Enhancing foot ulcer prevention and adherence through personalised footwear and insole design features: insights from N- of-1 trials

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Abstract

This study investigates the impact of personalised footwear and insole design and modification features on offloading efficacy and patient adherence in people at risk of diabetes-related neuropathic plantar forefoot ulceration.

This study involved a series of non-randomised, unblinded N-of-1 trials with 12 participants who had a history of neuropathic plantar forefoot ulcers recruited from three sites in Sydney, Australia. Barefoot and in-shoe plantar pressures were measured using Mobilemat™ and F-Scan® plantar pressure mapping systems by TekScan® (Boston, USA). Adherence to footwear use was captured using participant self-report. Other outcome measures were participant preference toward footwear, insole design and quality of life.

The study identified foot-specific pressure thresholds crucial for effective offloading and ulcer prevention. It showed that the current plantar pressure threshold (<200 kPa or >30% reduction) recommended by the guidelines may not apply to all participants. Reulceration prevention may require a pressure threshold as low as 103 kPa at one site and as high as 352 kPa at another site in the same participant to keep the individual foot in remission. It underscores the significance of considering individual participant's factors such as the site of amputation, current activity level, and the use of mobility aid. The recommended footwear needs to meet the criteria for the participant's intention of use, whether for outdoor use for walking, shopping, medical appointments, social or religious events, occupational purposes or indoor use. In these populations, considering indoor-specific footwear design and options helps to increase adherence and reduce the risk of ulcer occurrence and recurrence. Moreover, factors such as comorbidities, biomechanics, and adherence significantly impact ulcer prevention outcomes.

Participant-centric footwear designs that fit individual participants' needs are emphasised as a key strategy to enhance adherence, influenced by social support and healthcare involvement. The study advocates for prioritising patient-centric device designs to achieve therapeutic success. However, further research is needed to investigate the effectiveness of these parameters in improving offloading and adherence, thereby promoting physical and emotional health and overall well-being.

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 [1–6]. Nearly 34% of people with diabetes will develop a foot ulcer in their lifetime [7]. This can lead to infection and amputation; diabetes is the main reason for non-traumatic amputation [8,9]. Previous foot ulceration or amputation is a risk for future amputation [1,3,5,10]. Additional risk factors include a higher body mass index (BMI) and structural foot deformities [2–4,6], such as hammertoes and hallux valgus [11,12].

Diabetic peripheral neuropathy (DPN) is a risk factor for the development of ulceration [13]. Over 30% of persons with diabetes will develop DPN [14], and the incidence increases with age [15,16]. DPN can affect the autonomic, sensory and motor nervous systems. Sensory neuropathy interrupts the protective feedback mechanism of touch and pain [17]. 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 [18–21]. 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 predispose a diabetic foot ulcer [21–24].

Neuropathic foot ulcers in persons with diabetes occur mostly at the plantar forefoot [11,25,26] and correspond to areas of peak plantar pressure (PPP) [27]. Bennetts et al. [28] 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 increased PPP observed in this region [29]. For this reason, plantar pressure mapping is used to guide footwear and insole manufacture and judge their effectiveness [30].

Reducing plantar pressures is considered a key factor for wound healing and the prevention of ulcer recurrence [31,32]. Footwear and insoles are important treatment modalities for offloading these pressures [33,34]. The desired offloading threshold should be < 200 kPa to ensure ulcer-free survival at the forefoot [35]. Some studies also recommended that a pressure relief of 25–30% compared with the baseline be effective [36,37]. The evidence for effective design characteristics of footwear and insole that can reduce plantar pressure are limited in the literature [38] and further exploration of the various design and modifications of footwear and insole can bridge the gap in the literature [39,40].

Materials and Methods

The trial protocol for this study has been published previously [41] and some additional details are presented in this section.

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[42–45] have recruited 10 to 25 participants to generate a series of N-of-trials for this trial. A sample size of 21 participants was expected to help create a series of N-of-1 trials for more robust statistical data analysis.

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, considerations were given before selecting and recruiting the participants that they would be available for ongoing appointments.

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 an existing 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 Appendices 1 and 2.

Sample size calculation

The sample size was calculated to be 21 for this trial based on the calculation undertaken by Nikles et al. [44] 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. The same criterion were used, assuming no period effect or treatment time interaction, resulting in 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 [44].

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.

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 [30].

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 [46], 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 [46]. 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.

Blinding

In this study, blinding was not used as blinding is recommended but not mandatory in N-of-1 trial [41]. 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.

Interventions

Outcomes and instrumentation

The primary outcome of this study is in-shoe plantar pressure below the recommended pressure threshold of < 200 kPa or a > 30% reduction from baseline. 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.

Footwear

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 moulded or 3D printed custom insoles to fit into their prefabricated medical-grade 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. The details of the 3D scanning systems and apps interface is shown in Fig. 1.

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 [47].

In-shoe plantar pressure was measured using F-Scan® wireless system by (Tekscan®), Boston, USA. The F-Scan® sensors have four sensels/cm² [40] 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 [48]. 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.

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 [34] and any specific recommendations resulting from the literature review [49] and Australian pedorthists survey study [50]. Footwear modifications were informed by data from the in-shoe pressure analysis [51], 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 [52] and prefabricated medical-grade footwear could only consist of conventional heat moulded insoles [49,53] or digitally optimised, 3D printed insoles [54]. 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 [53]. The design concepts were adopted from the above-mentioned study as there were inconsistencies and variations in footwear and insole design in our earlier survey [50]. Hence, the design concepts were adapted based on current practices in Australia [50] and earlier literature review [49].

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 our earlier literature review [49] survey [50]. The evidence-based was consistently followed for all footwear and insole concepts which were guided by studies [49,50].

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. Figure 2 shows the image of shoe-A with insole-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. Figure 3 shows the image of shoe-B.

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. Figures 4 and 5 show the imgaes of insole-B.

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. Figure 6 shows an image of insole-C.

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.

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 1 outlines the components and concepts used in the study here for reference.

Table 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 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

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 [51]. 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.

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 [55].

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.

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) and adherence. 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.

Results

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/m^2) 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 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 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 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 appearanc of the footwear. Did not prefer custom-made footwear ir fear of the appearanc of them although th fund was available a 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 pref a custom-made ankl boot if access to a health func was available. His Right foot deformity suggests requiremer for additional cushioning to slow down callu build-up an 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 lower heel footwear (5mm heel height) as this was th most comfortab position fo him and improved balance while walking an standing

Table 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	Hypertension, 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 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 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.

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 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 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

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 5 and 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 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 4

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

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_ri
01	Shoe-B + Insole-C	MTH 2–3	MTH 5	589	342	352	352	-40%	335	148
02	Shoe-B + Insole-C	Hallux	Hallux	417	374	315	306	-27%	736	558
03	Shoe-A + Insole-A	MTH 4–5	MTH 1	275	289	243	257	-6.60%	429	589
04	Shoe-B + Insole-C	Hallux	Hallux	417	361	315	211	-49.40%	736	533
05	Shoe-B + Insole-C	MTH 1	MTH 1	954	1007	684	482	-49.48%	447	744
06	Shoe-A + Insole-A	Hallux	Hallux	513	985	804	342	-33.33%	739	775
07	Shoe-B + Insole-B	Hallux	MTH 2–3	487	245	210	198	-59.34%	389	253
08	Shoe-B + Insole-B	Hallux	MTH 1	433	417	333	238	-45%	778	594
09	Shoe-B + Insole-B	MTH 1	MTH 1	246	374	207	140	-43%	444	432
10	Shoe-A + Insole-A	MTH 2–3	MTH 2–3	222	235	209	186	-16.20%	248	236
11	Shoe-B + Insole-C	Hallux	Hallux	539	457	396	314	-41.74%	375	308
12	Shoe-B + Insole-B	MTH 2–3	MTH 2–3	757	689	438	365	-51.80%	912	677

Table 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 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 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 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

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%

The above table and figure (Table 6 and Fig. 7) 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 "summary of the footwear and insole concepts". As per Table 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 2 and 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.

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.

The paired sample t-test revealed that the mean difference before and after Shoe A + Insole A (mean difference = 116.667, SD = 104.410, 95% CI between 7.095 and 226.238) was statistically significant ($t = 2.737$, $df = 5$, $p < 0.05$).

The same test revealed the mean difference before and after Shoe B + Insole B (mean difference = 302.625, SD = 167.082, 95% CI between 162.941 and 442.309) was statistically significant ($t = 5.123$, $df = 7$, $p < 0.001$).

The paired sample t-test revealed the mean difference before and after Shoe B + Insole C (mean difference = 243.700, SD = 151.026, 95% CI between 135.662 and 351.738) was statistically significant ($t = 5.103$, $df = 9$, $p < 0.001$).

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 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 7 and Fig. 8 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 [56,57] 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 [58] 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 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 [59]. 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 [59]. 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 (prefabricated medical grade footwear with major modifications and custom-made insoles) 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.

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 necessary 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 7, 8 and Figs. 8–11 describe detailed information about the participants' satisfaction.

Table 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 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.

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.

Participants' satisfaction with in-shoe plantar pressure reduction and adherence

There is no association between a change in in-shoe plantar pressure and participants' satisfaction, as shown in Table 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. According to Table 9, the results reveal a positive correlation between positive satisfaction scores and walking adherence, whereas negative correlations are observed between positive satisfaction scores and both indoors and outdoors adherence. Conversely, negative satisfaction scores show a negative correlation with walking adherence, yet demonstrate positive correlations with both indoors and outdoors adherence. This is partly showing negative correlation due the hypothesised wearing period classification for three main activities by the participants.

Table 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

Table 9.

Patient satisfaction score and the correlation with adherence

Correlations

			Satisfaction Score (Positive)	Walking [Adherence]	Indoors [Adherence]	Outdoors [Adherence]
Spearman's rho	Satisfaction Score (Positive)	Correlation Coefficient	1.000	.467	-.135	-.531
		Sig. (2-tailed)	.	.126	.676	.076
		N	12	12	12	12

Nonparametric Correlations

Correlations

			Satisfaction Score (Negative)	Walking [Adherence]	Indoors [Adherence]	Outdoors [Adherence]
Spearman's rho	Satisfaction Score (Negative)	Correlation Coefficient	1.000	-.056	.220	.595*
		Sig. (2-tailed)	.	.862	.493	.041
		N	12	12	12	12

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 living in the metropolitan area 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 [60]. The trend of participants' characteristics is reasonably representative of those found in the clinical audit [50].

This is the first series of N-of-1 trials for a personalised 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 [61]. 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 [62], 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 [63]. 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 [64,65]. In interpreting these findings, it's important to consider potential influences such as the Hawthorne effect and self-report bias, which may impact participant behaviour and the accuracy of reported data [66]. Personalised footwear design that is the participant's goal and intended activity oriented [67] and when the participant has a favourable social and family environment [50], 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 [68].

Patient adherence is important because it determines the outcome of the therapy [69] and is affected by fit, ease of use and walking comfort [70]. The perceived value of footwear and insoles are also influencing factors for adherence in people with diabetes and neuropathy [65].

Patient satisfaction is important because it positively influences adherence [62] and is affected by aesthetics and perceived self-image in the social image [65].

The treatment goal of all 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 "Footwear and insole design and modifications effect on in-shoe plantar pressure" and "Summary of all footwear and insole concepts' efficacy in plantar pressure reduction (T0-T3)".

In addition, this trial has repeatability and direct application to individual participant treatment as the best-personalised treatment method [68]. This trial method appeals to participants in generating feelings of being more involved and seeing accurate feedback to responses [44]. 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 [49] 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 [71]. Barefoot and in-shoe pressure values and ROIs are not the same for the same participant due to biomechanical and footwear design influences [71]. 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 [72]. 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 [73]. However, the commonly available plantar pressure measurement systems and the sensors differ in thickness, flexibility, and sensor density [49], and it is not unlikely to have a different pressure reading for the same foot and footwear when a different system is used [74].

There was an unexpected finding in this study with participant 03 that is 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 [75,76] 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 [49]. 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 [30]. 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 [74,77]. Hence, a comprehensive foot assessment [77,78], 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 [79,80]. Patients' comorbidity [81,82], tissue resistance, and plantar loading [55], skin properties and shear force [34,83,84] 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 [85]. 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 [86,87]. 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 [67]. 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 [88] 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 [49,89].

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 [59]. The pedorthists' survey also describes various strategies the practitioners follow to overcome adherence-related challenges and increase adherence for improved clinical outcomes. Our earlier pedorthists survey study [50] 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 [49,90,91]. 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 [49,92]. Some cultures do not allow wearing outdoor footwear indoors or wearing any footwear indoors at all [90,92]. 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 [82]. 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 [69,93–95]. 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 [96,97]. 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 [49,86]. For example, in research, the footwear assessment and evaluation tools are driven by the podiatry profession [98], and the footwear design, manufacturing and modifications algorithms are pedorthic profession-driven approaches [52,53,88]. 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 [49,86].

The impact of funding

There are various providers that provide funding for footwear and insoles for eligible patients [99]. 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 [100] and this is supported by Australian pedorthist survey [50] and NADC HRFS service standards [93].

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 [101] 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 [102,103] 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 [46]. 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.

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.

Conclusion

As per the author’s best knowledge and available evidence, 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.

Abbreviations

ANOVA, analysis of variance

CRF, Case report form

PIS, Participant information sheet

HREC, Human research ethics committee

HRFS, High-risk foot service

IRMA, Integrated research management application

NBMLHD, Nepean blue mountains local health district

NHMRC, National health and medical research council

PPP, peak plantar pressure

QOLS, quality of life scale

RDMP, Research data management plan

RGO, Research governance office

SCU, Southern cross university

Declarations

Definition

Pedorthist: A person who provides medical grade footwear and/or orthotic appliances and appropriate advice to a patient after assessment and analysis of the patient's problem(s). This includes the provision of prefabricated footwear, modification of prefabricated footwear, custom-designed and manufactured footwear and/or orthotic appliances, and advice on the need and application of medical-grade footwear, orthotic appliances, and other footwear.

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Authors' contributions

SA is the Chief Investigator; he led the protocol development and managed the stakeholders' relationship. AB contributed to the study design and protocol development. AS contributed to the ethics application for the NBMLHD and SSA for the Nepean hospital site and approval process. MAK contributed to the study design and data anyalysis. MZH contributed to the data analysis process. SN contributed to the study design conceptualisation and protocol development. All authors read and approved the final manuscript.

Funding

As the footwear and insoles are part of the standard treatment for each participant, the funding were be provided by the funding source to which each participant had access. This includes HealthShare Enable NSW [104], private health funds, aged care packages, Closing the Gap or self-funded by participants based on their eligibility criteria. Foot Balance Technology (owned by the chief investigator) provided support for the F-Scan® and Mobilemat™ systems and relevant sensors. There were be no cost to participants for the sensors.

Availability of data and materials

The datasets during the study are available from the corresponding author on a reasonable request. All data will be de-identified before making it available to authorised parties.

Ethics approval and consent to participate

The ethical aspects of this research project have been approved by the Nepean Blue Mountains Local Health District (NBMLHD) Human Research Ethics Committee (HREC) and the Southern Cross University HREC. The approval numbers are 2020/ETH02250 and 2020/093, respectively. Written informed consent was obtained from each participant by one of the research teams of the respective site at the time of initial assessment and baseline information collection. A copy of the consent form can be available by contacting the corresponding author.

Consent for publication

A written consent on publication were obtained from each patient where patient personal information will remain deidentified.

Competing interests

The authors declare that they have no competing interests.

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Figures

Figure 1

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

Figure 2

Shoe-A with Insole-A

Figure 3

Shoe-B

Figure 4

Insole-B, 3D Printed Shell

Figure 5

Insole-B, Hand Finished with Top Cover

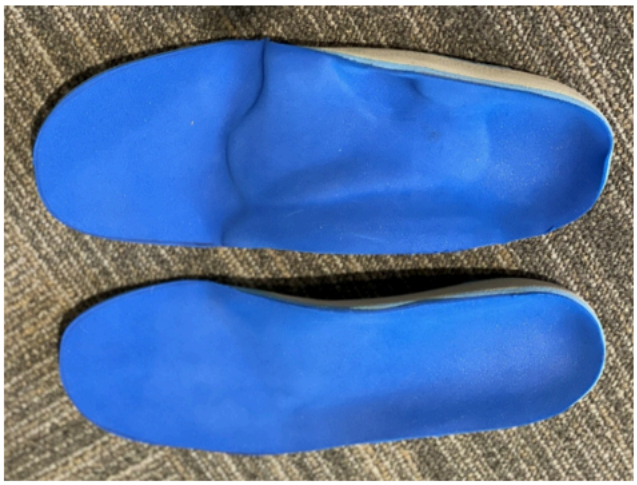

Figure 6

Insole – C

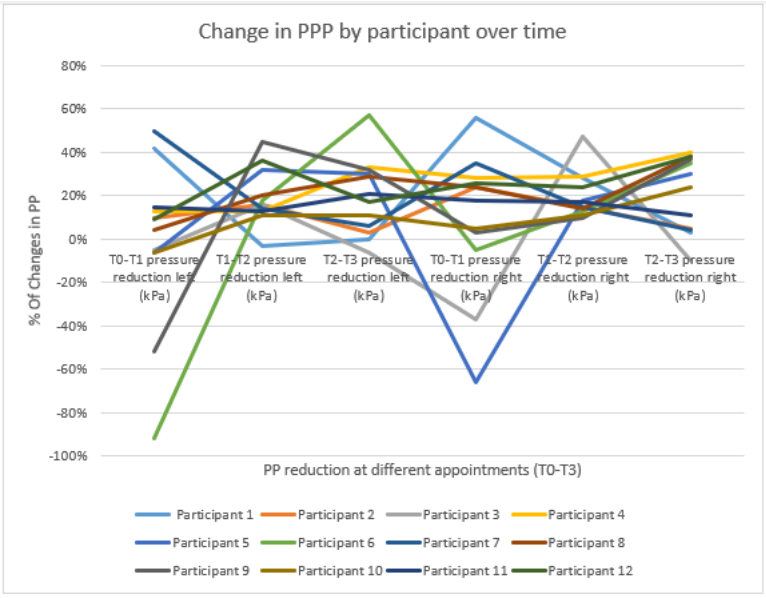

Figure 7

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

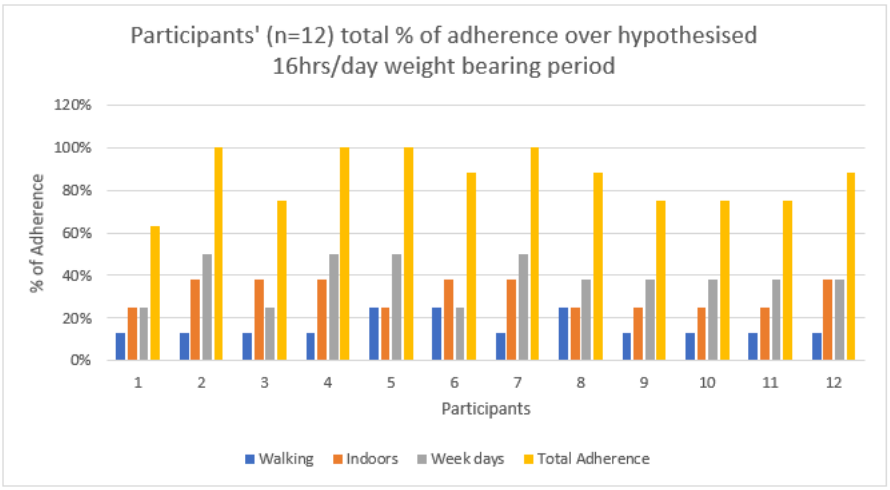

Figure 8

Participants' total % of adherence during weight-bearing activities

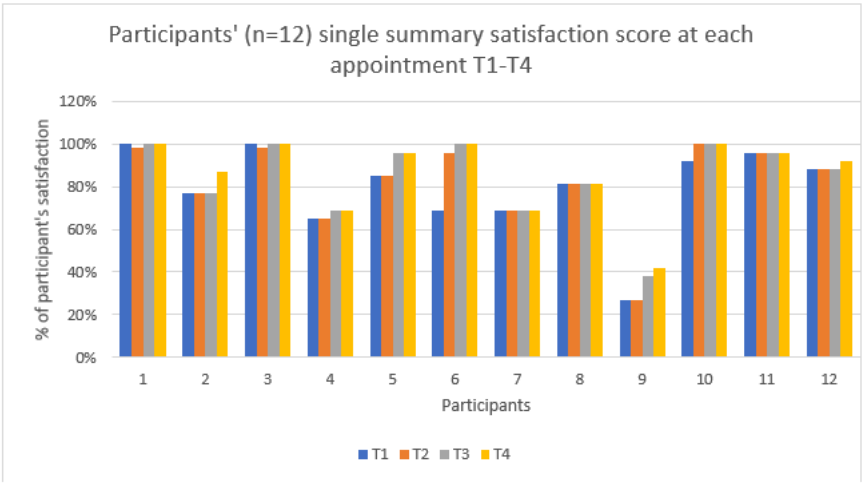

Figure 9

Participants' single summary satisfaction score at each appointment

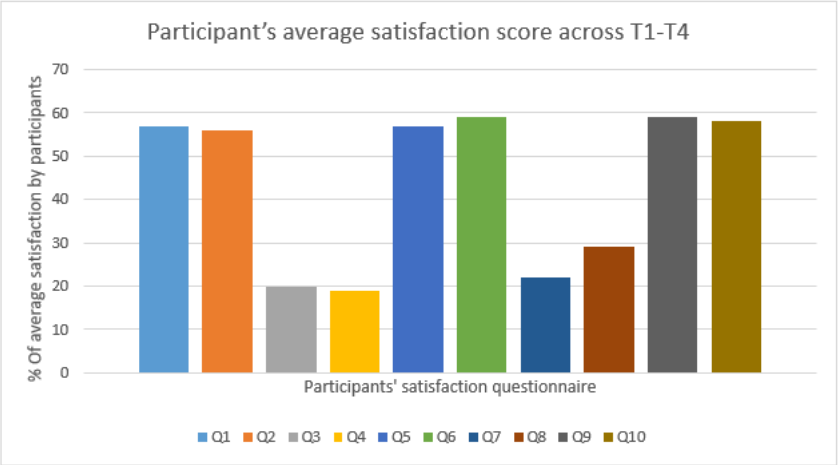

Figure 10

Participants' average satisfaction scores across T1-T4

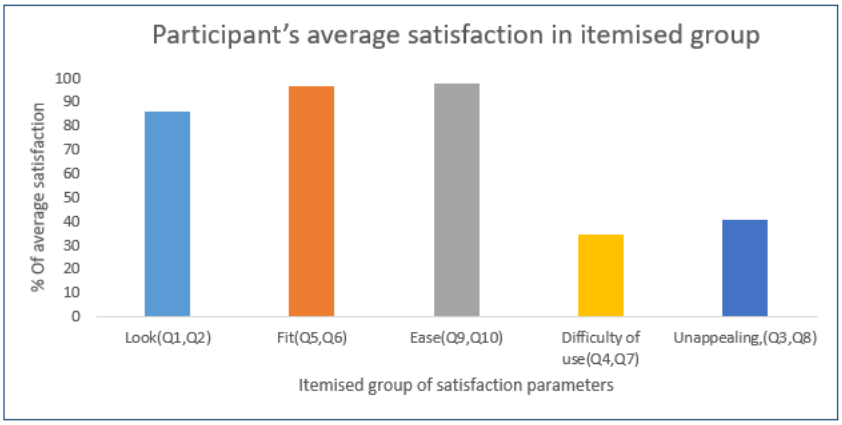

Figure 11

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

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- Appendix1and2.docx