47%) of the participants had a history of forefoot ulceration. Around one-third, 34% (n=24) of participants, had forefoot amputation, and around 34% (n=24) had undergone a digital amputation.

The most common comorbidities in this group were rheumatoid arthritis (RA) 36%, Peripheral vascular disease (PVD) 41%, lymphodema 20%, and posterior tibialis tendon dysfunction (PTTD) 26%.

The main funding providers for footwear in this population group, comprising 78% (n=55), was Enable NSW, followed by privately (self) funded at 10% (n=7), Closing the Gap at 4.3% (n=3), private health insurance 2.9% (n=2), and aged care package 1.4% (n=1).

This shows the complexity of patients, highlights the variations in social issues, funding models, cultural needs, and personal preferences, and how this might impact the outcome of patient care through appropriate footwear and insoles for their conditions. This guides the variations in the case studies to represent a "typical" male or female patient seen at the pedorthics clinic, particularly the sociodemographic, foot pathology, and comorbidity characteristics.

Clinical case studies

The audit results were used to create four ‘typical patient’ case studies based on the categories of age, gender, country of birth, duration of diabetes and neuropathy, foot pathology, comorbidity, and health fund access provision for representing patients who come to pedorthic clinics for the provision of appropriate footwear and insoles. The cases were verified by an expert panel and incorporated into Study 3 which was used to help understand Pedorthic prescribing practices.

7.3.3 Study 3: Australian pedorthist's survey

The purpose of this study was to examine the current prescription habits of Australian pedorthists when designing and altering footwear and insoles with the goal of offloading for neuropathic plantar forefoot ulcer prevention and improved patient adherence for the four case studies developed in Study 2.

The survey questionnaires explored pedorthist's practice in terms of:

1. Footwear design and modification parameters and

2. Insole design and modification parameters, including adherence-related challenges for footwear and insoles and their overcoming strategies.

Multiple-choice and open-ended questions were used to explore pedorthist's prescribing behaviour in terms of the case studies. The criteria explored in Sections 2 and 3 were adopted from Studies 1 (Ahmed et al., 2020) and DFA guidelines (van Netten, Lazzarini, et al., 2018).

Nineteen pedorthists completed the survey (45% of pedorthists).

This study highlighted the complexity of footwear as an intervention for people with diabetes-related foot disease and the high level of variation possible because of the multiple components associated with shoes. Given that the primary goals of footwear as an intervention are to prevent injury (largely by accommodating existing foot deformities) and reduce plantar pressure, it is clear that there are a number of different routes to achieving this goal, which will be impacted heavily by patient preference and adherence. Therefore, a less clinically prescriptive approach may be necessary that takes into account a range of social and more subjective factors, such as patient preference and goals, activity levels, funding source, and availability, and the availability of different materials and footwear – this then leads into the n=1 study that varied a number of attributes of footwear with a goal of achieving the greatest reduction in plantar pressure while optimising patient adherence.

The results present a lot of variation in clinical recommendations for the same patient; however, they appear largely based on valid considerations and assumptions. The variations in recommendations were in footwear type, upper height, heel height, toe spring, rocker sole

design profile, insole casting method, insole materials, and insole design parameters. This also highlights the need for an evidence-based guideline to guide practice and help reduce variations in clinical practice or provide guidance that can increase the consistency of prescribing patterns. Evidently, there is no 'one size fits all' – and there is probably no 'rule' to dictate that. The results of this study, together with the results from Study 1 (Ahmed et al., 2020), have been used to form the knowledge base for footwear and insole design and modifications and to test those parameters in Study 4 towards recommending a set of design principles for footwear and insole design and modification prescriptions.

7.3.4 Study 4: A series of N-of-1 trials

This study, building on prior research, used a patient-centred N-of-1 trial approach to tailor footwear and insole design to individual patient needs. Twelve patients participated in individual N-of-1 studies, testing two footwear prototypes and three insole prototypes with customisation. The interventions aimed to reduce plantar pressure and improve adherence.

Baseline pressure analysis was conducted, and intervention footwear and insoles were decided at the initial appointment (T0), with a maximum of three modification rounds to achieve acceptable pressure offloading. Patient satisfaction and adherence data were collected at each appointment (T1-T4). The results demonstrate the substantial reduction of plantar pressure with tailored responses to individual patient needs.

The study emphasises the importance of considering patient needs, preferences, and pathology in treatment plans. The proposed design principles take into account these complex factors for improved clinical and patient adherence outcomes.

7.4 Design Principles

Here, the design principles for footwear prescription for people with diabetes-related foot disease and at risk of neuropathic plantar forefoot ulceration that arose from the above studies are outlined. These principles underpinning footwear and insole design aim to guide pedorthists involved in prescribing footwear for people with diabetes-related foot disease to prescribe and produce footwear based on the best evidence for plantar pressure offloading

and strategies to improve patient satisfaction and adherence. The outcomes of Studies 1 (Ahmed et al., 2020) and 3 (Australian pedorthists survey) provided the knowledge base of various footwear and insole design and modification parameters in the literature and in real practices by the pedorthists. The common agreements and the variations were both noted, and patient adherence-related challenges and overcoming strategies were also noted (Study 3). Then these parameters were tested further, and the outcome on individual patients through a series of N-of-1 trials (Ahmed et al., 2022) to establish more specific design and modification parameters for specific forefoot pathologies in people with diabetes and neuropathy and their adherence-related factors to improve the outcomes were also established.

These parameters were then presented in a patient-centric Clinical Decision Support Database (CDSD) for footwear and insole prescribing to ensure the prescription is made based on the most suitable option for the individual. These are presented in Table 7.2. This CDSD theme aims to ensure the maximum possible adherence by the person when all possible factors are considered for the individual associated with their therapy and treatment goals. Then, the information or output from this CDSD is taken into the framework of a set of design principles for the technical prescription to ensure optimum clinical outcomes such as plantar pressure offloading and walking comfort, ease of use of the patient and such. This information is aligned with the workflow presented in Figure 7.2. The core information for this set of design principles is based on our systematic literature review (Ahmed et al., 2020), DFA guideline (van Netten, Lazzarini, et al., 2018), Australian pedorthists' survey (Study 3), the series of N-of-trials (Study 4) and Bus, Zwaferink et al.'s algorithm (2020). The main framework of the CDSD is based on the results of Study 4 and the other studies (Ahmed et al., 2020; van Netten, Lazzarini, et al., 2018), including Study 3 results that have been used to complement the database. Table 7.3 presents the CDSD model function principles which can be used for clinical decision making for the pedorthists.

The treatment goals underpinning this set of design principles are to:

1. Optimise patient satisfaction and adherence to therapy (by improving walking comfort, ease of use and aesthetics, and also considering the personal circumstances of the patients).
2. Protect the foot from injury and cause no further injury to the foot.
3. Reduce peak plantar pressure.

4. Optimise balance and mobility.

To achieve this treatment goal requires that the patient will wear the footwear >80% of the time (Keukenkamp et al., 2022); therefore, a further treatment principle is that the footwear needs to meet the aesthetic and/or social requirements of the patient and /or their main decision maker (e.g., spouse or partner).

The footwear needs to be affordable for the patient (NADC, 2018; Kaminski et al., 2021), and the guidance towards available funding is as important as educating the patient on foot self-care (Jarl & Lundqvist, 2016). The inability to afford the cost of therapy and having no access to health funds can limit treatment options in this population group (Jarl & Lundqvist, 2016).

The footwear needs to be fit for its purpose (Paton et al., 2014). To increase adherence by achieving the patient's goals and aesthetic requirements, additional individual factors need to be considered as appropriate, such as appropriateness for the climate and cultural and religious beliefs.

A summary of the design principles for footwear and insole design and modifications in the form of an infographic to demonstrate the workflow and relevant measures in each step has been presented in Fig 7.2 below.

Figure 7.2

Workflow and infographic for the design principles for footwear ad insoles

7.4.1 Multidisciplinary and person-centric team approach

The person to be treated needs to be engaged in the process at the very beginning and needs to be at the centre of the overall activities. All relevant health professionals need to be engaged and provide input into the care plan. Engaging a friend or family or a carer as appropriate is very important for better treatment and adherence-related outcomes. Studies 3 and 4 have demonstrated the evidence of these approaches for a positive outcome.

7.4.2 Comprehensive assessment of the lower limb

A comprehensive assessment of the person's foot condition and foot structure, current mobility status and mobility goals are the second steps in the process. Some of the information is also available in the referral and medical notes. The person's goals recorded in the referral form need to be checked against during the assessment for currency and a clear understanding by all parties involved in the process.

Other assessment aspects involve assessing the extent of peripheral neuropathy, foot deformities, areas of high pressure (ROIs), and any previous or existing foot ulcers or wounds. Attention should be paid to the person reporting any pain or discomfort at any part of the foot or lower limb or during any specific activities or mobility phases.

7.4.3 Understanding the person's needs and setting treatment goals

Gathering information on the person's lifestyle and daily activities, including social and religious rituals, is critical for a comprehensive treatment plan and device design workflow. Understanding the person’s needs relating to occupation, exercise routines, and specific foot and mobility-related challenges are integral parts of the workflow. Assessing the mobility of the upper limb is important to identify the person’s ability that influences donning and doffing. Person’s affordability to the therapy and access to funds are also important factors to consider when designing the treatment plan. Studies 3 and 4 report on the importance of fund access for these populations. From this step, tailored primary design features to suit the person's goals can be drawn. Studies 3 and 4 have demonstrated evidence of these workflows.

7.4.4 Assess footwear history and footwear wearing period

It is important to encourage the person to bring any current and old footwear to evaluate the footwear choices and gait patterns in real life. A thorough assessment to identify any issues or discomfort associated with their existing footwear, such as poor fit, excessive pressure points, or lack of cushioning and support, needs to be conducted. An in-depth exploration to identify the current wearing period of footwear indoor and outdoors events of going barefoot or in socks are critical for appropriate device design principles and setting education goals. Studies 3 and 4 have demonstrated evidence of these workflows that influence the treatment plan and device design specifications.

This information complements the CDSD parameters under *"Person's preferences and intended activity"*.

7.4.5 Determine foot measurements, shape, and footwear type.

Measuring the person's feet by using any suitable methods to determine the correct size and shape is critical for footwear selection. The width, length, arch type, and any foot abnormalities or deformities are the guiding factors for the correct size, width, and type of footwear to be recommended. The measuring process involves acquiring three-dimensional data of the foot, ankle, and leg to obtain precise measurements to make the shoe last or to determine the shoe size and width. This helps determine the ideal footwear type, such as custom-made or prefabricated footwear with or without modifications and the type of insoles required. The ratio of rearfoot volume and forefoot volume is critical to determine the appropriate footwear type to optimally offload the forefoot PP. For example, a Cavus foot with narrow rearfoot and wide forefoot should be recommended a fully custom-made footwear and insole for a better fit and reduce shear that a prefabricated medical grade footwear in unable to deliver. Very often, the prefabricated medical-grade footwear is too loose at the back when an adequate forefoot width is chosen for this type of foot. Some participants in Study 4 (Table 6.2) have demonstrated evidence of such needs.

7.4.6 Prescribing appropriate footwear features

Proper fit of the footwear is the most critical factor in offloading and adherence to the therapy, and the benefits multiply when they are equipped with appropriate design features such as a soft and seamless interior. Other critical design features for the footwear are cushioning and shock absorption, breathability, adjustable closures, and sturdy and supportive soles. Strong evidence is present for rocker sole design features for optimum plantar pressure offloading and maintaining stability, as reported in Studies 1 (Ahmed et al., 2020), 3 and 4.

7.4.7 Prescribing appropriate insole features

The selection of an appropriate casting method and cast modifications are influential factors in outcomes when designing an insole that is optimal for PP reduction and increasing contacts.

The selection of appropriate materials for various layers can achieve the above goals.

Other strategies for enhancing offloading are through increased MLA heights, adding metatarsal bar, dome or pad and ideal positioning of them, material hardness and height of them. Studies 1 (Ahmed et al., 2020), 3 and 4 have confirmed the features and benefits of such strategies.

7.4.8 Evaluate offloading and ensure pressure redistribution.

It is very important to evaluate the efficacy of PP offloading and redistribution of the designed devices through in-shoe pressure mapping at the fitting of current footwear and insole and during any subsequent post-modifications. Various strategies are successful in increasing the offloading capacity of the footwear, and rocker design parameters for PP offloading and balance are the most popular ones. Its efficacy and design features have been reported in Studies 1 (Ahmed et al., 2020), 3 and 4,

Among other popular strategies to increase PP offloading are the insole modifications that include the removal of hard materials, adding local cushioning, and replacing top covers. Studies 1 (Ahmed et al., 2020), 3 and 4 have reported the features and benefits of such strategies.

This information helps develop the CDSD parameters under the *"Pressure offloading evaluation method,"* and the parameters are extracted from our systematic literature review (Ahmed et al., 2020), Australian pedorthists' survey (Study 3) and the series of N-of-trials (Study 4).

7.4.9 Provide education and regular follow-up.

The success of the treatment plan and the footwear and insoles are largely dependent on education on wearing footwear and insoles, regular reviews, repair, maintenance, and timely replacement. It is also important to refer to a podiatrist or other relevant health professional when necessary.

Person's satisfaction and adherence to the devices can vary depending on various factors, and it is critical to keep monitoring person's satisfaction and adherence to footwear and insoles. If there are any concerns or issues reported by the person or observed during the appointments, it is critical to attend to any issues that arise.

Foot pathologies associated with neuropathic plantar forefoot ulcers

The table below describes the common pathology seen in people with diabetes and neuropathy and associated with plantar forefoot ulceration. This is a general guide for the pedorthists for what pathology this design principle suits. This information is collated from the systematic literature review (Ahmed et al., 2020).

Table 7.1

List of forefoot pathology based on the literature review.

Foot Pathology	Description
Neuropathy	"The neuropathic foot is described as a loss of peripheral nerve function, which can be sensory, motor, autonomic or, usually, a mixture. This loss of function leads to structural changes and function of the foot towards ulceration and subsequent amputation."
Hyperkeratosis	"It is commonly called calluses, and the formation of calluses is due to repeated excessive pressure on the skin. In patient with neuropathy, the presence of callus increases peak plantar pressure and increases the risk of ulceration in that area. Calluses are commonly seen in diabetic feet, even in the absence of neuropathy."
Bony prominences at metatarsal heads	"Claw and hammer toes are associated with plantar fat pad displacement and metatarsal head prolapse on the plantar surface. Any ulcers in the metatarsal heads need to be treated with urgency, especially in the hallux base, due to the increased risk of amputation."
Hallux Abducto Valgus (HAV)	"Due to the structural deformity caused by HAV and the abnormal foot shape, the normal push-off becomes difficult and results in increased friction on the medial aspect of the 1st MTP Joint."
Flexible flat gait foot	"Flexible flatfoot results in reducing the shock-absorbing capacity of the foot and increases pressure on the medial border."
Rigid flat foot	"The rigidity of this condition results in excessive pressure on the medial border of the foot. Ankle-high shoes with shock absorber heel, stronger medial heel counter, and rocker with apex position posterior to metatarsal heads are ideal features to protect the foot from worsening in positioning."
Forefoot amputation	"There are many similarities in the effect of forefoot amputation with Hallux amputation, with the additional risk of the foot taking an equines structure and increased pressure at the lateral border of the foot. (Sage, Pinzur, Cronin, Preuss, & Osterman, 1989) The shock absorption capacity decreased due to the stiffness of the foot structure."
Hallux amputation	"Amputation of the Hallux results in altered pressure distribution, and the pattern is significantly influenced by this (Lavery et al., 1995). During the push-off phase, the force is transferred through the 1st metatarsal bone and results in increased shear force. This mechanism frequently results in a wrinkle on the shoe's upper and pressure ulcers on the dorsal aspect of the foot."

Table 7.1

List of forefoot pathology based on the literature review (Continued).

Foot Pathology	Description
Hammer & clawed toes	"A typical neuropathic foot with stiff structure and minimal shock absorbing and contact area due to the dorsiflexed position of the Metatarso Phalangeal Joints (MTPJ's)."
Limited joint mobility	"Limited joint mobility in the diabetic foot has been described by the limited range of motion (ROM) at the ankle joints and 1st Metatarso Phalangeal Joints (MPJ) (Boffeli et al., 2002; Lobmann et al., 2002; Murray et al., 1996; Nube et al., 2006; Van Gils & Roeder, 2002) Ankle joint limited ROM or equinovarus foot structure increases the pressure at the forefoot area, specifically at the metatarsal zone, which accelerates the risk of ulceration in that area. In addition, Hallux limitus or rigidus can generate foot ulcers in the medial and dorsal aspects of the 1st Hallux (Lázaro-Martínez et al., 2014). As the foot is stiff in nature (Delbridge et al., 1988), the force is transferred through the heel during heel strike, yielding less shock absorption within the foot at the gait cycle. As the forefoot has limited dorsiflexion, that results in friction between the forefoot and shoe at the push-off phase."

7.5 Design considerations

7.5.1 Upper design

For footwear upper height, the following classification is used:

a. Low cut = below the malleolus.
b. High cut = at the level of the malleolus.
c. Extra high cut = above the malleolus and up to the knee.

The purpose of the adequate upper height of footwear is to influence forefoot plantar pressure reduction and accommodation of the feet (Ahmed et al., 2020).

Principles to prevent or reduce injury

Current evidence: Some common principles need to be considered when prescribing footwear for people with diabetes and neuropathy (Bus, Zwaferink, et al., 2020). Each shoe must have sufficient interior space in length and width, with a minimum of 1 cm space in length between the longest toe and the inner of the shoe. The toe box must be sufficiently high to accommodate a non-correctable claw, hammer toes, or a hyperextended hallux. The inner lining should not have any seams. Shoes should have laces or velcros depending on hand functions, and BOA lacing and zippers can be considered for further support to aid foot entry.

Management of oedema

Current evidence: With the presence of oedema or vulnerable skin in the lower leg, a low-cut shoe is preferred to avoid pressure from the shoe upper or the top line on the sensitive area. If a high-cut shoe is indicated, the inner should be padded, and the top edge of the shoe should be above the vulnerable area. A 1.5mm-thick flat layer of material (single or multiple layers as needed) below the insole creates the opportunity to moderate interior volume with changing oedema (Bus, Zwaferink, et al., 2020).

7.5.2 Footwear upper flexibility

Treatment goal: The treatment goals related to upper flexibility are the accommodation of the feet, supporting feet structure and ensuring walking comfort and ease of use. Patient's stability increase, reduced risk of falls and improved balance are some of the key focuses for footwear upper design.

Current evidence: If the lower limb pathology has a combination of muscle weakness of the tibialis anterior or peroneus longus muscles, an extra high cut upper with reinforcement between the upper and lining should be considered (Bus, Zwaferink, et al., 2020). This is to support the dorsiflexion of the ankle.

Another alternative approach is to add an external orthosis or bracing in the form of an ankle-foot orthosis (AFO) when a foot drop is present.

7.5.3 Rocker sole profile

Treatment rationale: The purpose of a rocker sole is to reduce peak pressure under the forefoot (Ahmed et al., 2020) by redistributing the plantar pressure.

- With fully custom-made shoes, the rocker is applied in the insole, with the outsole following this insole rocker configuration one-on-one.
- With prefabricated medical-grade footwear, the rocker is in the outsole.

Current evidence for rocker apex position: The rocker apex is the central point on the rocker axis and should be at 60-65% of the shoe length or 10-15mm behind the metatarsal heads (MTHs) (Ahmed et al., 2020). The % of the length is measured from the rear of the shoe to provide optimal balance for pressure relief under the different metatarsal heads. This relates to a rocker axis that is ~1.3cm proximal to MTH 1 and ~2.6cm proximal to MTH 2 for shoe size US9.5 (Bus, Zwaferink, et al., 2020). Barefoot pressure mapping or, a pedograph or in-shoe pressure mapping, or both should be considered for the further precision design of the rocker profile.

Considerations for severe neuropathy or poor balance

The rocker apex position must be set carefully for people with severe neuropathy and poor balance. A distal apex location may help support them during the stance phase.

Current evidence for rocker angle: The rocker angle is the angle between the ground and the bottom surface of the shoe from the rocker apex forward and should be 15-20° in each shoe, independent of shoe size (Bus, Zwaferink, et al., 2020). This should be guided by pressure mapping or a pedograph and checking the balance of the person. The thickness of the rocker sole also needs to be considered with the aim of fall risk assessment and aesthetics of the footwear. This should determine the precise rocker angle for the prescribed footwear.

Current evidence for apex angle: The apex angle is the angle between the rocker axis and the longitudinal axis of the shoe and should be 95°(Ahmed et al., 2020; Chapman et al., 2013). This means that the rocker axis is medially more distal than laterally. With an exhortation position of the foot, the rocker axis must be corrected to give an apex angle of

95° in the direction of walking (Bus, Zwaferink, et al., 2020). This angle may change where the metatarsal head orientations are unique, and the ROI for offloading is unique.

7.5.4 The outsole profile

Treatment rationale: The purpose of the outsole is to protect the midsole that contains the rocker profile and support the rocker profile structurally. This is the interface between the walking surface and the other parts of the footwear that accommodate the foot. It is also one of the most visible and visual factors affecting patient satisfaction and adherence.

A number of different outsole options are possible. There is not sufficient evidence to be prescriptive about the outsole except the shape of them based on practical requirements, such as with a separate heel or in a wedge shape. A separate heel is considered for the patient's aesthetic preference or occupational needs, and the wedge shape is considered when the base of ground contact needs to be more, and the stability and balance of the patient are the priorities.

The footwear outsole should provide cushioning and can be made supple or toughened or can be reinforced with a carbon, fibreglass or metal layer over the partial or entire length of the footwear to create a rigid outsole profile that cannot be bent. The shoe outsole should have adequate shock absorption characteristics while providing sufficient durability for active users and be as lightweight as practically possible. With clearly reduced proprioception, opt for a semi-rigid outsole for improved balance. It is important to consider slip-resistant outer soles for people with moderate to severe peripheral neuropathy.

7.5.5 Tongue

The footwear tongue can be made supple or reinforced, and it is always padded. A rigid tongue with thermoplastic material reinforcement is used mainly with forefoot amputation.

7.5.6 The heel height of the footwear

Treatment rationale: The heel of the footwear can have several configurations, and this aid with ankle ROM and stability. Changes in heel height influence forefoot PP and stability of the person.

Current evidence: Normal heel height for men is 1.5-2cm, and for women, 2.5-3cm in regular prefabricated footwear (Bus, Zwaferink, et al., 2020). Our findings from Study 4 are to have a heel height between 1 and 1.5cm for improved offloading at the forefoot. An increased heel lift or height is provided in fully custom-made shoes via heel lift in the shoe and in prefabricated shoes via heel lift in the insole (maximum 1 cm) (Bus, Zwaferink, et al., 2020). This can be limited if the footwear is a low-cut version. The increased heel lift in pes equines is dependent on the available ankle range of motion.

7.5.7 The insole design, material and modification features

Treatment rationale: Insole can provide base or surface of foot contact, support the medial and transverse arches and accommodate any bony prominences through an appropriate deflection and combination of multiple cushion materials. They also provide cushion to the overall foot, reduce shock during weight-bearing, help stabilise the foot and reduce shear when objectively designed.

The casting method for capturing the plantar foot profile is recommended to be a non-weight-bearing or semi-weight-bearing cast and 3D scan with the aim of further correction of the cast digitally, where possible, for an improved outcome. This concept is verified by our Study 3. The other casting method that can sometimes be recommended is a full-weight-bearing cast when indicated and can be filled with plaster or 3D scanned to make the mould for insole production as practical for the facilities. For a plaster cast mould, generally, a conventional heat moulding of multilayered and multi-density materials is used. For the 3D scanned and designed process, the output can be either by CNC milling of multi-density and multilayered block or 3D printing method out of soft filament or powder with specific geometric pattern or lattice design.

Current evidence: The base of the insole in fully custom-made footwear should be with good structural strength capable of shape retention during manufacturing and providing support during everyday use by the patient. This layer also provides the base layer for the mid-layers and top cover to form the complete insole. The hardness of the base layer can be from 55° Shore A onwards, such as a 5-mm-thick micro cork. The base layer can be of dual density with multilayers, and the upper of the base layer materials hardness can be 35-40° Shore A, such as a 5-mm-thick Ethylene Vinyl Acetate (EVA). This layer provides shock

absorption properties during weight-bearing. With prefabricated pedorthic footwear, the base may consist of 6-mm-thick EVA (35-40° Shore A) (Bus, Zwaferink, et al., 2020). Any other suitable materials with similar compressibility and durability can also be considered (Postema, 2018). A 3D printed three-quarter or full-length base with thermoplastic polyurethane (TPU) filament of 45-55° Shore A or a filament with similar functionality can also be used when a 3D print insole is considered.

The insole mid-layer primarily provides shock absorption during weight-bearing and contouring to the plantar foot profile for increasing base of contact and may be made of a 3-6mm thick Poron or PPT. The hardness of the mid-layer can be between 30-35º Shore A. The thickness is dependent on whether custom-made footwear or prefabricated footwear is considered and the level of cushioning required for optimum pressure offloading of the specific foot.

The top layer of the insole is recommended to provide cushion and sometimes specifically to reduce shear. This layer can be made out of Plastazote or similar characteristic material, and the thickness can be 3-5mm and is also dependent on footwear type and offloading requirements. A Plastazote is more effective in pressure offloading than the leather insole top cover (Arts et al., 2015). Other patient-specific factors may be considered when choosing an appropriate type of top cover materials from the range of commercially available materials.

7.5.8 The metatarsal additions (Metatarsal bar, pad or dome)

Treatment rationale: Metatarsal additions can help reduce plantar pressure at the metatarsal area significantly (Ahmed et al., 2020).

Current evidence:

- A transmetatarsal bar is recommended to offload all metatarsal heads (Deshaies et al., 2011). A metatarsal bar or dome is recommended if only one metatarsal head is the ROI to offload the plantar pressure (Bus, Zwaferink, et al., 2020).
- The material of the metatarsal additions should be 5-11mm thick (Ahmed et al., 2020), made out of PPT or PORON, TPU (or similar 3D printable filament) with 30-35º Shore A hardness. These configurations are proven to be effective and more

comfortable for the persons, as found in our study four. The addition is covered by the insole top cover.

- The location of the addition should be 6-11 mm proximal to the metatarsal head in a static position (Ahmed et al., 2020; Hastings et al., 2007). Consider the top cover thickness, as this will change the effective position of the addition, moving it more distally.

7.5.9 The medial arch support

Treatment rationale: A medial foot arch support is proven to reduce a greater amount of peak plantar pressure at the forefoot (Ahmed et al., 2020).

Current evidence: Addition of 3-5mm height to the existing foot medial arch support obtained from the total contact through a semi-weight-bearing cast or scan (Arts et al., 2015; Telfer et al., 2017). A full-length medial arch support, in combination with a full-length varus wedge, can improve plantar pressure offloading under the Hallux (Guldemond et al., 2007).

When a plantar fascia is tightly tensioned, or nodules in the fascia (e.g., in patients with Morbus Ledderhose [plantar fibromatosis]), customisation of the medial arch support should be considered. Support at the sustentaculum tali could be an alternative approach (Bus, Zwaferink, et al., 2020).

7.5.10 The insole modifications

Treatment rationale: The removal of hard material (a local cut-out) at the previous ulcer location or a peak pressure area (ROI) and adding a cushion to that area with a softer density (up to 30º Shore A) material can reduce peak plantar pressure (Ahmed et al., 2020).

Current evidence: The cut-out should be circular or slightly oval in shape in the walking direction and be minimally larger than the ROI. The cut-out should be 5mm deep and padded with a 3mm durable material up to 30º Shore A (Bus, Zwaferink, et al., 2020). The top cover of the insole should be checked regularly and replaced as needed. The replacement frequency of the top cover could be between three to six months, depending on the use and requirements of positioning or adding the metatarsal additions (Ahmed et al., 2020; Arts et al., 2015).

Table 7.2

Person-centric CDSD for footwear and insole prescription for people with diabetes and at risk of neuropathic plantar forefoot ulceration

CDSD Parameters	Descriptions
Person's preferences and intended activity (PPIA)	Low-cut casual shoes for outdoors and walking (PPIA1), A low-cut dress shoe (PPIA2), A low-cut indoor shoe with a soft fabric upper (PPIA3), High-cut casual shoes for outdoor and walking (PPIA4), A high-cut dress shoe (PPIA5), Low-cut summer sandal or shoe (PPIA6), High-cut summer sandal or shoe (PPIA7), Extra high-cut casual shoes for outdoor and walking (PPIA8), An extra high-cut dress shoe (PPIA9), Extra high cut summer shoe or sandal (PPIA10), Extra high cut reinforced upper for drop foot (PPIA11), Separate AFO for drop foot (PPIA12)
Foot structure and shape (FSS)	Normal (FSS1), Wide (FSS2), Very Wide (FSS3), Narrow heel, wide forefoot (FSS4), Swollen rearfoot, narrow forefoot (FSS5), Mismatch foot shape (FSS6)
Main foot pathology (MFP)	Limited joint mobility of the ankle (MFP1), Pes cavus and claw toes (MFP2), Claw and hammer toes (MFP3), Flexible pes planus with hallux valgus (MFP4), Rigid pes planus with hallux valgus (MFP5), Hallux Rigidus (MFP6), Hallux Limitus (MFP7), Pes equines (MFP8), Hallux or toe amputation (MFP9), Forefoot amputation (MFP10)
Co-morbidity (CM)	PAD/PVD (CM1), Drop foot (CM2), Lower limb edema (CM3), Higher BMI (CM4), Poor vision (CM5), Renal disease, needing dialysis (CM6), History or at risk of falls (CM7), Leg length discrepancy (CM8)
Person's body weight (PBW)	60-75 Kg (PBW1), 76-90 Kg (PBW2), 91-110 Kg (PBW3), 111-130 Kg (PBW4), 131+ Kg (PBW5)

Table 7.2

Person-centric CDSD for footwear and insole prescription for people with diabetes and at risk of neuropathic plantar forefoot ulceration (Continued)

CDSD Parameters	Descriptions
Person's mobility status (PMS)	Active at home and indoors (PMS1), Active in the community (PMS2), Mostly staying at home (PMS3), Active outdoors and a regular bushwalker (PMS4), Limited mobility, uses 4WW for balance (PMS5), Limited mobility, uses single walking aid for balance (PMS6), Can reach to the toes easily (PMS7), Both hands and fingers are full functioning (PMS8), Single hand and fingers are full functioning (PMS9)
Family/partner/carer/peer preferences and advocacy (FCPA)	Family/partner/carer/peer agrees to person's choice (FCPA1), Family/partner/carer/peer does not agree to person's choice being impractical or contradicting and advocates towards practitioner's recommendations (FCPA2), Family/friend/carer agrees to person's choice, but peer does not agree due to impractical or contradicting choices (FCPA3), A common agreement was made following further discussion, motivation and advocacy with all parties on the appropriate footwear choices that person is well accepting (FCPA4)
Fund options (FO)	Self-fund with the flexibility of pursuing the best recommendations (FO1), Self-fund with limitations or restrictions in pursuing the best recommendations (FO2), Health fund support with a co-payment by the person (FO3), Health fund support without a co-payment by the person (FO4), Non-government organisation (NGO) or donor's support for funding (FO5)
Fund options influence footwear type selection (FOIS)	Yes (FOIS1), No (FOIS2), Partially (FOIS3)
Footwear type (FWT)	Fully custom-made (Orthopedic medical-grade footwear) (FWT1), Prefabricated medical-grade footwear (pedorthic footwear) without any further modification (FWT2), Prefabricated medical-grade footwear (pedorthic footwear) with further modification (FWT3)

Table 7.2

Person-centric CDSD for footwear and insole prescription for people with diabetes and at risk of neuropathic plantar forefoot ulceration (Continued)

CDSD Parameters	Descriptions
Footwear style (FWS)	Casual shoe (FWS1), A dress shoe (FWS2), Indoor shoe (FWS3), Walking shoe (FWS4), Leisure shoes e.g. Golf, lawn bowling (FWS5)
Footwear upper height (FWUP)	Low cut (FWUP1), High cut (FWUP2), Extra high cut (FWUP3), Slide (FWUP4)
Footwear lining material (FWL)	Soft Leather lining (FWL1), Micro-fabric with a padded back (FWL2), Mesh with a padded back (FWL3)
Footwear fastening system (FFS)	Lace (FFS1), Velcro (FFS2), BOA lacing (FFS3), Lace or velcro with a medial zipper for easy foot entry (FFS4), Lace or Velcro with lateral zipper for easy foot entry (FFS5), Lace or Velcro with medial and lateral zippers for easy foot entry (FFS6), Hook & Dow Stick with Velcro (FFS7), Hook & Dow Stick with zippers and larger ring with the runner (FFS8)
Pressure offloading evaluation method (POEM)	In-shoe pressure analysis (POEM1), Clinical experience and observations (POEM2), Ulcer recurrence (POEM3)
Footwear upper flexibility (FWUFL)	Suppled (FWUFL1), Rigid (FWUFL2), Stiffened/Reinforced (FWUFL3)

Table 7.2

Person-centric CDSD for footwear and insole prescription for people with diabetes and at risk of neuropathic plantar forefoot ulceration (Continued)

CDSD Parameters	Descriptions
Footwear upper stiffened location (FWUSL)	Medial (FWUSL1), Lateral (FWUSL2), Medial + Lateral (FWUSL3), Not required (FWUSL4)
Footwear tongue flexibility (FWTFL)	Suppled (FWTFL1), Stiffened/Reinforced (FWTFL2), Standard as comes with footwear (FWTFL3)
Footwear heel counter (FWHC)	Standard (FWHC1), Medial extended and reinforced (FWHC2), Lateral extended and reinforced (FWHC3), Medial + Lateral extended and reinforced (FWHC4),
Footwear heel height (FWHH)	Standard (FWHH1), Lowered (FWHH2), Increased (FWHH3)
Footwear heel modification (FWHM)	Heel rounded (FWHM1), Heel flared (FWHM2), Not required (FWHM3)
Footwear outsole (FWOS)	Suppled (FWOS1), Semi-rigid (FWOS2), Stiffened/Reinforced (FWOS3)

Table 7.2

Person-centric CDSD for footwear and insole prescription for people with diabetes and at risk of neuropathic plantar forefoot ulceration (Continued)

CDSD Parameters	Descriptions
Footwear rocker profile (FWRP)	No additional rocker is to be added (FWRP1); Additional rocker profile to be added (FWRP2)
Footwear rocker apex position (FWRAP)	Rocker apex position standard/just behind the metatarsal heads (FWRAP1), Rocker apex position early/posterior to metatarsal heads (FWRAP2), Rocker apex position delayed/anterior to metatarsal heads (FWRAP3)
Footwear rocker apex angle (FWRAA)	Standard (FWRAA1), Medial direction (FWRAA2), Lateral direction (FWRAA3)
Footwear rocker angle (FWRANG)	Standard/12-15° (FWRANG1), Moderate/≥20° (FWRANG2), Severe /≥30° (FWRANG3)
Insole type (INST)	Prefabricated/Standard insole that comes with the footwear (INST1), Custom-made insole (INST2)
Custom-made insole shape (CMINS)	Regular shape (CMINS1), Medial wall extended (CMINS2), Lateral wall extended (CMINS3), Medial + Lateral wall extended (CMINS4), Toe modelling for partial (toe/s) amputation (CMINS5), Forefoot modelling for forefoot amputation (CMINS6)

Table 7.2

Person-centric CDSD for footwear and insole prescription for people with diabetes and at risk of neuropathic plantar forefoot ulceration (Continued)

CDSD Parameters	Descriptions
Insole base layer material (INSBLM)	Hard/firm (INSBLM1), Medium hard (INSBLM2), Soft (INSBLM3)
Insole mid-layer material (INSMLM)	Medium soft (INSMLM1), Soft (INSMLM2)
Insole top layer material (INSTLM)	Soft (INSTLM1), Medium soft (INSTLM2), Very soft (INSTLM3)
Insole heel cup (INSHC)	Regular (INSHC1), Lowered (INSHC2), Increased (INSHC3)
Insole heel wedge (INSHW)	Medial (INSHW1), Lateral (INSHW2)
Insole MLA height (INSMLAH)	As per cast/scan (INSMLAH1), increased (INSMLAH2)

Table 7.2

Person-centric CDSD for footwear and insole prescription for people with diabetes and at risk of neuropathic plantar forefoot ulceration (Continued)

CDSD Parameters	Descriptions
Insole metatarsal addition (INSMA)	No metatarsal addition (INSMA1), Metatarsal bar (INSMA2), Metatarsal pad (INSMA3), Metatarsal dome (INSMA4), Morton's extension (INSMA5), Reverse Morton's extension (INSMA6)
Insole metatarsal addition position (INSMAP)	Standard/just behind the metatarsal heads (INSMAP1), Early/posterior to metatarsal heads (INSMAP2), Standard position for Morton's extension (INSMAP3), Standard position for Reverse Morton's extension (INSMAP4)
Insole metatarsal addition thickness (INSMATH)	Standard/just supporting the metatarsal heads (INSMATH1), Increased/correcting the metatarsal heads alignment (INSMATH2)
Insole metatarsal addition material type (INSMAMAT)	Hard/firm (INSMAMAT1), Medium soft (INSMAMAT2), Soft (INSMAMAT3)
Insole modification (INSMOD)	Removal of hard materials (INSMOD1), Local cushioning (INSMOD2), Replacement of top cover (INSMOD3), No further modification required (INSMOD4)

The above information in Table 7.2 has the potential to put through a decision tree through an artificial intelligence (AI) powered database to use for machine learning and to develop an AI-powered clinical decision support system (CDSS) on specific footwear and insole type selection for each person based on their main pathology, comorbidity, preferences, and mobility status (treatment goals)

How this CDSD works:

Table 7.3

Workflow and output of the CDSD model with a hypothesised case scenario

		CDSD Parameters description	Selected parameters code
Decision input	Person-centric data	Person's preferences and intended activity (PPIA)	PPIA6
		Foot structure and shape (FSS)	FSS2
		Person's mobility status (PMS)	PMS6
		Family/partner/carer/ peer preferences and advocacy (FCPA)	FCPA4 PPIA10
	Diagnosis-related data	Main foot pathology (MFP)	R MFP5 L MFP7
		Co-morbidity (CM)	CM1 CM3 CM4
		Person's body weight (PBW)	PBW4
	Fund data	Fund options (FO)	Yes
		Fund options influence footwear type selection (FOIS)	Yes
Decision output	Footwear design and modification features	Footwear type (FWT)	FWT 3
		Footwear style (FWS)	FWS1
		Footwear upper height (FWUP)	FWUP3
		Footwear lining material (FWL)	FWL2
		Footwear fastening system (FFS)	FFS4
		Footwear upper flexibility (FWUFL)	FWUFL1
		Footwear upper stiffened location (FWUSL)	FWUSL4
		Footwear tongue flexibility (FWTFL)	FWTFL3
		Footwear heel counter (FWHC)	FWHC2
		Footwear heel height (FWHH)	FWHH2
		Footwear heel modification (FWHM)	FWHM3
		Footwear outsole (FWOS)	FWOS3
		Footwear rocker profile (FWRP)	FWRP2
		Footwear rocker apex position (FWRAP)	FWRAP2
		Footwear rocker apex angle (FWRAA)	FWRAA1
		Footwear rocker angle (FWRANG)	FWRANG1
	Insole design and modification features	Insole type (INST)	INST2
		Custom-made insole shape (CMINS)	CMINS2
		Insole base layer material (INSBLM)	INSBLM1
		Insole mi-layer material (INSMLM)	INSMLM1
	Pressure Offloading Evaluation	Pressure offloading evaluation method (POEM)	POEM1

Result of the hypothesized case scenario: A low-cut sandal design was the patient's initial desire, but the clinical requirements suggest extra high-cut sandal design shoes (due to lower limb edema). The family was involved, and a common agreement was made following further discussion, motivation, and advocacy with all parties on the appropriate footwear choices that person was well accepting. Patient had a wide foot structure, limited mobility, and used a hand walking aid for maintaining balance. The patient had rigid pes planus and hallux valgus on the right foot and hallux limitus on the left foot. The patient also had PAD/PVD, lower limb edema and a higher BMI (body weight 120 kg). Patient's affordability was dependent on health fund availability and access to health funds. A prefabricated medical-grade casual design extra high-cut upper design footwear with further sole modification was planned. Microfabric upper lining suitable for PVD/PAD and edema and Velcro fastening systems with medial zipper were selected. The footwear needed a rigid forefoot rocker and a higher-density rigid outsole to withstand the higher body weight. The overall thickness of the sole needed to be lower to reduce weight and improve balance, which was achieved by adding a standard rocker angle and positioning the apex posterior to the metatarsal heads and in the medial rocker direction. The insole was a custom-made insole with a regular shape, a medial extended wall with a lowered heel cup and a medial heel wedge due to edema and pes planus feet. A Bilateral Morton's extensions were added with standard thickness with firm material, where the insoles had a hard base, medium soft mid-layer and soft top cover. No additional modifications to the insoles were required. An in-shoe plantar pressure measurement system was used to evaluate the PP reduction efficacy of the footwear and insoles.

7.6 Limitations of the thesis

Pedorthics is a small profession, but it plays a vital role in managing long-term plantar pressure offloading for patients with high-risk feet. Various National guidelines and standards (NADC, 2018; Ahmed et al., 2020; Kaminski et al., 2021; van Netten, Lazzarini, et al., 2018) have recognised the importance of engaging pedorthists in the multidisciplinary team to bridge the gap and enhance patient care. However, the relatively small numbers of registered and certified

pedorthists mean that only small sample sizes were available to understand the maximum variations in prescription and practice habits.

Footwear is a complex intervention that needs to meet clinical and patient personal goals and aesthetics. There are some additional variations that may play roles in the decision-making, such as family or spouse's preferences, health fund availability, climate, and cultural influences. The methods used and the set of design principles derived from this thesis have set the cornerstone for future studies for various patient groups to explore future findings towards evidence-based guidelines.

The studies in the thesis were conducted during the Covid-19 pandemic, which impacted each study. That impacted every study associated with this thesis, especially Studies 2 to 4. The impact was on delay in ethics approval as COVID-19-related studies were given high priority at the university's HRECs, the local health districts, and the site-specific ethics committees. Covid-19 also impacted the number of study participants and the timeliness of this research.

The set of design principles for footwear and insole design and modifications derived from this thesis was set out to try to determine the 'science' of orthopedic footwear manufacture for people with diabetes, but it is not a sole science; it is heavily contextually dependent on social issues and patient preferences. Future research based on this set of design principles can increase the scope of practice for various populations.

7.7 Conclusion

The most recent guideline on footwear and insole design and modification for people with diabetes and neuropathy by Bus, Zwaferink et al. (2020) is aimed at recommending for up to 80% of the population seen in the clinical environment. This guideline (Bus, Zwaferink, et al., 2020) is for fully custom-made footwear only and is only feasible for people in developed countries who have different health education and healthcare systems with a variety of fund options. This is a foot pathology-driven guideline and does not include comorbidity, participant's mobility concerns, and preferences on footwear choices (Bus, Zwaferink, et al., 2020). However, there is a 20% gap that those people are likely to have more complex conditions and

requirements without a proper personalised guideline (Ahmed et al., 2020). Moreover, all the current guidelines are developed based on the environment of the developed countries with better healthcare systems. (Bus, Zwaferink, et al., 2020; van Netten, Lazzarini, et al., 2018). A set of design principles that are universally applicable including the provision for people from different climates and developing countries, are nonexistent (Ahmed et al., 2020). Hence, our set of design principles is universal and bridges the gap in practice to help the practitioners enable practical decision-making to design personalised footwear and insole for people at moderate to high risk of plantar forefoot ulceration. This set of design principles also includes design and modification features for fully custom-made and prefabricated medical-grade footwear (Pedorthic footwear) provision with further modification to match the affordability, intended activities and increased adherence.

The set of design principles and knowledge gained from this thesis would benefit future researchers exploring personalised medical device design for other healthcare domains. Further research is encouraged for improved clinical and adherence-related outcomes.

CHAPTER 8 | Conclusion

This chapter presents the conclusion focusing on the findings and implications of the studies and the thesis. It outlines the contributions of the research to a few domains, such as improvement in prescribing footwear and insoles, reiterating the role of pedorthists in Australian healthcare systems, a set of tailored design principles for footwear and insole and related adherence, policy influence for clinical practice and health funds and service model optimisations.

8.1 Footwear and insole as an intervention for preventing diabetes-related foot ulceration and amputation

Diabetes often leads to foot ulcers due to neuropathy and vascular issues (Boulton et al., 2005; Ghanassia et al., 2008; Molines-Barroso et al., 2013; Peters et al., 2007; Pound et al., 2005; Waaijman et al., 2014), affecting 34% of patients (Armstrong et al., 2017). Preventing ulcers is challenging due to limited evidence, lack of adherence insights, and insufficient consideration of patient preferences and socioeconomic factors (Ahmed et al., 2020; van Netten, Lazzarini, et al., 2018).

The need for personalised treatment approaches to increase adherence is evident (Bus et al., 2013a; Chantelau et al., 1990; López-Moralet al., 2019; Praet & Louwerens, 2003).

Variations in design parameters were evaluated for offloading properties in Study 4 of this thesis, a series of N-of-1 trials to see their efficacy and relation to individual patients, resulting in a set of design principles for footwear and insole prescriptions. The design principles also have considerations for patients' pathology, comorbidity, sociodemographic, intended use, aesthetic preferences, climate, and cultural and religious perspectives, which is an extension and complementing existing guidelines for the same purpose (Kaminski et al., 2021; van Netten, Lazzarini, et al., 2018).

Further research is needed to validate the set of design principles to establish evidence-based guidelines for the same purpose in conjunction with new evolving materials and manufacturing methods. To improve clinical and adherence-related outcomes, special research focuses on patient satisfaction, and adherence-related parameters to guide a person-centric device design are also needed to prioritise.

8.2 The role of the pedorthist in the Australian Health Care system for high-risk foot management

Pedorthics in Australia is professionalising, recently becoming a member of the Allied Health Professions Australia (AHPA) (2022). As a growing profession, pedorthics requires an evidence-based practice guide within various health domains. This study aims to guide evidence-based pedorthics practice for high-risk foot care in diabetes and neuropathy.

The study provides evidence to bridge gaps in current Australian guidelines (Kaminski et al., 2021; van Netten, Lazzarini, et al., 2018) and complement future National and International guidelines for improved adherence.

High-risk foot care requires an interdisciplinary team approach, and pedorthists are one of the core professionals within the team to take the role of long-term offloading (NADC, 2018) through the provision of appropriate footwear and insoles in the Australian health care system. Pedorthists are also recognised for their roles in clinical management (Ahmed et al., 2020), designing, manufacturing and modification of pedorthic footwear (Bus, Zwaferink, et al., 2020), and related research (NADC, 2018; Kaminski et al., 2021; Perrin et al., 2021; van Netten, Lazzarini, et al., 2018).

8.3 A set of design principles for footwear and insole interventions in people with diabetes and neuropathy

This study helped the development of a set of design principles for footwear, insole design and modifications (reported in Tables 7.2, 7.3 and general discussions in section 7.5 in chapter 7) that incorporate the individual needs of patients with diabetes-related foot complications while

delivering the best evidence-based care to support those needs. The most recent algorithm by Bus et al. (Bus, Zwaferink, et al., 2020) in the Netherlands on footwear and insole design and modification for people with diabetes and neuropathy is recommended for up to 80% of the population seen in the clinical environment. This guideline (Bus, Zwaferink, et al., 2020) is for fully custom-made footwear only and is only feasible for people in developed countries with better health education and healthcare systems with various fund options.

Moreover, all the current guidelines are developed based on the environment of the developed countries with the developed healthcare system (Bus, Zwaferink, et al., 2020; van Netten, Lazzarini, et al., 2018) and universal guideline that includes the provision for people from a different climate, and developing countries are non-existent (Ahmed et al., 2020). Hence, our proposed set of design principles in this thesis helps bridge the gap in practice to help the practitioners enable practical decision-making to design personalised footwear and insole for people at moderate to high risk of plantar forefoot ulceration.

8.4 Policy improvement for clinical practice and health fund guidance

This thesis recommends a set of new and optimised prescription guidance in the form of design principles through a number of studies: Study 1 (Ahmed et al., 2020), Study 3 (Australian pedorthists survey) and Study 4 (Ahmed et al., 2022) (a series of N-of-1 trials) for footwear and insole design and modifications, including adherence in people with diabetes and neuropathy. These design principles are tailored for individual patients to achieve maximum outcomes from a clinical and adherence perspective. These will help improve current guidelines (Kaminski et al., 2021; van Netten, Lazzarini, et al., 2018) for future versions and will bridge the identified gap of adherence-related factors in those guidelines. This research has also shown the influence of health funds on adherence through Studies 3 and 4. This thesis recommends design principles for a person-centric device design considering a person's pathology, comorbidity, sociodemographic conditions, mobility status, and intended use to maximise clinical and adherence-related outcomes. For example, the Therapeutic Goods Administration (TGA) (2022) has recently introduced a new regulation around medical devices effective from February 2021, and it is making it mandatory in Australia that any medical device needs to be personalised in the

categories of patient-matched, custom-made or adaptable medical devices. The TGA guidelines also require a precise specification of the medical devices based on the patient's anatomical and pathological requirements and the clinician's reasoning for such a prescription for that specific patient (adherence factors). The findings of this thesis and the proposed design principles are within the TGA requirements for personalised medical device guidelines.

These considerations, as per the proposed design principles in a structured manner on the referring and prescribing clinicians' reports, would provide all the person-specific relevant considerations. This approach will help health funds and policymakers make informed decisions for individuals in terms of accessing funding for footwear and insoles. This is also supported by other studies (Jarl & Lundqvist, 2016) that accessing health funds can positively influence adherence and health outcomes. Having no access to health funds can lead to no therapy access for people with diabetes and neuropathy (Abbas et al., 2011).

8.5 Optimisation of foot care service models

This research helped optimise the health service model and scale up models to serve many more people who need high-risk foot care services in long-term offloading. It makes recommendations

on design and modification features for all kinds of pedorthic footwear, such as fully custom-made and prefabricated medical-grade footwear provisions with further modification to match the affordability and increased adherence. This is also within the TGA recommended guidelines (TGA, 2022) for medical device prescribers, manufacturers, and consumers. This can enhance the model of decentralised healthcare services and scope for central fabrication with the intervention of disruptive modern technologies and ever-changing healthcare business and service models. This also enables the scalability of services where there are serious service gaps globally, particularly in developing countries (Abbas et al., 2011; Shankhdhar et al., 2015) of such novel approaches in plantar pressure offloading through appropriate personalised footwear and insoles for people with high-risk feet.

The set of design principles, concepts and knowledge gained from this thesis would benefit future researchers in exploring and establishing evidence-based personalised medical device

design for improved clinical and adherence-related outcomes in people with diabetes and neuropathy. Further research is encouraged to validate the design principles in this thesis, and the knowledge can be used in other health professionals' domains.

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APPENDICES

Appendix 1 - Foot pathologies associated with neuropathic forefoot ulcers

Foot pathologies associated with neuropathic forefoot ulcers

Foot Pathology	Description
Neuropathy	"The neuropathic foot is described as a loss of peripheral nerve function which can be sensory, motor, autonomic or, usually, a mixture of all. This loss of function leads to structural changes and function of the foot towards ulceration and subsequent amputation."
Hyperkeratosis	"It is commonly called calluses and the formation of calluses is due to repeated excessive pressure on the skin. In the patient with neuropathy, the presence of callus increases peak plantar pressure and increase the risk of ulceration in that area. Calluses are commonly seen in the diabetic foot even in the absence of neuropathy."
Bony prominences at metatarsal heads	"Claw and hammer toes associated with plantar fat pad displacement and metatarsal head prolapse in the plantar surface. Any ulcers in the metatarsal heads need to be treated with urgency, especially in the hallux base due to increased risk of amputation."
Hallux Abducto Valgus (HAV)	"Due to the structural deformity caused by HAV and the abnormal foot shape, the normal push-off becomes difficult and result in increased friction on the medial aspect of the 1st MTP Joint."
Flexible flat foot	"Flexible flatfoot results in reducing the shock absorbing capacity of the foot and increases pressure on the medial border."
Rigid flat foot	"The rigidity of this condition results in excessive pressure on the medial border of the foot. An ankle high shoes with shock absorber heel, stronger medial heel counter, a rocker with apex position posterior to metatarsal heads are ideal features to protect the foot from worsening in positioning."

Foot pathologies associated with neuropathic forefoot ulcers (continued)

Foot Pathology	Description
Limited joint mobility	"Limited joint mobility in the diabetic foot has been described by the limited range of motion (ROM) at the ankle joints and 1st Metatarso Phalangeal Joints (MPJ). (Boffeli et al., 2002; Lobmann et al., 2002; Murray et al., 1996; Nube et al., 2006; Van Gils & Roeder, 2002) Ankle joint limited ROM or equinovarus foot structure increases the pressure at forefoot area, specifically at the metatarsal zone which accelerates the risk of ulceration in that area. In addition, Hallux limitus or rigidus can generate foot ulcers in the medial and dorsal aspect of the 1st Hallux (Lázaro-Martínez et al., 2014). As the foot is stiff in nature (Delbridge et al., 1988), the force is transferred through heel during heel strike yielding less shock absorption within the foot at gait cycle. As the forefoot has limited dorsiflexion, that results in friction between the forefoot and shoe at the push-off phase."
Forefoot amputation	"There are many similarities in the effect of forefoot amputation with Hallux amputation with the additional risk of foot taking an equines structure and increased pressure at the lateral border of the foot.(Sage et al., 1989) The shock absorption capacity decreased due to the stiffness of the foot structure."
Hallux amputation	"Amputation of the Hallux results in altered pressure distribution and gait pattern is significantly influenced by this. (Lavery et al., 1995). During the push-off phase the force is transferred through the 1st metatarsal bone and results in an increased shear force. This mechanism frequently results in a wrinkle on the shoe upper and pressure ulcers on the dorsal aspect of the foot."
Hammer & clawed toes	"A typical neuropathic foot with stiff structure and minimal shock absorbing and contact area due to the dorsiflexed position of the Metatarso Phalangeal Joints (MTPJ's)".

Appendix 2 - Description of footwear features designed to reduce neuropathic forefoot plantar ulcer occurrence found in the literature

Appendix 2A - Description of footwear features designed to reduce neuropathic forefoot plantar ulcer occurrence found in the literature

Description provided on footwear upper and sole design	Study(s)
"Bottine (12.5 CM) or high shoe (16 CM) for upper height Toughened outsole, resilient material on the heel Toughened leg and tongue Rocker profile outsole with early and normal pivot point"	Arts et al., 2012, Bus et al. 2013 Preece et al. 2017 Rizzo et al. 2012
"Fully custom made orthopaedic footwear and semi-custom (extra depth + width off-the-shelf footwear)" Thin, seamless cotton socks	Arts et al. 2015
"Lucro stock diabetic shoes (SDS) with toughened outer-sole with forefoot rocker"	Busch et al. 2003
"Fully custom footwear manufactured with features of Ankle high shoes, stiffened rubber outsole with rocker bottom sole. Modification: Outsole rocker pivot point relocation and rocker angle"	Bus et al. 2011
"Toughened rocker profile rubber outsole, shoes or sandals with smooth leather, adjustable front and back straps for sandals or closed in shoe"	Charanya et al. 2004
"Van Lier®, Netherlands, Outer sole shore type A: 86"	Guldemond et al. 2007
"Standard diabetic shoes (extra depth leather shoes, Dr. Foot Technology Co.,)"	Lin et al. 2013
"Semi-rigid rocker sole (Wellwalk technology with Vibram Strips) and rigid rocker sole (reinforced with composite fiber). The rocker sole was anteroposterior rocker and pivot point behind the metatarsal heads with 20 º rocker angle. The shoes had rigid heel counter, extra depth toe boxes (14 to 16 mm deeper than standard shoes), lace or buckle closures."	López-Moral et al. 2019

Appendix 2A - Description of footwear features designed to reduce neuropathic forefoot plantar ulcer occurrence found in the literature (continued)

Description provided on footwear upper and sole design	Study(s)
"SoleTech new shoes, style E3010"	Mueller et al. 2006
"Modular non-bespoke diabetic shoes with soft leather upper, plain vamp, secure fastening, microfibre lining material, padded collar, wall toe puff, EVA micro rubber sole unit with rocker where the apex is posterior to metatarsophalangeal joints line (County Orthopedic Footwear Ltd)."	Paton et al. 2012
"8 types of rocker sole configuration by two types of rocker angle 15º & 20º each for the apex positions of 52, 57, 62, 67% of shoe length. (Duna, Italy)"	Preece et al. 2017
"Semi rigid outer sole or stiff rocker sole, a stable heel counter, and adjustable laces or Velcro straps"	Tang et al. 2014

Appendix 2B - Description of insole features designed to reduce neuropathic forefoot plantar ulcer occurrence found in the literature

Description provided on insole design	Study
"Custom made foot orthoses crafted for each individual foot"	Arts et al., 2012
"Most frequent single modifications are replacement top cover of the insole, local cushioning of the insole, the addition of pad to the insole. Combined modification of insole: Above items and removal of local materials as an addition."	Arts et al. 2015
"Flat insoles with rear base: 42º Shore hardness and anterior base 20º Shore hardness 6mm thick Lunasoft® and 3mm overall top-cover of PPT with 17º Shore A hardness."	Busch et al. 2003
"Fully custom insoles with multi-density and multi-layered materials, an open cell or cross cell material top cover. Modification: Local removal of material on the insole, local softening, adding metatarsal, hallux pad or bar on the insole, replacement of the top cover"	Bus et al. 2011
"Custom made insole made from multilayered materials with cork base added with micro cork, a mid layer of EVA base multiform. Additional metatarsal pad or bar with extra arch support."	Bus et al. 2013
"Insole made of 12 mm microcellular rubber (MCR), shore value 20º"	Charanya et al. 2004
"Metatarsal dome, arch supports, and extra arch supports Insoles made of 5mm Lunalastic as the top layer, 8 mm Lunasoft SL as the bottom layer, 1.1 mm Rhenoflex 3208® as internal reinforcement. Every layer of arch support has 5 mm thickness of Lunalastic material."	Guldemond et al. 2007

Appendix 2B - Description of insole features designed to reduce neuropathic forefoot plantar ulcer occurrence found in the literature (continued)

Description provided on insole design	Study
"3mm Shore A 35º EVA as 1st layer, 2 mm Velcro and velvet in 2nd layer and 6 mm Shore A 50º Poron in the third layer"	Lin et al. 2013
"Multilayered with 40º shore hardness EVA base and Poron top cover, cut-out in the affected metatarsal head."	López-Moral et al. 2019
"Insole base with 5mm 50º Shore A EVA with three different metatarsal bar (MB) positioning out of two different types materials: 20º Shore A EVA, 20º Shore A Poron"	Martinez-Santos et al. 2019
"1.27 cm thick number 2 plastazote with shore value approx. 35, metatarsal pad (MP), positioned proximal to metatarsal heads".	Mueller et al. 2006
"Full length 3 mm blue medium density Ethylene Vinyl Acetate (EVA) shell and 6mm gray poron top cover".	Paton et al. 2012
"SM-2, 3 & 4: ¾ custom insoles with EVA base and 3mm PPT full-length top cover SM-5 & 6: Custom insoles with EVA base and 3mm PPT full-length top cover".	Praet et al. 2003
"Insoles from the static footprint and foam box impression, configured with arch support, metatarsal bar, soft fillers. Insole materials: PPT, Duuroterm, Alcaform"	Rizzo et al. 2012
"Custom insoles: 35 & 55 Shore A hardness EVA (14mm thickness) for custom made insoles manufactured from positive plastar molds, metatarsal bars proximal to II-IV MTH's. Prefabricated insole: Hardcore EVA base, 12 Shore hardness microfiber top layer (GloboTec® comfort 312750501400)"	Tang et al. 2014

Appendix 3 - Clinical audit tool

Clinical audit questionnaire and database

Version 1

Sl#	Age (Years)	Sex	Country of Birth	Aboriginal/Torres Strait Islander?	Postcode	Duration of diabetes	Duration of neuropathy	Type of diabetes		Height (cm)	Body Weight (kg)	Forefoot Pathology												Co-morbidities							Footwear Fund provider
								T1DM	T2DM			Neuropathy	HAV	Hammer toe	Clawed toe	Overriding digits	Forefoot amputation	Partial amputation	Forefoot ulcers	Bony prominence	Flexible flat foot	Rigid flatfoot	LJM	Cavus foot	hyper keratosis	RA	PVD/PAD	Lymphodema	PTD	Altered foot posture	History of Ulceration	

Appendix 4 - Australian Pedorthists Survey Questionnaire

Current practice of Australian pedorthists in prescribing footwear and insoles to prevent diabetic neuropathic ulceration and re-ulceration at plantar forefoot

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Q1 Thank you for your participation in this survey. Please fill out all questions as by cases that you would do in your everyday clinical practice. mentioned below.

Q2 What is the post code of your primary pedorthic practice?

○ _____

Q3 Case-1: Mary Smith is a 65 Years old female, Caucasian background, 86 kg weight, 170 cm height and very much full of life who lives in a privately owned home with her husband. She has a history of Type-2 Diabetes Mellitus (10 years+) and peripheral neuropathy (7 years+). Mary has recently healed plantar ulcer under the Hallux on the right foot. Bony prominence under 1st and 5th metatarsal heads (MTH's), bilaterally, Hammertoes and hallux abducto valgus (HAV), R>L, Hyperkeratosis on dorsal of 2 nd -3 rd interphalangeal joints (IPJ). Peripheral vascular disease and feet swell towards the end of the day. Initially, she was treated at a high-risk foot clinic and currently under community podiatry care. Mary does not qualify for state funding or NDIS and has private health insurance with top cover. She is also willing to pay the gap towards funding for her therapeutic footwear and insoles. What would you prescribe for her footwear and insole design and modifications? Please write your answer to this case in questions Q4-Q8.

Q9 Case-2: Reginald Bruce is 55 Years old male, Australian Aboriginal background, 98 kg weight, 178 cm height, long term smoker and used to work as a social worker until recently. He is active and goes to the bush to collect his own food. He has a history of Type-2 Diabetes

Mellitus (10 years+) and peripheral neuropathy (5 years+). He has recently healed plantar ulcer under the 3rd metatarsophalangeal joint (MPJ) on left foot, osteomyelitis, tailor bunion and calluses on the lateral aspect of the 5th on the left. Bilateral Hammertoes, R>L, Hallux amputation on Right foot (2 years ago). He also has rigid cavus feet. Initially was treated at a high-risk foot clinic and then discharged to community podiatric care, however, has not attended for some time, nor no ongoing preventative care. His therapies are funded by Closing the Gap program. What would you prescribe for his footwear and insole design and modifications? Please write your answer to this case in questions Q10-Q14.

Q15 Case-3: Suken Das is 70 Years old male with Fiji Indian background, currently on a disability pension and lives in a community housing, currently not working. He gets carer support for three days/week. He is of 116 kg weight, 172 cm height, with history of T2DM (18 years+) and peripheral neuropathy (12 years+). He has recently healed plantar ulcer at 1st metatarsophalangeal joint (MPJ) on the right foot, hallux limitus on the left. He has significant oedema/ fatty tissue around his ankles, bilateral rigid flat foot, trans-met amputation on left foot (3 years ago). Nephropathy, hypertension. Initially was treated at a high-risk foot clinic and currently under community podiatry care. What would you prescribe for his footwear and insole design and modifications? Please write your answer to this case in questions Q16-Q20.

Q21 Case-4: Cathy Lee is 55 Years old female, and she is from an Asian background, currently on a disability pension. She is of 76 kg weight, 170 cm height, with history of Type-1 Diabetes Mellitus (39 years+) and peripheral neuropathy (10 years+). She is a single mum and lives in her own home with her 30 Y/O daughter. Cathy is an artist and used to work as a volunteer at the local museum and local art gallery, but currently not very active. She has recently healed plantar ulcer at 2 nd MPJ on Right foot. Over-riding digits 2nd over 3 rd on Right, 2nd and 3rd toes amputated on the left (3 years ago), bony prominence and severe hyperkearotosis under 4th and 5th MTH on the left, Bilateral HAV. ATL (6 months ago), Rheumatoid Arthritis, retinopathy, at falls risk, Hyper-tension. Initially was treated at a high-risk foot clinic and currently under community podiatry care. What would you prescribe for

her footwear and insole design and modifications? Please write your answer to this case in questions Q22-Q26.

Q4 Footwear design parameters (please select as many parameters as applicable, describe them where appropriate and add any other recommended parameters in the additional boxes)

- ☐ Medical Grade Footwear without modification (Brand) (1) _____
- ☐ Custom made footwear (2) _____
- ☐ Medical Grade Footwear with modification (3) _____
- ☐ Rocker sole design parameters (4) _____
- ☐ Mid-sole materials (5) _____
- ☐ Sole materials (6) _____
- ☐ Upper materials (7) _____
- ☐ Lining materials (8) _____
- ☐ Re-lasting or widening (9) _____
- ☐ Lace up (10) _____
- ☐ Velcro fastening (11) _____
- ☐ Additional parameters for shoe design 1 (12) _____
- ☐ Additional parameters for shoe modifications 2 (13) _____
- ☐ Additional parameters 3 (14) _____
- ☐ Additional parameters 4 (15) _____

Q5 Insole design parameters (please select as many parameters as applicable, describe them where appropriate and add any other recommended parameters in the additional boxes)

☐ Prefab insole (Brand) (1)
_____

☐ Custom made insole (2)
_____

☐ EVA Base (Hardness/Density) (3)
_____

☐ Tri-lam base (18)

☐ Poly Base (Thickness) (4)
_____

☐ Carbon Base (5) _____

☐ Poron/PPT mid-layer (Thickness) (6)
_____

☐ EVA Mid-layer (Thickness) (7)
_____

☐ Plastazote topcover (Thickness) (8)
_____

☐ EVA Topcover (Hardness and Thickness) (9)
_____

☐ Leather topcover (10) _____

☐ Adding additional arch support (11)
_____

☐ Metatarsal dome (Size and positioning) (12)
_____

☐ Metatarsal Bar (Size and positioning) (13)
_____

☐ Local deflection/removal of materials ((14) _____

☐ Local cushioning (15) _____

☐ Additional parameters 1 for insole design (16) _____

☐ Additional parameters 2 for insole design (17) _____

Q6 What are the common challenges you may have with your recommendations and the patient's acceptance of them? How do you overcome those challenges?

☐ Possible Challenges (1) _____

☐ Possible solutions to those challenges (4) _____

Q7 How do you evaluate the offloading success?

☐ Clinical judgement based on experience (2)

☐ Ulcer recurrence (4)

☐ By In-shoe pressure measurements and analysis (5)

Q8 Any other observations or comments you may have about this patient's diagnosis and footwear, insoles prescriptions, please include below:

☐ Additional comments 1 (1)

_____

☐ Additional comments 2 (2)

_____

☐ Additional comments 3 (3)

_____

Appendix 5 - Trials publication coverage

Ahmed *et al. Trials* (2022) 23:1017
https://doi.org/10.1186/s13063-022-06968-5

Trials

STUDY PROTOCOL Open Access

Footwear and insole design parameters to prevent occurrence and recurrence of neuropathic plantar forefoot ulcers in patients with diabetes: a series of N-of-1 trial study protocol

Sayed Ahmed[1*], Paul Butterworth[1], Alex Barwick[1], Anita Sharma[2,3], Md Zobaer Hasan[4,5] and Susan Nancarrow[1]

Abstract

Background: Foot complications occur in conjunction with poorly controlled diabetes. Plantar forefoot ulceration contributes to partial amputation in unstable diabetics, and the risk increases with concomitant neuropathy. Reducing peak plantar forefoot pressure reduces ulcer occurrence and recurrence. Footwear and insoles are used to offload the neuropathic foot, but the success of offloading is dependent on patient adherence. This study aims to determine which design and modification features of footwear and insoles improve forefoot plantar pressure offloading and adherence in people with diabetes and neuropathy.

Methods: This study, involving a series of N-of-1 trials, included 21 participants who had a history of neuropathic plantar forefoot ulcers. Participants were recruited from two public hospitals and one private podiatry clinic in Sydney, New South Wales, Australia. This trial is non-randomised and unblinded. Participants will be recruited from three sites, including two high-risk foot services and a private podiatry clinic in Sydney, Australia. Mobilemat™ and F-Scan® plantar pressure mapping systems by TekScan® (Boston, USA) will be used to measure barefoot and in-shoe plantar pressures. Participants' self-reports will be used to quantify the wearing period over a certain period of between 2 and 4 weeks during the trial. Participant preference toward footwear, insole design and quality-of-life-related information will be collected and analysed. The descriptive and inferential statistical analyses will be performed using IBM SPSS Statistics (version 27). And the software NVivo (version 12) will be utilised for the qualitative data analysis.

Discussion: This is the first trial assessing footwear and insole interventions in people with diabetes by using a series of N-of-1 trials. Reporting self-declared wearing periods and participants' preferences on footwear style and aesthetics

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Appendix 6 - Participant Information Sheet

Participant Information Sheet

Version 1

Research Project Title:

A series of single participant clinical trial to explore what footwear and insole design features can reduce risk and prevent the occurrence of foot ulcers under the forefoot in persons with diabetes and loss of sensation in the feet.

My name is Sayed Ahmed, and together with my supervisors Professor John Hurley, Professor Susan Nancarrow, Dr Paul Butterworth and Dr Alex Barwick, we are conducting a clinical trial. We are researching the prescriptions of footwear and insole design and modification. To do so, we would like to invite you to participate in a study. In this study, we will investigate what footwear and insole design parameters help to reduce the risk of developing foot ulcers at the forefoot in people with diabetes and neuropathy.

What is the research?

This research explores how the way we make shoes and insoles (foot orthoses) might reduce the pressure on the feet that causes ulcers in people with diabetes and neuropathy.

What does the research involve?

In this proposed study, you will have five one to one consultation with the principal researcher. The initial assessment and consultation will include the selection of appropriate footwear style, measuring, casting and 3D scanning of feet. We will also discuss together the technical specification of footwear and insole that reflects your preferences and clinical requirements for

the foot pathology and co-morbidity. We will also carry out barefoot static and dynamic pressure, and in-shoe pressure measurements on your current footwear at the initial assessment.

There will be another four review appointments with the principal researcher. The second review appointment will be once the footwear and insole are ready to fit and the third review in two weeks from the initial fitting of footwear and insoles. The remaining two review appointments will be in four weeks after each previous appointment. Your footwear and insoles may be modified/repaired based on the assessment/review/in-shoe plantar pressure assessment during each review appointment.

Your personal data will remain de-identified and confidential.

How long will I be involved?

Participation in this project is totally voluntary. The total participation time for the study will be approximately three to four hours over four to five months period. It is expected that the initial consultation will be for an hour, and the remaining four review consultations are around 30 minutes each. This will include review, measure, modify and fit the footwear and insole. Anyone can withdraw from this research at any time without any penalty. You can keep the footwear and insole provided to you as part of the study, but you need to return the orthotimer sensors to the researcher that are attached to your insoles.

Risk

In this study, your footwear will be designed for you, using the best available evidence. The main difference you will experience from being involved in this study is that we will measure the changes to your feet more often (four times over three months time period). There are no risks in being involved in this study compared to standard diabetic footwear provision. In fact, because we are monitoring your feet so closely, the risks should be reduced. If, however, you do experience any discomfort or notice any changes as a result of the footwear, please stop wearing them and contact the researcher immediately. The principal researcher can be contacted on mobile at 24/7 to discuss any risk that may arise. The mobile number is 0425…..

Who will fund for the footwear and insoles?

Unfortunately, there is no research fund available for this project to cover the cost of the footwear and insoles. However, there may be other fund options available to you such as ENABLE NSW, DVA, NDIS, Workers Insurance, and so on which will be advised by the referring podiatrist. There will be no upfront or ongoing cost to you to participate in this research. The cost of sensors used for the F-Scan system and Orthotimer will be funded by the researcher.

Our responsibilities to you

Confidentiality: The findings of the research will be submitted for publication; however, no person participating in the study will be identified in any way. Only the group data will be presented.

Payments to participants: Unfortunately, there is no funding available to pay you in this research. However, you will be given a pair of diabetic bamboo socks at free of cost, and you will keep the footwear and insoles provided to you during the research.

Benefits to the broader community: The primary aim of the research is to reduce risk and prevent forefoot ulceration in persons with diabetic neuropathy. This is anticipated to be done by a better understanding of their needs and address them more effectively in terms of clinical needs, aesthetics and functionality of prescribed devices. This will potentially save huge health care cost for the public health system or privately paying patients. It is anticipated that this will also have a significant positive impact on the personal, emotional and social well-being of the person.

Your responsibility

If you participate in this research, you are asked to sign the consent form and make yourself available for the planned initial and follow-up appointments with the principal investigator/researcher.

Consent

Please read the consent form carefully and circle Yes or No for each statement, and sign if you wish to participate in this study.

Feedback

“If you would like to receive a summary of the research when it is finished, please tick the box in the consent form and where you can leave your email address to receive a copy of the summary.

Ethics Approval

This research has been approved by the Human Research Ethics Committee of Southern Cross University. The approval number is 2020/093.

The research also has been registered in the Australian New Zealand Clinical Trials Registry (ANZCTR), and the trial registration number is **ACTRN12620000699965p.**

Complaints about the research/researchers

If you have concerns about the ethical conduct of this research or the researchers, the following procedures should occur. All information is confidential and will be handled as soon as possible.

Write to The Ethics Complaints Officer, Southern Cross University, PO Box 157, Lismore NSW 2480. Email: ethics.lismore@scu.edua.u

All information is confidential and will be handled as soon as possible.

Thank you for considering participating in this research.
If you agree to do so, please sign and return the accompanying Consent Form.

Contact details:

Principal Researcher

Sayed Ahmed

Mobile: 0425……..

Principal Supervisor

Professor John Hurley

Appendix 7 - Consent Form

[Insert Logo]

Title	Footwear and insole design parameters to prevent occurrence and recurrence of neuropathic plantar forefoot ulcers in patients with diabetes; - A series of N-of-1 trials.
Short Title	*[Short Project Title]*
Protocol Number	*[Protocol Number]*
Project Sponsor	School of Health & Human Science, Southern Cross University
Coordinating Principal Investigator/ Principal Investigator	*Professor John Hurley*
Associate Investigator(s)	Sayed Ahmed Dr Paul Butterworth Dr Alex Barwick Professor Susan Nancarrow
Location	Nepean Hospital St Vincent Hospital St George Hospital

Consent Form - *Adult providing own consent*

Declaration by Participant

☐ I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

☐ I understand the purposes, procedures and risks of the research described in the project.

☐ I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to *School of Health & Human Science, Southern Cross University,* concerning my disease and treatment for the purposes of this project. I understand that such information will remain confidential.

☐ I acknowledge that any regulatory authorities may have access to my medical records **specifically related** to this project to monitor the research in which I am agreeing to participate. However, I understand my identity will not be disclosed to anyone else or in publications or presentations.

☐ I have had an opportunity to ask questions and I am satisfied with the answers I have received.

☐ I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the study without affecting my future health care.

☐ I understand that I will be given a signed copy of this document to keep.

Name of Participant (please print) _____

Signature _____ Date _____

Declaration by Study Doctor/Senior Researcher†

I have given a verbal explanation of the research project, its procedures and risks, and I believe that the participant has understood that explanation.

Name of Study Doctor/
Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide an explanation of, and information concerning the research project.

Note: All parties signing the consent section must date their own signature.

Questionnaire	*NEUROPATHY-SPECIFIC QUALITY OF LIFE.docx*	Neuropathy specific quality of life	1	23-Oct-2020
Questionnaire	*Subject Satisfaction Questionnaire.docx*	Subject Satisfaction Questionnaire	1	23-Oct-2020
Report forms	*Participants inclusion criteria.docx*	Participant Inclusion Criteria	1	23-Oct-2020
Report forms	*Foot Examination form.docx*	Foot examination form	1	23-Oct-2020
	Human Research Ethics Application Approval Notification.pdf	Evidence of prior scientific review.		
	Change of Protocol Application Approval Notification.pdf	Evidence of prior ethics review by HREC, Southern Cross University.		
	Project Registration	The output from form the Project Registration		