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Footwear and insole design features for offloading the diabetic at risk foot - A Systematic Review and Meta-Analyses

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Abstract

Title: Footwear and insole design features for offloading the diabetic at risk foot - A Systematic Review and Meta-Analyses

The aim of this systematic review is to identify the best footwear and insole design features for offloading the plantar surface of the foot to prevent foot ulceration in people with diabetic peripheral neuropathy. We searched multiple databases for published and unpublished studies reporting offloading footwear and insoles for people with diabetic neuropathy and non-ulcerated feet. Primary outcome was foot ulcer incidence; other outcome measures considered were any standardised kinetic or kinematic measure indicating loading or offloading the plantar foot. Fifty-four studies, including randomized controlled studies, cohort studies, case-series, and a case-controlled and cross-sectional study were included. Three meta-analyses were conducted and random effects modelling found peak plantar pressure reduction of arch profile (37 kPa (MD, -37.5; 95% CI, -72.29 to -3.61; $p < 0.03$), metatarsal addition (35.96 kPa (MD, -35.96; 95% CI, -57.33 to -14.60; $p < 0.001$) and pressure informed design 75.4kPa (MD, -75.4kPa; 95% CI, -127.4kPa to -23.44 kPa; $p < 0.004$).The remaining data were presented in a narrative form due to heterogeneity. This review highlights the difficulty in differentiating the effect of different insole and footwear features in offloading the neuropathic diabetic foot. However, arch profiles, metatarsal additions and apertures are effective in reducing plantar pressure. The use of pressure analysis to enhance the effectiveness of the design of footwear and insoles, particularly through modification, is recommended.

INTRODUCTION

Foot ulceration is amongst the most serious complications of diabetes mellitus [1]. It is expected that 19-34% of people with diabetes will develop a foot ulcer at some point [2]. Foot ulceration is known to precede 80% of all diabetic lower limb amputations [3,4]. A longitudinal study of a diabetic community reported new ulcer incidence as an estimated 2% annually [5] whilst other studies have noted ulcer re-occurrence rates of 30-40% in the first year after an ulcer episode [2,6,7]. Prevention of foot ulceration occurrence and reoccurrence are now recognised as key strategies in reducing the concomitant burden to patients with diabetes and the healthcare system [8].

The cause of diabetic foot ulceration is multifactorial [9]. However, reducing high plantar loads or foot pressures is one mechanism by which foot ulceration may be prevented [10]. Elevated dynamic plantar pressures during locomotion contribute to the development of plantar diabetic foot ulcers when in the presence of neuropathy [11,12]. Guidelines recommended that people with diabetes wear appropriate 'diabetic footwear' designed to reduce repetitive stresses at all times [13]. Systematic reviews have demonstrated the effectiveness of footwear and insoles in offloading the plantar load under the foot and preventing ulceration [14-18]. However, these have not identified the best insole design or feature and footwear specification or modification for use when reducing plantar load for foot ulcer prevention in people with diabetes and neuropathy.

Therefore the purpose of this systematic literature review is to identify the best footwear and insole design features for offloading the plantar surface of the foot to prevent foot ulceration in people with diabetes. It is anticipated that this information will inform a standardised protocol for the clinical design of therapeutic insoles and footwear to offload the foot and reduce ulcer risk in people with diabetes and neuropathy.

More specifically, the objectives are to identify the key design features with regard to:

- profile/shape of the insole, shoe upper and shoe outsole
- material type and properties of the insole and shoe outsole
- modifications made to the insole and shoe outsole
- fabrication techniques used for the insole and shoe

METHODS

This systematic review was performed and reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) Guidance [19]. The systematic review was prospectively registered on the PROSPERO database for systematic reviews (CRD42017072816).

The population of interest was adults over 18 years of age with type 1 or 2 diabetes mellitus and peripheral neuropathy. The primary outcome was foot ulcer incidence; other outcome measures considered were any standardised kinetic or kinematic measure indicating loading or offloading the plantar foot (such as plantar pressure, pressure-time integral, total contact area, dynamic measures of centre of pressure trajectory or velocity) and any standardised clinical measure indicating loading/offloading of the plantar foot (such as callus/lesion reduction). Side effects/adverse events as a result of the design features were additional outcomes of interest. We excluded studies on people with active ulceration, major amputation of the foot or Charcot arthropathy because we considered that the unique patho-mechanics and gross deformity associated with the severity of these conditions would unduly influence the design features of the footwear and insoles.

This review included both experimental and epidemiological study designs including randomised controlled trials, non-randomised controlled trials, quasi-experimental, before and after studies, prospective and retrospective cohort studies and analytical cross-sectional studies. Studies were included if they made one of the following comparisons: Footwear and/or insole design feature compared to another therapeutic footwear and/or insole design feature; footwear and/or insole design feature compared to no intervention. Qualitative studies, case reports and systematic reviews were excluded.

The initial literature search was performed on 27 July 2016 by one researcher (RC) and covered publications in English and was not restricted by date. The search was updated on 27 December 2017 and 30th October 2019. The following databases were searched: Excerpta Medica Database (EMBASE) via Ovid, Medline and Cochrane Database of Systematic Reviews, AMED (EBSCO), Cumulative Index to Nursing and Allied Health Literature (CINAHL), MEDLINE, Joanna Briggs Institute Database of Systematic Reviews, and PROSPERO. A search for unpublished studies was undertaken in EThOS, Pearl, Web of Science, Google Scholar, SIGLE. The search strings were prepared with the help of an evidence synthesis specialist. An example of the search from one of the databases is provided in Electronic Supplement Material 1. Title and abstract of all papers retrieved by the literature search were screened independently by two researchers (RC and JP) to determine whether the paper met the inclusion criteria with disagreements resolved by discussion. Full text articles were then retrieved and further screened by two researchers (RC and JP) independently for inclusion in the review. In addition, a hand search was undertaken using the references from journal articles.

RESULTS

The initial electronic search generated 7384 articles of which 2094 were duplicates (figure 1). In the screening phase, 4750 were excluded based on their title and a further 466 excluded on title and abstract leaving 74 articles for full text assessment. We excluded 28 of these articles based on irrelevant study population (n=12), irrelevant study design (n=4), irrelevant outcome/ intervention (n=12) leaving 46 [20-65] included in the final review. As the initial search was undertaken in July 2016, updated searches were performed in December 2017 yielding 6918 articles, from which an additional three studies [66-68] were included and November 2019 yielding 7821 articles from which a further five studies [69-73] were included.

Data extraction

Data extraction of included studies was conducted using JBI Meta-Analysis of Statistics: Assessment and Review Instrument (JBI-MAStARI)[74]. In this phase, the general and contextual data was extracted in relation to the population, study design, interventions (features, design, modifications and materials of footwear and insoles) and outcomes. In addition, relevant information was extracted in the results section. Data extraction was carried out by (RC) and checked by the second reviewer (JP).

Data analysis and synthesis

In this review, we summarised study findings quantitatively and pooled study effects in a meta-analysis when appropriate using JBI MAStARI [74]. Meta-analysis was performed using random-effects models for continuous variables, calculating mean differences using the inverse variance method. Meta-analysis was based on changes from baseline for peak pressure when the mean and SD were reported where any footwear or insole design feature, modification, material or method could be distinguished. Means and SD's of data was required to be included in the meta-analysis; we contacted four corresponding authors to request this data when not included in the article; two authors did not respond and one no longer had access to the data.

For all estimates, we computed the 95% confidence intervals (CI's). We quantified statistical heterogeneity using the I-Squared statistic (I^2) and considered heterogeneity as low (<25%), moderate (>25% to 50%), or high (>50%) [75], although we did not pre-specify any degree of heterogeneity that would preclude meta-analytic pooling.

Assessment of study quality

Two reviewers (RC and JP) independently assessed the methodological quality of the studies using the relevant JBI critical appraisal tools [76]. Disagreements were resolved through consensus meeting.

A study was considered low risk of bias if all criteria was included. Summaries of the appraisal of study quality are included in electronic supplementary material 2. All studies had some form of bias with standards of reporting variable across studies and by study design. From the quality assessment of the randomised controlled trials (RCT's, all of the RCT studies had some form of bias (mean percentage of 'yes' scores = 65% ± s.d.29%). All RCT studies reported inclusion criteria of participants, p values and participants lost to follow up. The most frequent omissions related to the blinding of the assessor and participants, concealing of treatment allocation and outcomes measurement. Within all of the cohort studies, some form of bias existed (mean percentage of 'yes' scores = 56% (± s.d. 31%). The most frequent omissions related to confounding factors, short follow up periods and incomplete follow up. Within the case-controlled studies mean percentage of 'yes' scores = 70% (± s.d. 0%). Omissions related to confounding factors, lack of sample size justification and different criteria used for the identification of cases and controls. For the case series study, percentage of 'yes' scores = 60%. Omissions related to inclusion criteria, reporting of demographics and participants' characteristics. For the non-randomised cross over study, percentage of 'yes' scores = 75% with omissions relating to confounding factors and selection bias.

Characteristics of included studies

Study characteristics are reported in table 1. Fifty-four studies met the inclusion criteria. Study designs included: n=13 RCT's [23,25,31,38,42,49,55,56,61,62,70,73,77], n=37 cohort studies [20-22,24,26-30,32-37,39-41,43,45,47-49,51-54,57-60,64,66-68,71,72], n=2 case control studies [44,63], n=1 non-intervention case series study [46] and n=1 non-randomised cross sectional over trial [65]. Four authors reported results of the same study in different papers [21,22,39,40,45,47,49,50] and therefore results from these studies were described, but only one set of each results was used within any meta-analysis. Studies were published between 1975 and 2019, undertaken in US (n=17) [20,24,33,35,37,42,45-48,51,54,55,58,59,62,65], UK (n=10) [23,30,32,49,50,67,68,71,73,77], Netherlands (n=7) [21,22,26,27,36,52,64], Germany (n=4)[28,29,44,57], Italy (n=2)[56,61], Australia (n=3)[25,31,53], Taiwan (n=3) [39,40,43], Spain (n=2) [34,70], Thailand (n=2)[66,72], Austria (n=1)[41], Sweden (n=1)[38], Hong Kong (n=1)[60], India (n=1)[63]. The number of participants recruited to treatment groups ranged from seven to 298. Twenty-seven studies (50%) recruited participants with diabetes mellitus and peripheral neuropathy whilst 19 studies (35%) recruited participants with diabetes mellitus, peripheral neuropathy and history of foot ulceration; a further two studies recruited participants with diabetes mellitus and peripheral arterial disease; three studies recruited participants with diabetes mellitus and classified at high risk of foot ulceration; two studies recruited participants with diabetes mellitus only; two studies recruited participants with diabetes mellitus, peripheral neuropathy and high forefoot pressures; one study recruited participants with diabetes mellitus, peripheral neuropathy and foot deformity; one study recruited participants with diabetes mellitus and foot callus; one study recruited participants with diabetes mellitus and taking insulin; one study recruited participants with diabetes mellitus and classified at low risk of foot ulceration. Follow up time periods ranged from no follow up to five years.

Description of outcome measures

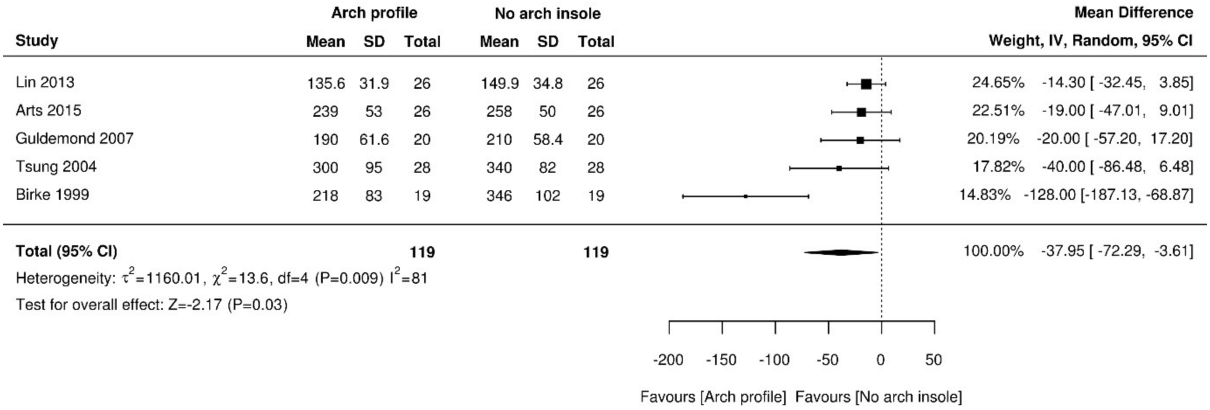
Twenty percent (n=11) of studies [29,34,42,54-56,58,61,62,70,77] reported foot lesions and ulceration as the primary outcome measure. Measurement of this outcome varied across all of the studies, with only one study [54] using a validated wound classification system; six studies [34,42,55,62,70,77] used a broad definition of 'lack of skin integrity through loss of the epidermis and dermis' and the remaining studies had no definition of an ulcer or lesion [29,56,58,61]. All of these studies used professional judgement to assess for the presence of ulceration, although two of the studies [55,62] used photographs as a means of blinded assessment. Four percent (n=2) studies [31,59] used the presence of callus as the primary outcome measure, one study [31] applied a non-validated grading system to assess callus condition, whilst the other [59] measured diameter and thickness of callus lesion. One study [57] reported ground reaction force (GRF) and electromyographic (EMG) activity of three muscles as outcome measures. One study [65] used temperature (°C) as an outcome measure, inferring a rise in temperature with increased risk status when testing the shear reduction device. Seventy two percent (n=39) of studies [20-27,30,32,33,35-41,43-53,57,60,63,64,66-68,71-73] used kinetic outcomes to evaluate the effectiveness of the footwear and insole intervention provided. However, there was considerable inconsistency in the measures amongst these studies, with mean peak pressure, maximum pressure, maximum mean pressure, mean total pressure, pressure time integral and force time integral all used.

Profile/shape of the insole, shoe upper and shoe outsole

Two features of insole profile were described in the majority of studies; arch profile and rocker profile. In total, 69% (n=37) of studies[20-29,34,36-38,41,43-46,48-51,53-56,58-64,66,68,73] reported using an arch profile as a feature of an insole (electronic supplementary material 3) and 37% (n=20) of studies [26,28-30,34,35,38,40,48-50,52,54-56,61,64,65,67,70] reported rockers as an added feature of the shoe outsole (electronic supplementary material 4). One study [39] lacked enough clarity in the description of the intervention to determine if a rocker feature was used in the diabetic footwear.

Only ten percent (n=5) repeated measure studies [21,24,36,43,60] measured the direct effect of an arch profile on mean peak pressure. According to the heterogeneity test, high heterogeneity existed (I^2=81%, א^2 =13.6, ז^2 = 1160, p=0.009). Therefore, random effects modelling was applied to consolidate the effect value. Figure 2 shows that that out of 119 participants, the addition of an arch profile reduced peak pressure by a mean of 37 kPa (MD, -37.5; 95% CI, -72.29 to -3.61; $p < 0.03$) when compared to a flat insole. For the remaining 31 studies [20,22,23,25-29,34,37,38,41,44-46,48-51,53-56,58,59,61-64,66,68] who reported using the arch profile as a feature of the insole, meta-analysis was not conducted due to an inability to isolate the effect of this feature from other features of the insole.

Figure 2 – forest plot of arch profile versus no arch profile



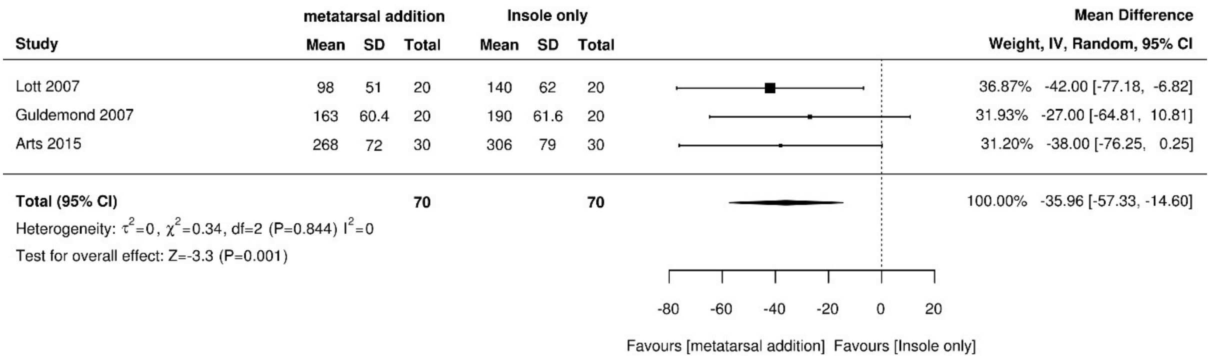
Four studies reported the effect of a rocker profile. One study reported that in 71-81% of participants tested an optimum peak pressure target value of under 200kPa could be achieved with a combination of apex position at 52% of shoe length and rocker angle of 20° [67]. Another study reported no interaction effect when altering apex angle, apex position and rocker angle compared to the control shoe [30]. A third study reported decreases in peak pressures and pressure time integrals in the posterior and anterior, central lateral and central medial forefoot with a standardised rocker shoe with apex position (83mm on medial and 87mm on lateral from front of shoe), angle thickness (24mm maximum thickness at rocker with 11mm rocker height at front end) compared to shoe without rocker [40]. A fourth study reported ulcer re-occurrence to be 64% with a semi-rigid rocker sole compared to 23% with a rigid rocker sole [70]. There was an inability to distinguish the effect of the rocker profile feature from other features of the footwear and insole for those remaining studies [26,28,29,34,35,38,48-50,52,54-56,61,64,65].

Modifications made to the insole and shoe outsole

Sixty-five percent (n=35) of studies [20-22,24,26,31,33,34,37,39,41,43,44,49,50,52-56,58,60-62,65,70] reported modification of footwear, although no separation of this feature from others would allow a pooled effect analysis to occur (electronic supplementary material 5). Fourteen studies [20-22,24,26,34,37,41,43,52,56,60-62] reported using extra-depth shoes as a modification, five studies used diabetic footwear [31,39,43,49,50] and one study [60] reported patient specific footwear, customised to the individual, but did not report the effect this had on any outcome measure.

Thirty-three percent (n=18) of studies [21-23,26,27,36-38,45-48,56,62,64,68,71,73] reported the use of metatarsal addition to the insole (supplementary material 6). Only three repeated measure studies [21,36,45] could distinguish the effect of a metatarsal addition independently from other insole and footwear features and were used for the meta-analysis. According to the heterogeneity test, high heterogeneity existed (I^2=0%, $\aleph^2$ =0.34, τ^2 = 0, p=0.844). Therefore, random effects modelling was applied to consolidate the effect value. Figure 3 shows that out of 70 participants, the use of a metatarsal addition in an insole reduced mean peak pressure by a further 35.96 kPa (MD, -35.96; 95% CI, -57.33 to -14.60; p < 0.001) when compared to an insole without metatarsal addition. There was a lack of description of the metatarsal addition and no clear indication of how or when to utilise it as a modification.

Figure 3 – forest plot of metatarsal addition compared to insole only



Twenty-two percent (n=12) of studies [21,22,26,27,34,43,48,53,64,68,70,73] modified insoles with the use of a cut out or aperture to target the site or lesion under the foot of clinical interest (electronic supplementary material 7). However, only two studies [21,43] reported the direct effect of this feature. Arts (2015) reported the reduction of in-shoe peak pressure of 21kPa from 253(48) kPa to 232(54) kPa with the removal of material in the insole for a variety of target locations [21]; and Lin reported reductions of MPP at regions of interest (ROI) located in the forefoot by 72kPa from 221.4(50.3) kPa to 149.9(34.8) kPa with the removal of 1cmx1cm² plugs from underneath ROI [43].

Thirteen per cent (n=7) of studies [27,31,33,36,42,73,77] used 'other' modifications. One study reported a 71% reduction on ulcer incidence when using 'intelligent' insoles with pressure detecting sensors compared to the control group [77]. One study reported a 9kPa reduction in mean peak pressure when adding a custom made five degree full length varus and valgus cork posts to the base of the insole for 20 participants with diabetic peripheral neuropathy and non-deformed feet [36]. The remaining studies did not report the effect of these modifications. One study reported balancing the ¾ length orthotic with the use of dental acrylic posts at the rearfoot [31] and another study used extra-density padding at the heel, forefoot and covering the toes as a modification [33]. Another study reported the use of wedge or medial skive on two occasions, prescribed at the discretion of an orthotist, but no rationale for use provided [73]. One study reported including elastic binders and two non-stick sheets placed between the upper and lower pad of the insole as part of their shear resistant insole [42] and one study used substantial heel cups in the design of their insole, although no specification was disclosed [27].

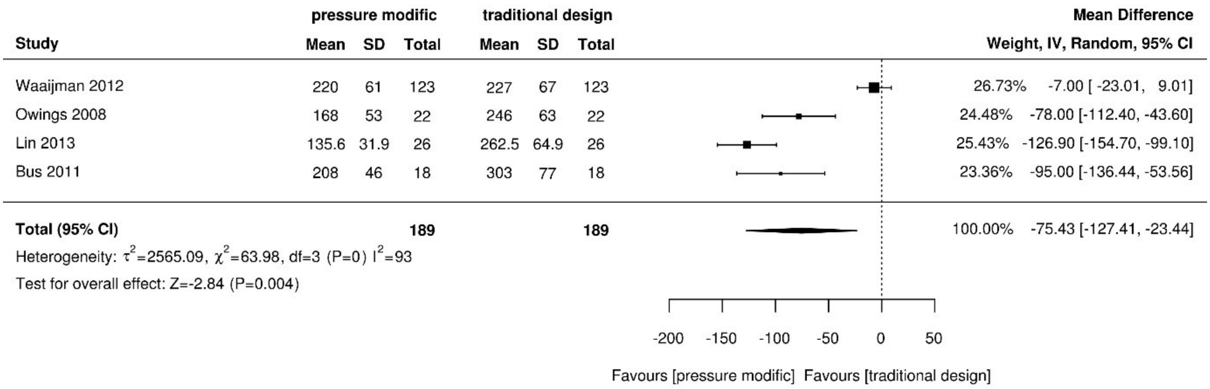
Fabrication techniques used for the insole and shoe

Forty-three per cent (n=23) of studies [20-22,25-27,31,37,38,45,48-50,54-56,60,61,63,65,66,68,72,73] used casting techniques to fabricate the insole and shoe (electronic supplementary material 8) and 20% (n=11) of studies [21,26,27,34,36,43,48,54,56,64,73] used kinetic information to inform the fabrication of the insole or shoe (electronic supplementary material 9). One study used both a 'traditional' foam box casting technique and a weight bearing foot scan technique [73]. Another study [44] used a pedorthist to prepare the insoles individually, although no further information was reported and one study [29] reported the manufacture of the shoe by a local shoemaker according to an algorithm, but did not disclose the technique of the insole fabrication. Three studies [23,49,50] used preformed insoles.

Only one repeated measures study [60] reported effects of casting techniques to manufacture insoles under different loading conditions. Therefore, pooled analysis was not possible due to the diversity of techniques and lack of reported outcomes. Tsung et al [60] reported decreases in MPP compared to shoe only condition of 13.4% when casted non-weight bearing, 13.8 % when casted with a semi-weight bearing insole, 8.1% when casted with a full weight bearing insole, and 2.4% with a flat insole.

Twenty per cent (n=11) of studies [21,26,27,34,36,43,48,54,56,64,71] used kinetic analysis to inform the design and modification of the insole (electronic supplementary material 9). Only one study [56] used ulceration as an outcome measure, the remainder using kinetic measures. Four repeated measure studies [26,43,48,64] reported the direct effect of using plantar based pressure analysis as a fabrication technique to inform the design and modification of the insole and shoe in reducing mean peak pressure. According to the heterogeneity test, high heterogeneity existed (I^2=93%, א^2 =63.98, ז^2 = 2565.09, p=0). Therefore, random effects modelling was applied to consolidate the effect value. Figure 4 shows that in 189 participants, MPP in insoles fabricated with the use of an in-shoe system was reduced by 75.4kPa (MD, -75.4kPa; 95% CI, -127.4kPa to -23.44 kPa; $p < 0.004$) compared to those insoles fabricated using traditional techniques not involving pressure measurement systems.

Figure 4 – forest plot of insoles modified by pressure information versus traditional design insoles



Material type and properties of the insole and shoe outsole

Sixty-nine percent (n=37) of studies [21-23,25-30,34,36,41-44,46,48-50,52-56,58,60-66,68,70-73] used a combination of materials with diverse properties to manufacture the insoles or shoe outsole (electronic material supplementary 10). Thirty per cent (n=16) of studies [20,23,27,29,34,35,46,48-50,52,54,55,58,60-62,68] used dual density constructs, thirty-nine percent (n=21) of studies [21,22,25,26,28,30,36,41-44,52,53,56,63-66,70,72,73] used tri or multi-density/layers. Five studies examined the influence of material on reducing MPP. One RCT [38] of 114 DPN participants directly examined the effectiveness of CMI's constructed of different materials. Comparisons of kinetic variables for a 35 shore Ethyl-Vinyl Acetate (EVA) CMI with a 55 shore hardness EVA CMI and a prefabricated insole (GloboTec, Comfort 312750501400) all within a standardised walking shoe were reported. The main pressure reduction between the CMI and the prefabricated insoles was achieved at the heel and in the overall peak pressure of 180kPa with the extra soft durometer 35 shore hardness EVA insoles as opposed to 189kPa for the soft 55 shore hardness EVA insole. The second study reported no statistical differences in reducing plantar pressures when comparing orthoses constructed of a single density material, Plastazote (Zotefoams Inc., Walton, KY) with a dual density material, Plastazote and Alliplast (Voltek, Brennia, VA) [46]. The third repeated measures study reported a significant difference in MPP between different densities of poron in walking conditions (p<0.0001) [24] although another study found no difference between Poron 96 and Poron 4000 in reducing peak pressure [32]. A fifth study reported the reduction of maximum peak pressure at the forefoot with the addition of a multifoam top cover onto the dual density custom made insole of plastazote and microcellular rubber [72].

DISCUSSION

The aim of this review was to identify the best footwear and insoles design feature for offloading the plantar surface of the foot to prevent foot ulceration in people with diabetes. More specifically, the objectives were to identify the key design features of footwear and insoles with regard to profile and shape, material type and properties, modifications and fabrication techniques.

Heterogeneity was found amongst the profile, modifications, material and fabrication techniques used in insoles and footwear design. Footwear and insoles can be viewed as multifaceted interventions where several features are frequently incorporated into the design. The studies highlighted the lack of a systematic approach to combining these features which makes it difficult to distinguish the effectiveness of individual features in offloading plantar foot pressures.

Within the review, we revealed variations in outcome measures, study design and quality. Six different outcome measures were used amongst the studies which makes meaningful comparison difficult. Identification of specific design features of footwear and insoles related to the primary outcome measure of foot ulceration was not possible. This was because all of the studies using foot ulceration as the outcome measure employed a combination of footwear and insole design features. The follow up time-points at which outcomes were measured varied considerably across studies. The methodological quality of the studies was generally poor. Only four studies [21,38,50,73] reported adherence to the insoles and footwear with one study excluding participants from analysis where there was a lack of substantial wear [73]. The inclusion criteria contained participants with diabetes who were at different stages of disease progression, further adding to the difficulty in making meaningful comparisons between studies. Some studies included people with no sensory neuropathy; some studies included those with sensory neuropathy and no previous foot ulceration and some studies included participants with sensory neuropathy and previous foot ulceration. Foot complication severity has been shown to be associated with increased plantar foot pressures [10]. However, this did not appear to influence the footwear or insole feature used.

Profile/shape of the insole, shoe upper and shoe outsole

Two types of profile features were described in this review; an arch and a rocker. The use of an arch profile replicating the contour of the plantar surface of the foot has traditionally been the 'gold-standard' for insole design for reducing pressure in the diabetic neuropathic foot [78]. This review found that 98% of studies reported using an arch profile as part of the insole configuration, although inconsistency exists in the reporting of the specifications. Our meta-analysis provides evidence that an arch profile when added to an insole can enhance the offloading effect by a further 37kPa when compared to an insole without an arch profile. It is postulated that by increasing contact with the plantar surface of the foot, thereby allowing an increased distribution of force over a greater area of the foot, plantar foot pressure will be reduced [79]. Our review demonstrated that seven studies incorporating an insole with an arch profile reported that an increase in surface contact area values correlates with reduced forefoot pressures [20,23,46,49,50,53,60]. However, Paton et al. reported that the increase in total contact area observed at issue, reduced by 50% after six months of insole wear, whilst pressure reduction remained constant [49,50]. The authors suggest that this could be attributed to the dynamic nature of gait and associated pressure reduction may be associated with changes in foot function, such as the prevention of foot pronation [80,81].

Nineteen studies modified the rocker profile of the shoe as a method of reducing peak pressure. The rigid sole added to the bottom of the shoe is designed to limit the movement at foot joints, particularly extension of the metatarsophalangeal joints at the propulsive phase of gait. This prevents movement of tissue across the plantar aspect of the foot and alters the forefoot loading pattern, specifically reducing pressure under the metatarsal heads by 30% to 50% [82,83]. Our review demonstrates the multiplicity of design variables in terms of rocker angle, placement, height and material. Preece et al., suggested an optimum design of a rocker, but reported further adjustments of rocker angle and position reduced pressure on the forefoot across the participants [67]. Chapman et al [30] reported high inter-subject variability for apex position in reducing pressure under the 1st MTPJ and hallux regions with no clear optimal position. Some consistency was achieved with reducing pressure under the 2nd to 4th MTPJ with an apex position of 50-60% of shoe length. The use of a rocker profile could be beneficial in reducing peak pressure under the diabetic neuropathic foot. However, the effectiveness of this feature may correlate with an individualised approach in the design of the rocker angle, placement, height and material, although no such design algorithm has yet been established.

Modifications

The purpose of modifications is to further adapt the footwear and insole by additional features. Three key modifications of insole and footwear design features were identified from this review; extra-depth footwear, metatarsal additions and sinks or apertures. However, the inability to distinguish the effect of individual modifications from other insole and design features for the majority of studies creates uncertainty on the effectiveness of their usage. Additionally, the assortment of each modification with variations in design, materials, placement and fabrication made direct comparison extremely difficult. Despite this heterogeneity meta-analyses verified the positive effect of metatarsal pad, cut-outs or apertures in reducing forefoot plantar pressures. However, the effectiveness in reducing plantar pressure varies considerably with placement of the modification. For example, Hastings et al., established a pattern of increases or decreases in MPP according to placement of the metatarsal pad proximal or distal to the metatarsal, although only an effect on the 2nd metatarsal head was observed [37]. A data driven approach using real time plantar pressure feedback, as utilised by 10 studies [21,26,27,34,36,43,48,54,56,64] intimates that the effectiveness of some modifications could be enhanced by more accurate siting using appropriate technology, such as real time pressure analysis.

Fabrication techniques used for the insole and shoe

Two different fabrication techniques for insoles and footwear were identified in this review; casting, and kinetic informed. Casting is traditionally used to capture the geometric shape of the patient's' foot to 'customise' the insole. Only one study examined the role of three types of casting technique in reducing peak pressure [60]. The authors reported an insole formed from a semi-weight bearing foot shape offered the greatest peak pressure reduction compared to full weight bearing and non-weight bearing foot shapes, but was not statistically significant. The remaining studies using a casting approach were not able to report any difference in reducing pressure using this fabrication method. This method of fabrication is believed to create an arch profile, which has been demonstrated as altering pressures in the plantar foot as reported by four studies [21,24,36,60]. However, one author, Paton et al., 2011, demonstrated no difference in reducing MPP and PTI when using a prefabricated insole compared to a customised insole [50]. Therefore, potentially all insoles with an arch profile, regardless of the casting technique employed, are effective in reducing plantar pressure in people with diabetes. This view complements another finding of this review that suggests an arch profile may optimise the effect of insoles for diabetic feet.

Ten studies [21,26,27,34,36,43,48,54,56,64] reported the effect of using in-shoe pressure measurement analysis to guide the fabrication of the footwear and insole. The use of a data driven approach for insole and footwear design has been heralded as authenticating plantar foot pressure reduction on an individual basis. Identification of the vulnerable plantar areas with pressure mapping, guides the design and alteration of appropriate personalized footwear and insoles in terms of materials, geometry and modifications. In addition, it provides a quantitative assessment of clinical outcome such that clinicians can be certain of achieving the desired treatment objective. Our meta-analysis supports this proposition although variations in methodology with this technique requires a more consistent approach to limit the inconsistency across clinical areas. Only one study [54] used pressure data to inform the design of the insoles; the remainder used the kinetic data to inform the modification of the insoles by iteratively testing and retesting until optimisation was reached. A lack of standardisation existed across all of the studies for temporal-spatial measurements and gait parameters contributing to the analysis. The use of different pressure analysis systems with dissimilar technical specifications and resolution provides additional inconsistency. Furthermore it should be acknowledged that foot plantar pressure values are only considered a surrogate measure of foot ulceration risk, and that no threshold for foot ulceration has yet been established [84].

Material type and properties of the insole and shoe outsole

Material choice is an important feature of any insole or footwear design. The material used, dependent on its mechanical and physical properties, will influence the insole or footwear's ability to redistribute or dampen forces effectively. This review found no consistency with individual materials used or thickness in the construction of footwear or insole. Only one study directly assessed the effect of material hardness in reducing peak plantar pressures [38]. Sixty-seven per cent of remaining studies used either dual or multi-density material constructions of footwear and insoles. Closed cell foam materials were most frequently sited at the interface between foot and insole and footwear as a top cover; denser materials constituted the base of the insole, EVA appearing the most popular material of choice for the base. A less popular material type was thermoplastics, potentially because these materials were traditionally used for functional devices aimed toward changing gait function and not reducing pressure. Combining materials of different properties is suggested as incorporating the desired properties from each material to best serve reduction in foot ulceration risk [85-87]. However the literature does not provide a sufficiently robust evidence base to inform the selection approach regarding material combination or thickness for the best offloading. Therefore, selection of materials is often influenced by the availability of materials locally and anecdotal evidence, rather than patient specific characteristics and effectiveness of offloading.

LIMITATIONS

The primary limitation of this review is the heterogeneity of study design and outcome measures of the studies included. Large variations in the description of footwear and insoles and uncertainty in the reliability and validity of the assessment and intervention methods exists. The diversity of features used limits the generalizability of the results, resulting in variation in the number of studies and participants included within the meta-analyses. This review was further limited by the inclusion of only English language studies, not including trial databases in the search database and exclusion of participants with charcot and foot amputation.

RECOMMENDATIONS

A consensus is required regarding how to report and measure the effectiveness of individual insole and footwear features in offloading the DPN foot. A core set of outcome measures and standardized time points would facilitate pooling of results in meta-analyses to enable more accurate conclusions to be drawn. Standardization of inclusion criteria is further required to ensure all participants enrolled in offloading trials of DPN have DPN. This would also include participants with charcot and foot ulceration. Improved consistency in the reporting of methodology, in line with the Consolidated Standards of Reporting Trials guidelines and International working group on the diabetic foot, is also recommended [84].

CONCLUSION

This systematic review highlights the difficulty in differentiating insole and footwear features in offloading the neuropathic diabetic foot. The amalgamation of features in insole and footwear designs makes consolidation of the body of knowledge difficult for understanding which feature to use at which time point. However, on the basis of this review we conclude that metatarsal additions, apertures and arch profiles are effective in reducing plantar pressure in this population, and therefore should be incorporated as footwear and insole features. Different casting techniques and materials also appear effective in reducing pressures, but we are unable to recommend any particular technique or type because of insufficient evidence. The use of pressure analysis to enhance the effectiveness of the design of footwear and insoles, particularly through modification, is recommended, specifically in patients with diabetes and peripheral neuropathy.

CONFLICTS OF INTEREST

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AUTHORS' CONTRIBUTION

RC, JF, JML and JP conceived and designed the study. RC designed the search string. RC and JP performed the literature search, assessed the literature, extracted data, and drew conclusions. RC wrote the manuscript. JF, JML and JP critically reviewed and edited the manuscript. All authors have read and approved the final manuscript.

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ETHICS APPROVAL

This review manuscript summarizes and informs of already published studies and thus does not require ethical approval.

DATA AVAILABILITY STATEMENT

The data that supports the findings of this study are available from the corresponding author upon reasonable request.

Figure 1. Flow diagram of study selection in July 2016 and updated in December 2017 and November 2019

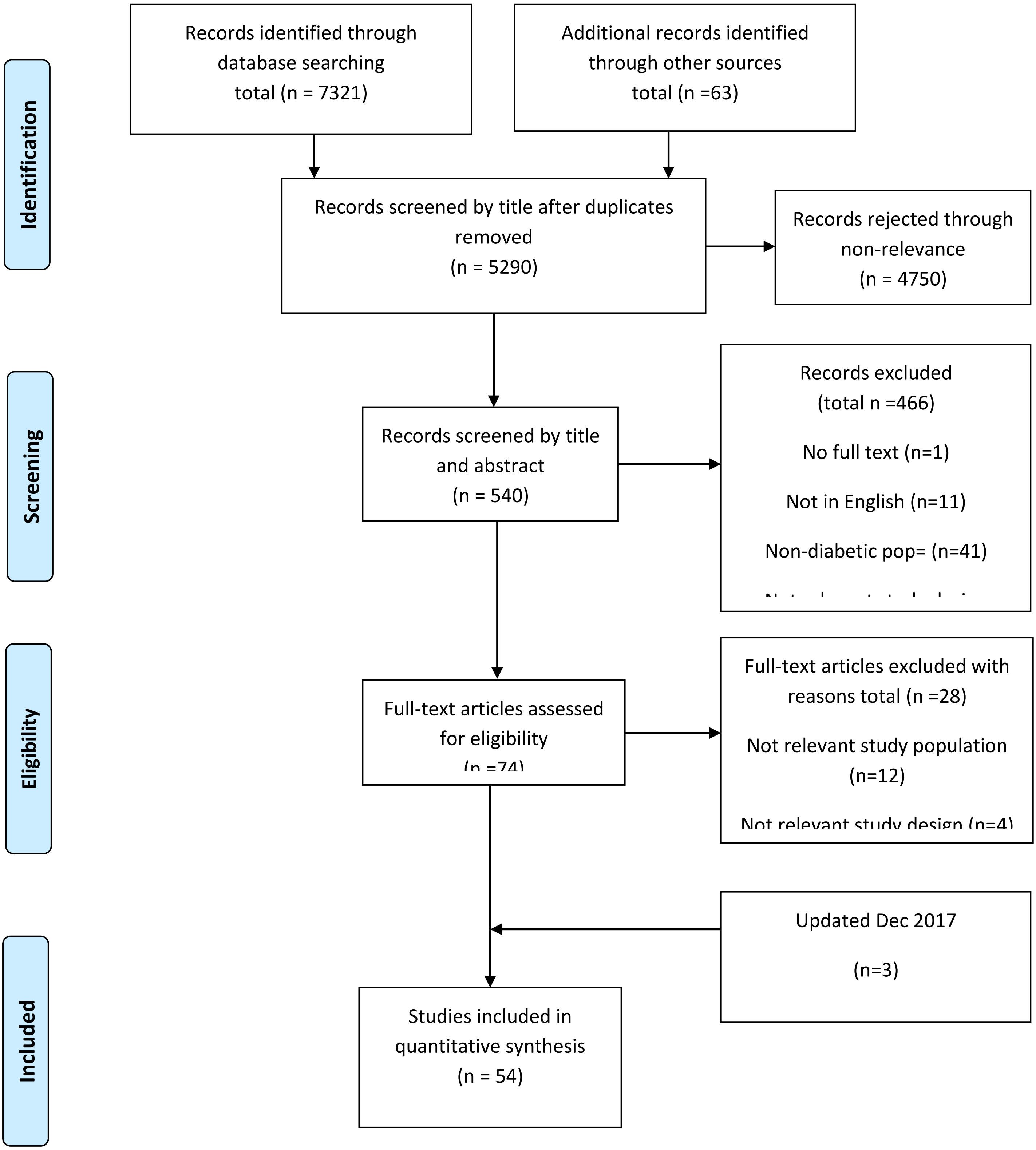

Table 1 – characteristics of studies

Author/year	Study setting	Study design	Participants	Age / years (s.d.)	Gender Male: Female	Comparator	Follow up period	Outcomes
Abbott et al, [77]	UK	RCT	N=58 DPN with history of previous foot ulceration	Control group 67.1 (9.6); interventio n group 59.1 (8.5)	51:7	No plantar pressure feedback provided	18 months	68% ulcer free in control group and 78% in intervention group
Albert & Rinoie [20]	US	Cohort study	n=8 DPN	67 (10.1)	Unknown	Without orthotic	3 months	PPP↓ 30-40% under 1st MTPJ & medial heel. 5-10% ↑Total contact area
Arts et al, [21]	Netherlands	Cohort study	n=85 DPN, recently healed plantar foot ulcer	62.6 (10.2)	70:15	Pre-modification	15 months	PPP↓23% at target location; PPP↓ 13.5-24% by adding metatarsal bar or pad with replacement of top-cover
Arts et al, [22]	Netherlands	Cohort study	n=171 DPN with recently healed ulcer	62.8 (10.2)	140:31	Barefoot	Unknown	PPP↓ 50-76% (deformed feet), 14-66% (non-deformed feet) 85% (previous ulcer location). 61% Successfully

								offloading below 200kPa & 62% at previous ulcer site.
Barnett [23]	UK	RCT	n=102 DM	Orthoses group=56 (20-75) Cleron group 62 (18-75)	68:35	3mm cleron flat insoles	6 months	With orthoses: (22% MPPP↓, 16% Pressure time integral↓ & 11%↑mean Contact area); With insoles (16% ↓MPPP, 10% Pressure time integral↓ & 2%↑ mean Contact area)
Birke et al, [24]	US	Cohort study	n=19 DM with history of foot ulceration	60.2 (9.8)	11:8	Patients own CMI & footwear & no orthosis	n/a	Mean PPP↓55% (wearing own CMI & shoe vs without insoles). mean PPP↓ 36-39% (standard shoe wearing ¼ inch medium hardness poron vs shoe without orthoses)
Burns et al, [25]	Australia	RCT	n=61 DM with PAD & MSK pain.	Custom group = 67.6(8.4) Sham group =65.4(10.3) (13.3)	37:24	Sham insole	8 weeks	Whole foot Mean PPP↓(18% CMI vs 8% sham); Rearfoot Mean PP↓(27% CMI vs 4% sham); Midfoot Mean PPP↓ (7% CMI vs 4% sham); Forefoot mean PPP↓(16% CMI vs 10% sham)

Bus et al, [27]	Netherlands	Cohort study	n=20 DPN with foot deformity	64.4 (11.2)	13:7	0.95cm PPT flat insole	n/a	PPP↓16% & Force time integral↓ with CMI vs 8% with flat insole at 1st MTPJ
Bus et al, [26]	Netherlands	Cohort study	n=23 DPN	59.1 (12.6)	17:6	Pre & post modification		All 35 ROI's successfully optimised with average of 30% ↓ PPP
Busch & Chantelau [28]	Germany	Cohort study	n=92 DPN with history of healed ulceration	64	49:43	Without footwear provided	19 months (shoes) vs 5 months (without shoes)	45% Absolute ulcer risk reduction for with shoes in 1st year
Chanteleau et al, [29]	Germany	Cohort study	n=50 DPN	59 (12)	31:19	With therapeutic footwear	25 months	Foot lesions =78% pre intervention vs 41% post
Chapman et al, [30]	UK/Germany	Cohort	n=24 healthy & n=24 people with DM	57 (8)	31:17	Control	n/a	Variations in apex angle: 14% maximum pressure↓(1st MTPJ) & pressure↑(heel) vs control. For variations in apex position: 39% maximum

								pressure↓ at 2-4MTPJ vs control. As rocker angle ↑ there was ↓ in PP (5th MTPJ) & ↑ in pressure (hallux).
Colagiuri et al, [31]	Australia	RCT	n=20 DM & with callus	Orthotic group 63(10); podiatry group 69(6)	5:15	Traditional treatment of callus	12 months	Callus grade improved in 16/22 callus sites (orthotic treatment group); remained unchanged in 23/30 & 7 deteriorated (traditional treatment group).
Cumming & Bayliff, [32]	UK	Cohort study	n=20 DM with vascular or neurological impairment	68	unknown	No insole	1 week	Mean total pressure: wearing insole (0.180kg/cm^2/s), no insoles (0.210kg/cm^2/s). Mean pressure redistribution Poron 96 (0.198kg/cm^2/s), Poron 4400 (0.211 kg/cm^2/s); total difference (0.013 kg/cm^2/s).
Donaghue et al, [33]	US	Cohort study	n=50 DM at high risk of	57.6 (34-78)	32:18	Old footwear	3 & 6 months	Peak force at baseline: socks only (6.15 kg cm^{-2}), own socks & shoes (4.46 kg cm^{-2}), new

			foot ulceration					socks & shoes (3.98 kg cm^{-2}). Mean PPP at 3 months with new socks & shoes (4.13 kg cm^{-2}) & 6 months (4.24 kg cm^{-2})
Fernandez et al, [34]	Spain	Cohort study	n=117 DM with high risk foot factors & history of ulceration	Unknown	93:24	2 years pre intervention	Follow up 24 months	Pre orthotic 147 ulcerations; post orthotic 22 ulcerations. Mean PPP with orthotic treatment ↓ 85.2kPa (left foot) & ↓87.6kPa (right foot)
Frykberg et al, [35]	US	Cohort study	n=25 subjects (10DM, 15 healthy) with various foot shapes	37 (13.5)	13:12	Patients own tennis or oxford shoe	n/a	For DM subjects Mean PPP with: own shoe (4.46 kg/cm^2), Surgical boot (4.89kg/cm^2), Surgical boot & rocker insole (2.50kg/cm^2). For non-diabetic subjects Mean PPP with: own shoe(2.07 kg/cm^2), surgical boot (2.13kg/cm^2), Surgical boot & rocker insole (1.13kg/cm^2)

Guldemond et al, [36]	Netherlands	Cohort study	n=17 DPN non deformed feet	Median 64 (44-78)	unknown	11 varying insoles	n/a	In central forefoot Mean PPP↓ with: metatarsal dome (32 kPa), standard arch (17kPa), extra arch support (45kPa). At medial forefoot Mean PPP↓ with: varus wedge (9kPa), metatarsal dome (42kPa), standard arch (12 kPa), extra arch support (38kPa). At hallux Mean PPP↓ with extra arch & varus wedge (52kPa).
Hastings et al, [37]	US	Cohort study	n=20 DPN	57.3 (9.3)	12:8	3 insole conditions	n/a	At 2nd MTPJ: PPP↓ (32%) when pad placed between 6.1 & 10.6mm proximally; PPP ↓(16%) when pad located 1.8mm distal to 6.1mm proximally; PPP↓ (57%) when distal part of met pad was 10.6mm proximal to met head; PPP↑

								when pad was further than 1.8mm distally or >16.8mm proximally.
Hsi et al, [39]	Taiwan	Cohort study	n=14 DPN	61.4 (8.3)	6:8	Patients' own shoes	n/a	Diabetic footwear: Pressure time integral (↓heel), (↓anterior to MTPJ), (↓at toe regions) (↑at the midfoot & posterior to MTPJ) PPP: (↓heel), (↓anterior to MTPJ), (↓at toe regions), (↑midfoot & posterior to MTPJ).
Hsi et al, [40]	Taiwan	Cohort study	n=10 DPN	63(9)	3:7	Patients' own shoes		Rocker sole ↓PPP & pressure time integrall in anterior lateral, central lateral & central medial forefoot & prolonged time to PPP in posterior forefoot but not anterior forefoot.
Kastenbauer et al, [41]	Austria	Cohort study	n=13 DM	56(8)	5:8	Leather styled Oxford shoe	n/a	At great toe PPP ↓ with: cork insole & in-depth shoe (16%), Adidas shoe(32%); CMI & in-

								depth shoe (33%); At 1st MTPJ PPP ↓ with: cork insole & in-depth shoe (27%), Adidas shoe(29%); CMI & in-depth shoe (50%); At 2/3rd MTPJ PPP ↓ with: cork insole & in-depth shoe (19%), Adidas shoe(47%); CMI & in-depth shoe (48%); At heel PPP ↓ with: cork insole & in-depth shoe (34%), Adidas shoe(34%); CMI & in-depth shoe (39%).
Lavery et al, [42]	US	Single physician blinded RCT	n=299 DPN previous ulceration or neuropathy & foot deformity	Shear group 69.4(10.0); Standard group71.5(7.9)	202:97	Insoles for standard treatment	18 months	3.5 times odds of developing an ulcer; 3 ulcers developed in shear resistant insole group, 10 ulcers developed in standard insole group
Lin et al, [43]	Taiwan	Cohort study	n=26 DPN	68 (9)	10:16	Standard shoe with insole	n/a	For regions of interest: 15.7% ↓Mean PPP (pre-plug removal); 32.3% ↓Mean PPP

								(post vs post plug removal); 14.3% ↓Mean PPP (arch addition to pre plug removal vs post plug removal). For Non-regions of interest 8.7% ↓Mean PPP (pre-plug removal vs barefoot); 2.2% ↑Mean PPP with pre vs post plug removal); 2.5% ↓Mean PPP (arch addition to pre plug removal vs post plug removal).
Lobmann et al, [44]	Germany	Case control	n=81 type 2 DM (n=18 DPN & high forefoot pressures vs n= 63 control)	Intervention group 63(9); control group 66 (10)	Unknown	Neutral shoes	8 weeks & 6 & 12 months	32.6% ↓Maximum PPP at issue 28% ↓ Maximum PPP at 6 months; 13% ↓ Maximum PPP at 12 months.
Lopez-Moral et al, [70]	Spain	RCT	N=51DPN and previous	Intervention group 61 (8.1);	Intervention group 24:2;	Semi-rigid rocker	6 months	Rigid rocker sole ↓ re-ulceration risk by 64%

			foot ulceration	control group 60 (8.6)	Control group 23:2			
Lott et al, [45]	US	Cohort study	n=20 DPN & history of ulceration	57.3 (9.3)	12:8	Barefoot	n/a	Mean applied pressure: barefoot (272 kPa); shoe (173 kPa), shoe & CMI (140 kPa); CMI & metatarsal pad, (98 kPa). Soft Tissue Strain at 2nd MTPJ: barefoot (38.2%), shoe (31.6%); shoe & CMI (28.9%); shoe, CMI & Metatarsal Pad (24.1%).
Martinez-Santos et al, [71]	UK	Cohort study	n=60 DPN	67(13)	40:20	Flat insole	n/a	PPP ↓ of 29KPa with metatarsal bar and EVA/poron materials
Mohamed et al, [46]	US	Case series comparison	n=16 DPN Type 2 (n=8 Plastazote vs n=8 Plastazote/Aliplast)	Plastazote group 68.4 (5.5); Plastazote/ Aliplast	8:8	No insole	1 month & 3 months	With CMI at baseline: decrease in PPP (12.0 N/cm²); Max Mean Pressure (4.9 N/cm²); Pressure Time Integral (5.6 N/cm²/s) &

				group 68.9(5.5)				↑Total Contact Area (21.2cm²). At follow up: decrease in PPP (10.5 N/cm²); Maximum mean pressure (5.2 N/cm²) & Pressure Time Integral (5.9 N/cm²/s) & ↑ Total Contact Area (20.2cm²).
Mueller et al, [47]	US	Cohort study	n=20 DPN & history of forefoot ulcer	57(9)	12:8	Shoes with standard insoles	n/a	19-24% PPP↓ (CMI), 15-20% PPP↓ (CMI +metatarsal pad); 16-23% Pressure Time Integral ↓ (with CMI), 22-32% Pressure Time Integral↓ (CMI +metatarsal pad & shoe).
Nouman et al, [66]	Thailand	Cohort study	n=16 DPN	58(9)	9:7	Without CMI	n/a	PPP↓26% at forefoot and 24% at toes with CMI
Nouman et al, [72]	Thailand	Cohort Study	N=16 DPN	unknown	9:7	Addition of multifoam top cover	n/a	forefoot maximum PPP 248.2kPa (61.92) with CMI; 211.6k Pa (47.01) with CMI and multifoam

Owings et al, [48]	US	Cohort study	n=22 DPN & high pressures (>750kPa) in MTPJ region	63.7(10.7)	11:11	Polypropylene shell with Korex sponge or plastazote cover; EVA shore 45 with procell or plastazote cover.	n/a	168kPa PPP at regions ff interest (shape based & pressure informed CMI); 211kPa PP (CMI shape based & 45 Shore EVA base with Procell or Plastazote top cover); 246kPa PPP (CMI polypropylene shell with Korex, sponge or plastazote top cover); In rocker shoes: 127 kPa PPP at regions of interest (shape based & pressure informed CMI); 178kPa PPP (CMI shape based & 45 Shore EVA base with Procell or Plastazote top cover); 200kPa PP (CMI shape based & polypropylene shell with Korex, sponge or plastazote top cover).

Parker et al, [73]	UK	RCT	n=57DPN	Traditional group 61.4 (10), digital group 66.3 (10.5)	45:7	Control insole 3mm poron	6 month	Compared with control insole PPP ↓14.91% with traditional insole and ↓24.43% with digital insole at baseline
Paton et al, [50]	UK	RCT	n=119 DPN	custom group 71(10) prefab group 70(10)	90:29	Pre-fabricated contoured shell	6 months	With CMI (37% ↓PPP at baseline & 6 months); (27% ↓Pressure Time Integral at baseline & 30% at 6 months); (32% ↑Total Contact Area baseline & 15% at 6 months). With Prefabicated insole: (35% ↓PPP at baseline & 31% at 6 months); (22% ↓Pressure Time Integral & 24% at 6 months); (29% ↑Total Contact Area at baseline & 15% at 6 months); No difference between CMI & prefabricated insole in PPP & Total Contact Area

Paton et al, [49]	UK	Observational cohort study	n=60 DPN	69	47:22	Pre-fabricated contoured shell	3, 6,12 months	↓PPP with CMI of 39% (0 months), 35% (6 months) & 36% (12 months)
Perry et a,l [51]	US	Cohort study	n=39 total: 13 DM, 13 DPN, 13 non diabetic	DM group 53.6(9.4); DPN group 52.8(7.3); Non diabetic group 54.2(9.7)	33:6	Sock only	n/a	Oxford shoes vs socks: 18% ↓Mean PPP (2nd MTPJ), 2.3% ↓Mean PPP (MTPJ's & heel); Running shoe vs socks 31% ↓Mean PPP (forefoot & heel)
Praet & Louwerens [52]	Netherlands	Cohort study	n=10 DPN	63 (44-78)	0:10	Oxford shoe without insole	n/a	3 Oxford type shoes show no significant ↓ in pressure vs baseline; rocker bottom shoes showed ~50% ↓PPP in central forefoot vs no rocker; mean ↑Total Contact Insole with insole (3.4-7.3 cm^2)

Preece et al, [67]	UK	Cohort study	n=102 DM at low risk and n=66 healthy control	57(9)	52:50	8 shoe conditions	n/a	Optimum location of 52% apex, 20˚angle and apex 95˚
Raspovic et al, [53]	Australia	Cohort study	n=8 DPN with past ulceration	61(48-68)	8:0	No insole	n/a	↓PPP, Pressure Time Integrals & ↑Total Contact Area
Reiber et al, [54]	US	Cohort study	n=24 DPN no history of ulceration	66(9.3)	unknown	Preformed insole	Upto 6 months	0 breaks in skin at 6 months
Reiber et al, [55]	US	RCT	n=400 DM with history of foot ulceration	62	309:91	Usual footwear	2 years	Number of feet ulcerated 15% (shoes & cork insoles), 14% (shoes & prefabs), 17% (control group)
Rizzo et al, [56]	Italy	RCT	n=298 DM at high risk	Standard group 66.2 (9.4) intervention group 68.1(14.1)	unknown	Standard care	12 months, 3 & 5 years	Foot ulceration development: At 12 months 13% (intervention) vs 38.6% (standard care). At year 3, 18% (intervention) vs 61% (standard care); At year 5, 24% (intervention) vs 72% (standard care)

Sacco et al, [57]	Germany	Cohort study	n=45 participants (21 control, 24 DPN)	DPN group 55.2(7.9) Control group 50.9 (7.3)	unknown	barefoot	n/a	1st Ground Reaction Force peak > during shod conditions & > propulsion force in diabetic group but 2nd Ground Reaction Force peak < in shod diabetic vs control group
Scherer [58]	US	Cohort study	n=7 insulin taking DM patients	38(28-59)	3:4	n/a	10 weeks	6 patients discontinued use of footwear (5 plantar irritation of heel & 1 hypertrophic lesions under 4/5th MTPJ's)
Soulier [59]	US	Cohort study	n=108 DM Caucasian non-smokers	55(19-55)	33:45	Own shoes	monthly	Significant change in callus size with running shoes
Tang et al, [38]	Sweden	RCT	n=114 DPN & previous ulceration	58 (15)	62:52	Prefabricated insole	2 years at 6 monthly	PPP= 180kPa (35 EVA insole); 189kPa (55 EVA insole); 211kPa (prefab)
Telfer et al, [68]	UK	Cohort study	n=20 DPN	64.4(9.2)	15:5	Barefoot	n/a	Optimised milled lowered PP by 41.3Kpa compared to CMI and optimised printed

								lowered PPP by 40.5kPa compared to CMI.
Tsung et al, [60]	Hong Kong	Cohort study	n=6 DPN vs n= 8 control	DPN group 56.2(6.2); control group 46.5(11.7)	unknown	Shoe-only	n/a	Mean PPP↓ 13.4% (Non Weight Bearing insole), 13.8 % (Semi Weight Bearing insole), 8.1% (Fully Weight Bearing insole), 2.4% (flat insole)
Uccioli et al, [61]	Italy	RCT	n=69 high risk/past ulcer	Pod group 59.6(11); Control 60.2(8.2)	43:26	Non-therapeutic shoes	12 months	Ulcer relapse 58.3% (control) vs 27.7% (intervention)
Ulbrecht et al, [62]	US	RCT	n=150 DPN recently healed ulcer	Experiment group 60.5(10.1); Control group 58.5(10.7)	104:46	Standard insoles	15 month	Ulcer occurrence control> insole; no difference in non-ulcerated lesion.
Viswanathan et al, [63]	India	Case control	n=241 DM previous foot ulceration	Gr1=59.1(8 .2); Gr2- 54.5(9.1);	156:85	Usual footwear	9 months	PPP↓ 57% (MCR insole); 61% (Polyurethane); 58% (moulded footwear) 39% (own shoe)

				Gr3=53.9(9.3); Gr4=59.1(11.7)				
Waajiman et al, [64]	Netherlands	Cohort study	n=117 DPN (85 experimental vs 32 control)	63.3(10.1)	unknown	Pre & post modification	3 monthly until 1 year	PPP↓ 23% (ulcer site) & 21% (highest PPP site)
Wrobel et al, [65]	US	Cross-sectional analysis	n=27 DPN pre-ulcer callus/past ulceration	65.1	14:13	Standard control insoles	n/a	↓Temperature of 64.1% (forefoot) & 48% (midfoot) with DFO

US-United States, UK –United Kingdom, DPN – diabetic peripheral neuropathy, DM – diabetes Mellitus, ↓-decrease, ↑increase, n/a – not applicable, CMI- Custom made insole, PPP-peak plantar pressure, MTPJ – metatarsal phalangeal joints

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Electronic supplement material 1 – example of search string

"(((diabet*).ti,ab OR (diabetes mellitus).ti,ab) AND ((foot).ti,ab OR (feet).ti,ab OR (neuropath*).ti,ab OR (ulcer*).ti,ab OR (pressure).ti,ab OR (gait).ti,ab OR (walking).ti,ab)) AND ((time).ti,ab OR (offload*).ti,ab OR (off-load*).ti,ab OR (insole*).ti,ab OR (orthos*).ti,ab OR (orthotic devices).ti,ab OR (therapeutic footwear).ti,ab OR (shoes).ti,ab OR (shoe inserts).ti,ab OR (footwear).ti,ab OR (footwear intervention*).ti,ab OR (footwear adaption*).ti,ab OR (padding).ti,ab OR (plug*).ti,ab OR (ankle foot orthos*).ti,ab OR (offloading device*).ti,ab OR (rocker bottom).ti,ab OR (rocker sole*).ti,ab OR (flange*).ti,ab OR (arch profile).ti,ab OR (post*).ti,ab OR (skive).ti,ab OR (metatarsal bar).ti,ab OR (kinetic wedge).ti,ab OR (cut out).ti,ab)"

Electronic supplementary material 2 -Quality appraisal of included studies

Quality appraisal of randomized controlled trials

	Q1 Was true randomization used for assignment of participants to treatment groups?	Q2 Was allocation to treatment groups concealed?	Q3 Were treatment groups similar at the baseline?	Q4 Were participants blind to treatment assignment?	Q5 Were those delivering treatment blind to treatment assignment?	Q6 Were outcomes assessors blind to treatment assignment?	Q7 Were treatments groups treated identically other than the intervention of interest?	Q8 Was follow up complete and if not, were differences between groups in terms of their follow up adequately described and analyzed?	Q9 Were participants analysed in the groups to which they were randomized?	Q10 Were outcomes measured in the same way for treatment groups?	Q11 Were outcomes measured in a reliable way?	Q12 Was appropriate statistical analysis used?	Q13 Was the trial design appropriate, and any deviations from the standard RCT design (individual randomization, parallel groups)
Abbott et al, 2019 [77]	Y	N	N	N	N	N	Y	Y	Y	Y	Y	Y	Y
Barnett 2002 [23]	Y	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Burns et al, 2009 [25]	Y	Y	Y	Y	N	U	Y	Y	Y	Y	Y	Y	Y
Colagiuri et al, 1995 [31]	Y	N	Y	N	N	Y	Y	N	Y	Y	U	Y	U
Hellstrand Tang et al, 2014 [38]	Y	U	Y	Y	U	U	Y	Y	Y	Y	Y	Y	Y

Lavery et al, 2012 [42]	U	Y	Y	N	N	U	Y	Y	Y	Y	U	Y	Y
Lopez-Morales et al, 2019 [70]	Y	N	N	N	N	N	Y	Y	Y	Y	U	Y	Y
Parker et al, 2019 [73]	Y	N	Y	N	N	N	Y	N	N	Y	Y	Y	Y
Paton et al, 2012 [50]	Y	N	Y	Y	N	Y	Y	Y	Y	Y	Y	Y	Y
Reiber et al, 2002 [55]	Y	Y	Y	N	U	Y	N	U	Y	Y	Y	Y	Y
Rizzo et al, 2012 [56]	Y	N	Y	N	N	U	Y	N	Y	Y	N	N	Y
Uccioli et al, 1995 [61]	U	U	Y	U	U	U	Y	Y	Y	Y	U	N	Y
Ulbrecht et al, 2014 [62]	Y	Y	Y	U	U	Y	Y	Y	Y	Y	Y	Y	Y
%	85	31	85	31	8	38	92	69	92	100	62	85	92

Quality appraisal of cohort studies

	Q1 Were the two groups similar and recruited from the same population?	Q2 Were the exposures measured similarly to assign people to both exposed and unexposed groups?	Q3 Was the exposure measured in a valid and reliable way?	Q4 Were confounding factors identified?	Q5 Were strategies to deal with confounding factors stated?	Q6 Were the groups/participants free of the outcome at the start of the study (or at the moment of exposure)?	Q7 Were the outcomes measured in a valid and reliable way?7	Q8 Was the follow up time reported and sufficient to be long enough for outcomes to occur?	Q9 Was follow-up complete, and if not, were the reasons to loss to follow-up described and explored?	Q10 Were strategies to address incomplete follow-up utilized?	Q11 Was appropriate statistical analysis used?
Albert & Rinoie 1994 [20]	Y	Y	N	N	N	Y	Y	N	Y	N/A	Y
Arts et al, 2012 [22]	Y	Y	Y	Y	Y	Y	Y	N	Y	N/A	Y
Arts et al, 2015 [21]	Y	Y	Y	Y	U	Y	Y	Y	Y	N/A	N
Birke et al, 1999 [24]	Y	Y	Y	Y	Y	Y	Y	N	Y	N/A	Y
Bus et al, 2004 [27]	Y	Y	Y	Y	Y	U	Y	N/A	Y	N/A	Y
Bus et al, 2011 [26]	Y	Y	Y	N	N	Y	Y	N	Y	N/A	N
Busch & Chantelau, 2003 [28]	Y	Y	Y	U	U	Y	U	Y	Y	U	Y

Chantelau 1990 [29]	Y	Y	U	N	N	Y	Y	Y	N	U	N
Chapman et al, 2013 [30]	N	Y	Y	N	N	Y	Y	N	Y	N/A	N
Cumming et al, 2011 [32]	Y	Y	Y	N	N	Y	Y	N	Y	N/A	Y
Donaghue et al, 1996 [33]	U	Y	U	U	U	U	Y	N/A	Y	N/A	Y
Fernandez et al, 2013 [34]	N	Y	N	Y	Y	Y	N	Y	U	N	N
Frykberg et al, 2002 [35]	N	Y	Y	N	N	U	Y	N/A	Y	N/A	N
Guldemond et al, 2007 [36]	N	Y	Y	N	N	Y	Y	N	Y	N/A	N
Hastings et al, 2007 [37]	U	U	Y	N	N	Y	Y	N	Y	N/A	Y
Hsi et al, 2004 [40]	Y	Y	Y	Y	Y	Y	Y	N	Y	N/A	Y
Hsi et al, 2002 [39]	Y	Y	Y	Y	Y	Y	Y	N	Y	N/A	Y
Kastenbauer et al, 1998 [41]	Y	Y	N	N	N	Y	Y	N	Y	N/A	Y
Lin et al, 2013 [43]	Y	Y	Y	U	U	Y	Y	N	Y	N/A	Y
Lott et al, 2007 [45]	Y	N	Y	Y	N	Y	Y	N	Y	N/A	N
Martinez-Santos et al, 2019 [71]	Y	Y	Y	N	N/A	Y	Y	N/A	N/A	N/A	Y
Mueller et al, 2006 [47]	Y	Y	U	N	N	Y	Y	N	Y	N/A	Y
Nouman et al, 2017 [66]	Y	Y	Y	U	U	U	Y	N	Y	N/A	Y
Nouman et al, 2019 [72]	Y	Y	Y	N	N	Y	Y	N	N/A	N/A	Y
Owings et al, 2008 [48]	N	Y	Y	U	N	Y	Y	N	Y	N/A	N

Paton et al, 2014 [49]	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	N
Praet & Louwerens 2003 [52]	N	Y	Y	U	U	Y	Y	N	Y	N/A	N
Perry et al, 1995 [51]	N	Y	Y	Y	Y	U	Y	N	Y	N/A	Y
Preece et al, 2017 [67]	Y	Y	Y	U	U	Y	Y	N	Y	N/A	Y
Raspovic et al, 2000 [53]	N	Y	Y	N	N	Y	Y	N	Y	N/A	N
Reiber et al, 1997 [54]	N	Y	Y	N	N	U	U	Y	N	N	N
Sacco et al, 2010 [57]	N	Y	Y	N	N	Y	Y	N	Y	N/A	Y
Scherer 1975 [58]	Y	N	N	N	N	U	N	Y	Y	N/A	N
Soulier. 1986 [59]	U	Y	N	N	N	Y	Y	Y	Y	N	Y
Telfer et al, 2017 [68]	Y	Y	Y	N	N	Y	Y	N	Y	N/A	Y
Tsung et al, 2004 [60]	N	Y	U	N	N	Y	Y	N	Y	N/A	N
Waaijman et al, 2012 [64]	Y	Y	Y	Y	Y	Y	Y	N	Y	N/A	Y
%	62	92	76	30	24	81	89	22	86	0	59

Quality appraisal of case controlled studies

	Q1 Were the groups comparable other than the presence of disease in cases or the absence of disease in controls?	Q2 Were cases and controls matched appropriately?	Q3 Were the same criteria used for identification of cases and controls?	Q4 Was exposure measured in a standard, valid and reliable way?	Q5 Was exposure measured in the same way for cases and controls?	Q6 Were confounding factors identified?	Q7 Were strategies to deal with confounding factors stated?	Q8 Were outcomes assessed in a standard, valid and reliable way for cases and controls?	Q9 Was the exposure period of interest long enough to be meaningful?	Q10 Was appropriate statistical analysis used?
Lobmann et al, 2001 [44]	Y	Y	N	Y	Y	U	N	Y	Y	Y
Viswanathan et al, 2004 [63]	Y	Y	Y	Y	Y	N	N	Y	Y	N
%	100	100	50	100	100	0	0.0	100	100	50

Quality appraisal of case series study

	Q1 Were there clear criteria for inclusion in the case series?	Q2 Was the condition measured in a standard, reliable way for all participants included in the case series?	Q3 Were valid methods used for identification of the condition for all participants included in the case series?	Q4 Did the case series have consecutive inclusion of participants?	Q5 Did the case series have complete inclusion of participants?5	Q6 Was there clear reporting of the demographics of the participants in the study?	Q7 Was there clear reporting of clinical information of the participants?	Q8 Were the outcomes or follow up results of cases clearly reported?	Q9 Was there clear reporting of the presenting site(s)/clinic(s) demographic information?	Q10 Was statistical analysis appropriate?
Mohamed et al, 2004 [46]	Y	Y	Y	U	U	N	N	Y	Y	Y
%	100	100	100	0	0	0	0	100	100	100

Quality appraisal for analytical cross-sectional study

Citation	Q1 Were the criteria for inclusion in the sample clearly defined?	Q2 Were the study subjects and the setting described in detail?	Q3 Was the exposure measured in a valid and reliable way?	Q4 Were objective, standard criteria used for measurement of the condition?	Q5 Were confounding factors identified?	Q6 Were strategies to deal with confounding factors stated?	Q7 Were the outcomes measured in a valid and reliable way?	Q8 Was appropriate statistical analysis used?
Wrobel et al, 2014 [65]	Y	Y	Y	Y	U	U	Y	Y
%	100	100	100	100	0	0	100	100

Electronic supplementary material 3 – profile of insole

Profile of insole	Studies (n=37)	Comparator	Comments
Flat insole (non-moulded insoles) and medial longitudinal arch profile(CMI)	Birke et al, 1999[24]	Non moulded insoles of different density materials in extra depth shoe	No specifications reported for non-moulded or CMI
Three types of CMI with medial longitudinal arch profile	Tsung et al, 2004 [60]	Different casting techniques to create digital image for CMI to individualise profile	Standardised adjustment technique in manufacture process, no specification of profiles
CMI with medial longitudinal arch profile	Arts et al, 2015 Arts et al, 2012[21,22]	Used as part of custom made feature to modify footwear	Static/dynamic impressions in foam box to individualise profile; modified using pressure data with additional arch support added at times
CMI with medial longitudinal arch profile	Paton et al, 2014; Paton et al, 2012 [49,50]	Prefabricated insoles with medial longitudinal arch profile	CMI individualised with prescription protocol for foot deformity; prefabricated profile based on shoe size
CMI with medial longitudinal arch profile	Lott et al, 2007 [45]	Barefoot, shoe and CMI with metatarsal pad addition conditions	No insole prescription or manufacture reported, no specification of profile
CMI with medial longitudinal arch profile	Fernandez et al, 2013[34]	Used as one component of custom made footwear	Foam box impression with pathology dependent prescription profile - for bony prominences a poron longitudinal inner arch piece also embedded

CMI with medial longitudinal arch profile	Reiber et al, 1997; Reiber et al, 2002[54,55]	Usual footwear	Used as one component in conjunction with specialist shoe plantar foot scanned to create individual profile; fitted to patient with modifications, no other specification of profile
CMI with medial longitudinal arch profile	Rizzo et al, 2012[56]	Standard treatment	Foam box, static impression to individualise profile but no specifications
CMI with medial longitudinal arch profile	Uccioli et al, 1995[61]	Non-therapeutic shoes	Shaped by cast but no specification of profile
Insole containing medial longitudinal arch profile	Scherer 1975[58]	Used as one component of custom made footwear	Proximally located medial arch within shoe to tip the heel into a varus position, location based on generalisation of foot size
CMI with medial longitudinal arch profile	Albert & Rinoie 1994[20]	Without orthotic	Rigid device from plaster of paris casts, no specification of profile
CMI with medial longitudinal arch profile	Burns et al, 2009[25]	Flat insoles	Use of plaster casts to individualise arch for CMI; no specifications of profile
CMI with medial longitudinal arch profile	Bus et al, 2011[26]	Used as one component of custom made footwear	Moulded base to individualise profile, modifications decided by clinician; no specification of profile or location of rocker
CMI with medial	Bus et al, 2004[27]	Flat insole	Cad-cam, tracings of feet and pressure data to individualise profile; medial longitudinal arch

longitudinal arch profile			profile plus heel cups (no direct specifications) with other modifications
Total contact insole (TCI) with medial longitudinal arch	Hastings et al, 2007[37]	TCI distal metatarsal pad, TCI proximal metatarsal pad	Foam box impression to individualise profile, no other specifications of profile
CMI with medial longitudinal arch profile	Tang et al, 2014[38]	Prefabricated insoles with medial longitudinal arch	Moulds to individualise to profile, no other specifications of profile
CMI with medial longitudinal arch profile	Kastenbauer et al, 1998[41]	Barefoot, Oxford-style shoe, original cork insole	Customised orthopaedic diabetic insole, no prescription, manufacturing or specifications reported
CMI with medial longitudinal arch profile	Mohamed et al, 2004[46]	Two CMI's constructed of different materials	No specification of manufacturing process or profile reported
Total contact orthoses with medial longitudinal arch	Nouman et al, 2017[66]	Without total contact insole	Foam box to individualise profile, modified according to a static blueprint, no other specifications
CMI with medial longitudinal arch profile	Owings et al, 2008[48]	Conventionally manufactured CMI's	Foam box to individualise profile with plantar pressure data
CMI with medial longitudinal arch profile	Telfer et al, 2017[68]	Shape based arch profile	Foam box to individualise profile but manufactured using shape, pressure and ultrasound data

CMI with medial longitudinal arch profile	Viswanathan et al, 2004[63]	No CMI	Positive mould cast to individuals profile, no other specifications
CMI with medial longitudinal arch profile	Waajiman et al, 2012[64]	Used as part of custom made feature to modify footwear	Mould or cast of foot to individualise profile, no other specifications
Non-moulded insole	Busch & Chantelau, 2011[28]	Group not provided with footwear and insole	Flat profile to fit inside therapeutic shoe
Unsure	Perry et al, 1995[51]	Oxford style shoe with no insole	Reported insole inside running shoe but no description of profile
Pre-fabricated insole	Barnett 2002[23]	Flat insole	Non-bespoke standardised specification of arch dependent on shoe size
Arched insole	Chantelau et al, 1990[29]	n/a	Constructed according to shape of the foot and corrected until satisfactory, but no specifications or manufacture technique reported
CMI with medial longitudinal arch profile	Ulbrecht et al, 2014[62]	Standard care orthoses	Foam box and digital scan to individualise profile, with intervention orthoses modified by plantar pressure data
CMI with medial longitudinal arch profile	Parker et al, 2019 [73]	Flat insoles	Medial arch profile with 10mm heel cup formed by either foam box or weight bearing scan. Weight bearing insoles templates were adjusted by an orthotist, but not disclosed if arch was adjusted
Unsure	Soulier 1986[59]	n/a	Running shoe insole with generic reasonable structure shoe, no specifications of profile

Unsure	Lobmann et al, 2001[44]	No insole	No description or specification of insole profile within shoe
CMI with medial longitudinal arch profile	Guldemond et al, 2007[36]	Different insole configurations including modifications of profile by reducing arch profile by 5mm, adding 5mm and 10mm arch supports	Casted foot to individualise profile
Medial longitudinal arched profile	Lin et al, 2013[43]	Flat insole	Latex arch support, placed under talus, navicular and base of 1st metatarsal, added to insole with double sided tape; size chosen to ensure sub-talar joint neutral position
Medial longitudinal arch profile reported as customized insoles	Raspovic et al, 2000[53]	Without insole	10 insoles of Non cast type – adhering pieces of D-shaped pad on flat base of medial longitudinal arch area; two neutral shell insoles. No reporting of specifications and positioning of pad.

CMI – custom moulded insole, TCO-total contact orthotic

Electronic supplementary material 4 rocker profile

Rocker modification	Studies (n=20)	Comparator	Comments
Stiff bottom rocker with early pivot to shoe outsole	Rizzo et al, 2012[56]	Standard care (no footwear)	Generalised specifications used on participants with previous ulceration or forefoot amputation, marked deformities, hallux amputation and hollow foot with claw toes
Urethane (Meramec Group, Sullivan, MO) rocker bottom to shoe outsole – men semi rocker forefoot made rigid with composite shank, women's shoes semi-rockered with non extended steel shank	Reiber et al, 1997; Reiber et al, 2002[54,55]	Usual footwear	No specifications of rocker profile reported; specified treatment objective to generate a smooth rolling motion from heel to toe with normal gait to decrease range of motion in tarso-metatarsal joints and reduce gait induced plantar stress-
Semi rigid rocker to shoe outsole	Uccioli et al, 1995	Non therapeutic shoes	Developed according to Towey guidelines; No further specifications reported
Semi rigid rocker to shoe outsole	Wrobel et al, 2014 [61,65]	Used in conjunction with different types of insoles	No further specifications reported
Anteroposterior rigid rocker to shoe outsole	Lopez-Moral et al, 2019 [70]	Semi-rigid rocker sole(Wellwalk	20 ° rocker angle between floor and sole under metatarsal heads with rigid (composite fibre) rocker

		technology with Vibram strips)	
Stiff convex walking sole to diabetic shoe	Busch & Chantelau, 2011[28]	Group not provided with footwear and insole	No specifications reported but aims to decrease plantar pressure beneath metatarsal heads and prolong pain free walking
EVA micro rubber sole on therapeutic footwear	Paton et al, 2014; Paton et al, 2012 [49,50]	Used in both intervention and control groups	Rocker added to forefoot positioned posterior to the metatarsal phalangeal joint line
Rigid rocker constructed of 1/16 x 1-inch spring steel shank embedded under the outsole of shoe	Owings et al, 2008[48]	Flexible shoe	Rocker angle 20°, located at 65% of the sole length as measured from the heel
Rocker to outer sole of shoe	Chapman et al, 2013[30]	12 different rocker designs	12 variations in apex angle (relative to metatarsal break), apex position (normalised to shoe length), rocker angle
EVA and 5mm folex rocker addition to the outsole of a standard shoe (Duna, Italy)	Preece et al, 2017[67]	Eight different rocker designs	Eight variations in rocker angle (15° or 20°) and apex position (52, 57, 62 and 67% from the rearfoot)
Either 1cm forefoot rocker (excessive pressure under 1st and- 5th	Fernandez et al, 2013[34]	Used as one component of custom made footwear	Rocker feature prescribed when increased vertical pressure in push-off stage of walking gait (hallux rigidus, functional limitus, 1st ray amputation or

MTPJ) or 1cm 'u' shaped rocker (excessive pressure under central metatarsals) to external sole of shoe			digit amputation) assessed by barefoot plantar pressure platform analysis.
Diabetic footwear with rocker outer soles	Hsi et al, 2004 [40]	Patients own shoes	Rocker sole addition comprised of 11mm height, 29mm thickness at the heel, 16mm at the front end and 24mm at the maximum of the rocker curve. The rocker started to curve up 83mm from the front end at the medial side and 87mm at the lateral side
Anterior wedge rocker added to insole	Frykberg et al, [35]	Surgical boot without insole, patients' own Oxford or tennis style shoes	Rocker modification of dense closed cell foam applied to the insole proximal to the metatarsal heads contained within a surgical boot
Rubber made walking sole shaped to rocker	Chantelau et al, 1990[29]	n/a	No specifications of rocker
Stiffened rubber outsole and roller configuration to shoe	Bus et al, 2011[26]	Used as one component of custom made footwear	Pressure informed modification of adding earlier or more significant rocker or roller either in shoe or outside shoe
Semi-rigid outer sole or stiff rocker bottom	Tang et al, 2014[38]	Used in both intervention	No specifications reported

		and control group	
Longitudinal outsole curvature	Praet et al, 2003 [52]	Variations in shoe and insole modalities	Variations of rocking axis position (60%, 61.5%, 63%, 65%, 67.5%) and rocking angle (5°, 8°, 10°, 23°)
Stiffened rubber outsole and roller configuration to shoe	Waajiman et al, 2012[64]	Used as one component of custom made footwear	Generalised construction with no specifications reported

Legend: MTPJ – Metatarsal phalangeal joint, EVA-Ethylene-vinyl acetate, n/a not applicable

Electronic supplementary material 5 - modifications to footwear

Extra depth modification	Studies (n=35)	Comparator	Comments
Off the shelf footwear			
Diabetic footwear (County Orthopaedic Footwear Ltd, UK)	Paton et al, 2014; Paton et al, 2012 [49,50]	Used in both intervention and control groups	Standardised footwear with more depth and width
Extra depth or DX2 footwear (p.w. Minor, Batavia, NY).	Ulbrecht et al, 2014[62]	Used in both intervention and control groups	Standardised footwear but could be adjusted at fitting to include stretching
Extra depth footwear (Dr Comfort, DJO, UK)	Wrobel et al, 2014 [65]	Used in both intervention and control groups	Standardised off-the-shelf-footwear
Extra depth footwear Sir Super Depth (p.w. Minor, Batavia, NY) 55 Durometer, 18 iron.	Albert & Rinoie 1994[20]	Used in both intervention and control groups	Not disclosed if patient specific
Extra depth	Rizzo et al., 2012[56]	Standard care	Semi-orthopaedic footwear on market with extra depth to fit Custom made insoles. Not clear if patient specific.
Extra width, depth and height (DVA/Seattle Footwear, US).	Reiber et al., 1997; Reiber et al., 2002[54,55]	Used in both intervention and control groups	Prototype footwear Extra width and height to toe box, increased depth to length of shoe. Not clear if patient specific.
Extra depth, width and height(Podartis s.r.l. Unipersonale – Crocceta del Montello, Italy)	Lopez-Moral et al, 2019 [70]	Used in both intervention and control groups	Therapeutic shoes with high toe box, enough width to accommodate toe deformities, depth 14 or 16mm deeper than standard footwear.
Extra depth (Thermomold, NY)	Birke et al, 1999[24]	Used in all interventions	Standardised off-shelf-shoe; not patient specific

Extra depth(Sole Tech, Advanced Orthopedic Footwear, style number E3010)	Hastings et al, 2007[37]	With and without insoles	Advanced orthopaedic footwear prescribed according to shoe size
Extra depth (Finn Comfort, Germany).	Kastenbauer et al, 1998[41]	Oxford style shoes	Standardised shoe. Unsure if patient specific
Standard diabetic shoes (Dr. Foot Technology Co, Taiwan)	Lin et al, 2013[43]	Used in all interventions	Xtra depth leather shoes
Extra depth	Telfer et al, 2017[68]	Used in all interventions	Only prescribed for use in trial runs
Suitable depth	Raspovic et al, 2000[53]	Used in all interventions	Footwear modified to be of 'suitable' depth, but no specifications reported.
Extra deep diabetic shoes (Dr Kong Footcare Ltd. Taiwan)	Tsung et al, 2004[60]	Used by all participants	Shoe selected to size, according to Tovey's principles. The first metatarsophalangeal joint should be accommodated in the widest part of the shoe and the length should allow 1-1.25cm between the end of the shoe and the longest toe
Bespoke footwear			
Ready-made diabetic footwear (Orthoaktiv, F.W. Kraemer, Remscheid, Germany)	Hsi et al, 2002[39]	Patients' own shoes	Standardised diabetic footwear
Extra depth or fully customised footwear	Arts et al, 2015 Arts et al, 2012[21,22]	Used by all participants	Either 'Extra-depth' off-the-shelf footwear or custom footwear made from last derived plaster cast of foot

Extra depth footwear	Fernandez et al, 2013[34]	Used by all participants	Prescribed footwear according to length and width of foot, using Dahmen's algorithm.
Extra depth shoes	Uccioli et al, 1995[61]	Ordinary shoes	Footwear designed according to Towey guidelines with super depth to fit insoles and toe deformities. Not clear if patient specific.
Extra width and depth	Scherer 1975[58]	Used by all participants	Manufactured according to shoe-size, foot width and length. Bespoke to patient.
Extra depth protective shoes(Thanner, Germany) with deep soft uppers and no toe-caps with a firm heel counter	Lobmann et al, 2001[44]	Used by all participants	Protective shoe manufactured according to Tovey's model. Unsure if patient specific
Customised footwear or extra depth	Bus et al, 2011[26]	Used by all participants	Participants received either 'Extra-depth' off-the-shelf footwear or custom footwear made from last derived plaster cast of foot
Customised diabetic footwear	Praet & Louwerens 2003[52]	Standardised footwear: rubber soled Oxford style shoe (model 7143-A, Vab der Hammen B.V. Waalwijk, the Netherlands), Xtra depth Oxford shoe (model 3116, Bimakon Hederland BV, Drunen, NL), Xtra-depth Diabetic shoe (Nimco Orthropedics,	Shoes fabricated by orthotist

		Berg en Dal, the Netherlands), Xtra-stretched shoe Nimco Orthropedics, Berg en Dal, the Netherlands)	
Retail footwear			
Running shoes (New Balance trainers 460, US) with accommodative padding added into insole, width sizing and smooth outsole pattern to reduce tripping indoors	Soulier 1986[59]	Used by all participants	Retail-footwear not patient specific
Extra width and depth running shoes (SAS, San Antonio, TX, US or New Balance, Boston, MA, US),	Donaghue et al, 1996[33]	Used by all participants	Retail footwear not patient specific

Electronic supplementary material 6 - metatarsal modifications

Metatarsal modification	Studies (n=18)	comparator	Comments
Metatarsal pad or metatarsal bar	Bus et al, 2011 Bus et al, 2004 [26,27]	n/a	Option of use being incorporated into Total Contact Insole chosen by orthopaedic shoe-maker to reduce Peak Pressure in Regions Of Interest based on PP data, tracings and static footprints in conjunction with other modifications
Metatarsal pad or metatarsal bar	Arts et al, 2015 Arts et al, 2012 [21,22]	n/a	No clear description of position, size, material, shape of pad or bar. Chosen as modifications by shoe technicians and repositioned to reduce PP in ROI >200kPa. Used in conjunction with arch support on occasion
Metatarsal pad and metatarsal bars	Ulbrecht et al, 2014[62]	n/a	No clear description of position, size, material, shape of pad or bar. Option of being incorporated into insole prescription for sub-metatarsal offloading Decision to use based on opinion of orthotist
Metatarsal pad	Hastings et al, 2007; Lott et al, 2007; Mueller et al, 2006 [37,45,47]	Three sizes of metatarsal pad made of cork, shore value 55°, selected to cover three central metatarsal heads,	Metatarsal pad applied to Total contact insole with adhesive backing. Orthotist/pedorthotist drew line to determine metatarsal head location for placement 1cm proximal.
Pre-metatarsal bar	Rizzo et al, 2012[56]	n/a	No clear description of position, size, material or shape of bar. Used in conjunction with a medial arch support. Used based on an individualised strategy based on consensus of three clinicians to lower high forefoot pressures.

Metatarsal pads 2nd to 4th MTPJ	Mohamed et al, 2004 [46]	n/a	No clear description of size, material or shape of bar. Added to six of 16 insoles after one month of use due to excessive wear or bottoming out in opinion of orthotist.
Metatarsal bar	Tang et al, 2014[38]	n/a	No clear description of material or shape of bar. Standardised bar, fitted proximal to the 2nd to 4th metatarsal heads within the CMI and prefabricated insoles. Adjustments including raising or lowering bar height, but no specifications or rationale given.
Metatarsal bar	Owings et al, 2008[48]	n/a	No clear description of size, material or shape of bar. Created within Total Contact Insole from automated design algorithm which identified pressure contour of MTPJ's.
Metatarsal dome	Guldemond et al, 2007[36]	n/a	11mm high foam rubber (Shore A 28) dome, positioned 5mm behind the 2nd to 4th metatarsal heads on the insole. Positioned from dynamic pressure sheet footprint.
Metatarsal or central head mounds	Fernandez et al, 2013[34]	n/a	No clear description of size, material or shape of bar. Used when elevated pressure over static bony prominence when joints were mobile in forefoot zone.
Metatarsal bars or pads	Telfer et al, 2017[68]	n/a	No clear description of position, size, material or shape of bar or pads. Manufacturer could use this if felt appropriate as per standard practice for CMI; met bar increased in height to reduce peak pressure in cad cam design
Metatarsal pad or bar	Parker et al, 2019 [73]	n/a	Used on two of the insoles at discretion of orthotist based on static pressure footprints. No clear description of position, size, material or shape of bar or pads
Metatarsal bar	Martinez-Santos et al, 2019 [71]	n/a	Distal location and shape defined where plantar pressure was 77% of the peak pressure. Used in combination with different void conditions

Metatarsal aperture	Barnett 2002[23]	n/a	Located at widest part of forefoot with material removed from insole and replaced by softer material into insole at metatarsal

PP=peak pressure; ROI=regions of interest; MTPJ=metatarsal phalangeal joint; n/a not applicable

Electronic supplementary material 7 - cut outs or aperture modifications

Feature	Studies (n=12)	Comparator	Comments
Removal of material	Arts et al, 2015 Arts et al, 2012 [21,22]	n/a	Removal of material at high pressure areas identified by pressure data, tracings and static blueprint
Removal of material	Bus et al, 2011[26]	n/a	Removal of material to reduce peak pressure at regions of interest identified by in-shoe system
Removal of material	Bus et al, 2004[27]	n/a	Removal of material at areas of high pressure identified by pressure data, tracings and static footprint
Removal of material	Waajiman et al, 2012[64]	n/a	33% of insoles modified by removal of material at ROI identified by PP in-shoe system
Cut out	Lopez-Moral et al, 2019 [70]	n/a	Cut out positioned at the previously ulcerated metatarsal head
Fenestrations	Fernandez et al, 2013[34]	n/a	6mm poron plug embedded in fenestrations for areas of high pressure and bony prominence and joints which showed insufficient mobility for selective offloading
Removable square plugs	Lin et al, 2013[43]	Pre-plug removal	Plugs 1cm x 1cm removed in forefoot area for ROI (highest mean peak pressure)

Aperture	Owings et al, 2008 [48]	n/a	3mm deep aperture for regions of excessive pressure >1000kPa
Aperture or u shaped rubber	Raspovic et al, 2000[53]	n/a	Sited under previous ulcerated site
Removal of material under metatarsal head	Telfer et al, 2017[68]	n/a	Used to reduce regional MPP to under 200kPa informed by finite element modelling
Local removal of material or softening of material	Parker et al, 2019 [73]	n/a	Utilised on seven of the insoles at discretion of orthotist, informed by static pressure footprints.
3mm void conditions	Martinez-Santos et al, 2019 [71]	Different void conditions created with altering material (no material, poron (20 Shore A), EVA (20 Shore A) alongside different metatarsal bar combinations	Distal border of void placed distal to area of peak pressure and used in conjunction with metatarsal bar;

n/a not applicable, ROI Region of Interest

Electronic supplementary material 8 - Casting technique

Casting technique	Studies n=23	Comparator	Comments
Plaster of Paris	Albert & Rinoie 1994[20]	n/a	No technique disclosed
Plaster of Paris	Burns et al, 2009[25]	n/a	Neutral suspension technique
Plaster of Paris	Tang et al, 2014[38]	n/a	Positive mould based on negative cast; patient prone positioned
Plaster of Paris or foam box	Arts et al, 2015 Arts et al, 2012[21,22]	n/a	Positive cast with additional modifications informed by shoe technician
Plaster of Paris	Viswanathan et al, 2004[63]	n/a	Positive mould, no other specifications
Plaster of Paris	Coagiuri et al, 1995[31]	n/a	STJ neutral, mid-tarsal maximally pronated.
Plaster of Paris or foam box	Waajiman et al, 2012[64]	n/a	No technique disclosed
Foam box	Rizzo et al, 2012[56]	n/a	Feet in neutral, knees 90°. Used with information from static footprint
Foam box	Nouman et al, 2017[66]	n/a	Sub talar joint in neutral, knees 90°. Modifications informed by information from static footprint
Foam box	Paton et al, 2014; Paton et al, 2012 [49,50]	n/a	Cad-Cam technique to mill Custom Made Insole

Foam box	Hastings et al, 2007[37]	n/a	Design and modifications based on clinical decision by orthotists
Foam box	Owings et al, 2008[48]	n/a	No technique disclosed
Foam box	Lott et al, 2007[45,47]	n/a	No technique disclosed
Foam box	Nouman et al, 2019 [72]	n/a	Cast obtained by a qualified orthotist; no other specifications disclosed
Foam box	Tsung et al, 2004[60]	Fully weight-bearing (standing on casting foot only) compared with semi-weight-bearing (standing only) with non-weight-bearing (sitting, ankle neutral, knee 90°)	
Cad-cam	Bus et al, 2011 Bus et al, 2004[26,27]	n/a	Based on plantar pressure data, tracings and footprint
Laser digitizer	Reiber et al, 1997; Reiber et al, 2002[54,55]	Standard preformed polyurethane insole	Weight-bearing, static image of contours of foot uploaded into software which creates 3D image of foot
Digital AMFIT (AMFIT Incorporated, Vancouver, WA, USA) system	Wrobel et al, 2014 [65]	Standard insoles	Image of foot digitized and used to manufacture insoles and Dynamic Foot Orthoses
'Cast'	Uccioli et al, 1995[61]	n/a	No technique disclosed
Foam box, cad cam, finite element	Telfer et al, 2017[68]	Shape date and milling produced insole	Individualised for each patient with different

			techniques compared to inform manufacturing processes
Foam box and weightbearing digital foot scan	Parker et al, 2019 [73]	Flat 3mm poron insole	Foam box devices manufactured with plaster impression, heat moulded to cast and hand finished by blinded technicians. Digital scan from barefoot standing and modified by orthotist based on static pressure data.

n/a not applicable

Electronic supplementary material 9 - fabrication informed by kinetic parameters

	Studies (n=11)	Comparator	Comments
Pedar-X (Novel, GmbH, Munich, Germany) in-shoe system	Bus et al, 2011; Waajiman et al, 2012; Waajiman et al, 2012 [21,26,64]	Used for all participants	Identify regions of interest>200kPa in the midfoot or forefoot; modified insoles using a set algorithm with up to three rounds of modifications to achieve regions of interest optimisation (25% below MPP or <200kPa).
Pressure platform (Novel EMED-SF, USA) for barefoot pressures	Bus et al, 2004[27]	Standard insole	Used barefoot plantar pressure data to inform custom made insole
Pedar X (Novel, GmbH, Munich, Germany) in-shoe system	Lin et al, 2013[43]	Used for all participants	Plugs were removed from the insole at the Region of interest=highest MPP

RScan (RScan International Lammerdries, Belgium) platform for barefoot	Fernandez et al, 2013[34]	Used for all participants	Used barefoot plantar pressure data and radiophotopodogram findings to inform for selective offloading using insoles
Static footprint taken with the patient standing barefoot	Rizzo et al, 2012[56]	Standard treatment	Used in conjunction with foam box impression of feet to identify problem areas requiring attention by three professionals in discussion.
Pedar (Novel, GmbH, Munich, Germany) in-shoe system for in-shoe plantar pressures	Reiber et al, 1997[54]	Standard insole	Data is used to create a 3D image template, from which the custom insole is milled from cork blanks, with modifications identified by physical landmarks, foot exam and foot pathology
EMED (Novel, GmbH, Munich, Germany) platform for barefoot dynamic testing	Owings et al, 2008 [48]	Insoles not designed by pressure data	Data used in conjunction with foam box cast and computer display to create insole with metatarsal bar and 3mm deep area aperture in areas >1000kPa;
Dynamic pressure sheet footprint to determine the locations of the metatarsals to position the metatarsal domes.	Guldemond et al, 2007 [36]	n/a	Used in conjunction with foam box casting
Static pressure collected with platform (Emed platform, Novel, GmbH, Munich, Germany)	Martinez-Santos et al, 2019 [71]	Used for all participants	Used in conjunction with 3D foot shape captured by scanner (Inescop, Spain)

n/a not applicable

Electronic supplementary material 10 – materials of insole and footwear

Materials	Studies (n=37)	Comparator	Comments
TL-2100 graphite with Naugahyde top cover (P.W. Minor and Sons, Batavia, NY)	Albert & Rinoie 1994[20]	n/a	Dual density and rigid device aimed at placing abnormal foot in an optimal functioning position; used only in pronated foot posture participants
10mm thick rubber-foam (Zellkautschuk, Berkemann, Hamburg, Federal Republic Germany) and other plastics (PPT and Platazote; Schein, Remscheid, Federal Republic Germany) insole; soft leather shoe	Chantelau et al, 1990[29]	n/a	Dual density insole designated 'cushioned'; thickness thought to attenuate greater force reduction
Shoes made from soft leather upper, outersole of microcellular rubber, with 5mm folex for rocker (Duna, Falconara Marittima, Italy)	Chapman et al, 2013[30]	n/a	Materials selected to prevent flexion of shoe
Rohadur thermal plastic (Ozthotics, Randwick, NSW, Australia	Colagiuri et al, 1995[31]	n/a	Material choice for 'control' of foot function to reduce plantar foot pressures
Thor Lo hosiery (Thor-Lo, Statesville, NC)	Donaghue et al, 1996 [33]	n/a	Unknown materials of shoes or hosiery
For static pressures: heat moulded laminar EVA insole (25°-60° Shore) base with a 3mm PPT layer	Fernandez et al, 2013[34]	n/a	Different density materials used dependent on whether pressure

heat moulded laminar EVA (25°-60° Shore) For pressure and boney prominence: EVA insole (25° -33° Shore) with maximum thickness of 1.5-2cms with high density EVA (60° Shore) bottom layer. 6mm Poron used to offload specific areas			static or pressure coincided with bony prominence. Shock absorbing material used in areas of bone protrusion or previous ulcer and wound sites.
Multi-layer orthosis EVA orthosis (40°Shore) with poron top cover; shoe material made of soft skin	Lopez-Moral et al, 2019 [70]	n/a	No rationale for material choice
Alipast and plastazote (Voltek, Brebbia, VA) insoles	Mohamed et al, 2004[46]	Plastazote (Zotefoams Inc., Walton, KY)	Combination used to theoretically increase longevity of insoles
Insole 1:thin polypropylene shell with Korex, sponge or plasatazote top cover; Insole 2: 45 Shore S EVA base with Procell or plastazote top cover; Insole 3: 35 Shore A Microcel Puff EVA base and a Poron or P-Cell top cover	Owings et al, 2008[48]	n/a	Dual density insoles with materials selected as commonly used in offloading.
3mm medium density EVA base with 6mm Poron top cover	Paton et al, 2014; Paton et al, 2012 [49,50]	n/a	Dual density for both the prefabricated and customised insole aimed at reducing plantar pressure; durability also measured after 12 months

Medium density rubber cork inserts, 1.5mm layer foam backed nylon tricot top layer Shoes made of high quality cowhide leather with urethane (Meramec Group, Sullivan, MO) outersole	Reiber et al, 1997; Reiber et al, 2002[54,55]	Standard study insole: closed cell polyurethane foam	Dual density insole; cork used for little set or deformation and top cover aims for 'cushioning interface between foot and insole
Shoes made of Bottine, soft thermformable leather; insoles made of PPT (Deer Park NY), Duoterm (Mibor, Alcoy, Spain) and Alcaform (Zotefoams Plc, Croydon, UK)	Rizzo et al, 2012[56]	n/a	PPT to relieve local pressure, Duoterm and Alcaform to absorb high pressure points
Natural leather skin upper, synthetic rubber sole	Scherer 1975[58]	n/a	No rationale provided
Shoes made of soft thermformable leather; Insoles made of Alcapy (Deer Park, NY) and Alcaform	Uccioli et al, 1995[61]	n/a	Alcapy to relieve local high pressures and Alcaform to absorb high pressure points
8mm Polylux, 8mm Combilux, 2.3mm Memorix, 3mm Remember and 0.7mm Calbino topcover (Thanner, GmgH, Hochstadt, Germany)	Burns et al, 2009[25]	Flat 4mm EVA and 0.7mm Calbino topcover (Thanner, GmgH, Hochstadt, Germany)	Mesh of materials combined; no rationale provided
Diabetiker SY2 modular viscoelastic insole of 2.5mm polyvinyl chloride (Kraemer, Remscheid, Germany)	Hsi & Lai, 2002; Hsi et al, 2004[39,40]	n/a	to act as shock absorbers with24 sensors embedded in insole
Shoe made from EVA and rubber (Softgummi) sole, cloth, rubber foam and leather uppers Insole made of:	Busch & Chantelau, 2011[28]	n/a	Soft density upper to avoid toe pressure strain,

Rear part containing 6mm lunasoft, 42° Shore A hardness; anterior part 6mm Lunaflex, 20° Shore A hardness; covered with 3mm thick PPT, 17° Shore A hardness)			firmer density rocker sole to decrease plantar pressures beneath metatarsal heads and prolong pain free walking; Tri-density, non-moulded insole aimed at cushioning forefoot area.
5mm Lunalastick and 8mm Lunasoft SL (NORA, Freudenberg, GmbH, Weinheim, Germany) top and bottom and 1.1mm Rhenoflex 3208 (Rhenoflex, GmbH, Ludwigshafen, Germany)	Guldemond et al, 2007[36]	n/a	Higher stiffness materials above Shore A 60° used to minimize the influence of cushioning on plantar loading
3mm Shore A 35° EVA in the first layer, 2mm Velcro and velvet in the second layer and 6mm Shore A 50° Poron in the third layer	Lin et al, 2013[43]	n/a	No rationale for material choice
14mm multi-combination insole EVA, polyethylene foam, elastomere, silicone	Lobmann et al, 2001[44]	n/a	Silicone with special arrangement to achieve the required degree of hardness
Custom made insole open cell urethane foam hardness 60-80 (Langer, Inc, Deer Park, NY, USA) with the addition of 2mm base and 0.7mm top cover	Bus et al, 2004[27]	Flat insole 0.95cm thick PPT(Langer, Inc, Deer Park, NY, USA)	Dual density materials frequently prescribed in

			diabetic foot practice
Multifoam as the top layer, Plastazote (Streifeneder ortho production GmbH, Emmering, Germany) as the second layer and microcellular rubber as the final stabilising layer	Nouman et al, 2017[66]	n/a	No rationale for materials given
5mm thick multifoam (30° Shore A hardness), 8mm thick Plastazote (25° Shore A Hardness) and 10mm thick microcellular rubber (70° Shore A hardness)	Nouman et al, 2019 [72]	Dual density insole of 8mm thick Plastazote (25° Shore A Hardness) and 10mm thick microcellular rubber (70° Shore A hardness)	Hypothesised that different combinations of materials would influence peak pressure and contact area
Rohadur (Ozthotics, Randwick, NSW, Australia) device with dual acrylic posts added to rearfoot to balance foot	Coagiuri et al, 1995[31]	n/a	Rigid orthotic to provide functional control providing foot contact shock absorption phase during normal pronation, midtarsal stability and propulsive thrust
Insole made of closed-cell polyurethane foam and soft insole cover	Frykberg et al, 2013[35]	n/a	No rationale provided
Dynamprene (neoprene based, Dupont) built into shoe sole of trainer;	Kastenbauer et al, 1998[41]	Barefoot, cork insole multilayer insole and in-depth custom insole made up of	Aimed at shock-absorbing but not specific to patient

		10 different layers (Schein Orthopadie Service, Reinscheid, Germany)	
1.27cm #2 plastizote (Shore 35°), 5.0mm thick cross-linked polyethelene foam blended with EVA insole and Cork (Shore 55°) met-pad	Hastings et al, 2007; Lott et al, 2007; Mueller et al, 2006 [37,45,47]	n/a	No rationale provided
¼" thick Poron 14°Shore Hardness	Birke et al, 1999[24]	Seven (17°,22°, 27°, 32°, 40°, 50° Shore hardness) densities of Poron tested in reducing mean peak pressure	Material selected as most popular non moulded orthosis material to reduce pressure
Insole made of Poron 96 (Rogers Corporation, Woodstock, CT)	Cumming & Bayliff 2011[32]	Insole made of Poron 4400 (Rogers Corporation, Woodstock, CT	One left and one right insole of each material issued to participants; mean total pressure measured after one week duration
35 durometer EVA base and added two non-stick sheets, held with elastic binders, between the upper pad and lower pad of 3mm thick 45 durometer EVA. To this a 3mm thick 20 durometer polyethylene foam top was added	Lavery et al, 2012[42]	Standard insole made of 35 durometer EVA base, lower pad of 3mm thick 45 durometer EVA. To this a 3mm thick 20 durometer	Intervention insole aimed at shear and pressure reduction characteristics

		polyethylene foam top was added	
4mm cushioned properties	Perry et al, 1995[51]	n/a	Insole within Nike Air Craft running shoe; no description of materials
Padded insoles	Soulier 1986 [59]	n/a	Insole within New Balance 460 running shoe; no description of materials
Insole made of polyurethane, EVA, or 10mm microcellular rubber insole and 8mm rubber sole, 5mm polyurethane foam insole, 5mm MCR midsole and 10mm EVA outer sole or10mm EVA as outer sole, 6mm cork as midsole and 6mm polyurethane	Viswanathan et al, 2004[63]	Insole of hard leather board,	Materials selected due to being lightweight, shock absorbent, flexible and highly durable
Insoles made of Rubbatex neoprene rubber top cover with 4-way stretch darlex (Richardson Products Incorporated, Frankfort, IL, USA), silicone layer that was based on firm density EVA base lined with ballistic nylon	Wrobel et al, 2014 [65]	Standard Insoles made of firm density plastazote and PPT bi-lam (American Plastics Arlington, TX, USA)	Intervention materials selected to decrease compressive forces and reduce sliding friction
Custom made insole of Nora Lunasoft A50° hardness (Freudenberg, Germany) and 3mm Poron top cover 3mm thickness	Tsung et al, 2004[60]	Flat insole made of Nora Lunasoft A50° hardness (Freudenberg, Germany) and 3mm Poron top	No rationale for material choice provided

		cover 3mm thickness	
Shoes mainly of leather with rubber outsole; insole of Mouldable cork or multifoam base, open or closed cell material top cover	Bus et al, 2011; Waajiman et al, 2012[26,64]	n/a	Materials selected as they are commonly used in practice
EVA (A35°) with laminated fabric PPT top cover	Ulbrecht et al, 2014[62]	n/a	No rationale provided
Shoes made of stiffened rubber and/or polyethylene reinforced outer sole with insole of Rhenoflex thermoplastic (Ludwigshafen-am-Rhein, Germany) with multifoam or cork base finished with plastazote (Zotefoams plc, Croydon, UK), leather or PPT (Langer Inc, Deer pArk, Ny, USA) top cover	Arts et al, 2015 Arts et al, 2012[21,22]	n/a	Materials selected using own companies design and manufacturing standards
Insoles made of EVA Shore hardness 35° or 55°)	Tang et al, 2014[38]	Prefabricated insole of mixture of thermoplastic, polyurethane, polyester and polycarbonate	Materials selected to assess ability to reduce kinetic variables
Rubber pad on unknown base for most of insoles; one insole of polyproprolene shell and one insole EVA shell	Raspovic et al, 2000[53]	n/a	No rationale provided
EVA insole with 3mm PPT cover; rubber sole leather Oxford shoe;	Praet & Louwerens 2003[52]	PU-soled Xsensible Xflex shoe; Polyurethane soled shoe; soft leather shoe with insole made of 10mm EVA with	Different shoe and insole material combinations; commonly used materials

		3mm PPT top cover & 3mm rocker; soft leather shoe with insole made of 10mm EVA with 3mm PPT top cover & 3mm rocker	
6mm Medium density EVA rearfoot (30-40 Shore A), 6mm poron (20 Shore A) at forefoot with topcover of leather	Parker et al, 2019 [73]	3mm flat Poron insole	No rationale provided
Insole made of medium density EVA (50° Shore A) with variety of modifications using void conditions (EVA 20° Shore A, Poron 20° Shore A) and	Martinez-Santos et al, 2019 [71]	Flat insole made of 3mm EVA 50° Shore A	No rationale provided
Prefabricated insole (10mm EVA base Shore A35, upper layer 6mm EVA Shore A 25) EVA and 1mm EVA shore A 25 top cover	Barnett 2002[23]	Cleron (control insole)	Modifications of heel and metatarsal with non-cellular polyurethane elastomer incorporated into shell of insole

Legend: EVA-Ethyl-Vinyl Acetate, PPT – Professional Protective Technology, n/a not applicable