EFFECTIVENESS OF PRESSURE-RELIEVING SHOES/INSOLES ON LOWERING THE PLANTAR PRESSURE OF DIABETIC FOOT: A META-ANALYSIS

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ABSTRACT. Since current reports demonstrated a higher prevalence of foot ulcers in diabetic patients who suffer from foot complication, the preventing occurrence of foot ulcers were the primary target in foot care. Clinical consensus introduced a variety of pressure-relieving products to diabetic patients and clinicians prescribed these products to their patients and recommended them used in daily life. However, available data were still controversial and whether these products could effectively reduce plantar pressure or not were uncertain. Thereby, this meta-analysis aimed first to summary all relevant findings in current database and secondly to explore whether pressure-relieving insoles/shoes can really relieve plantar pressure and what's differences between customized products (shoes/insoles) and standard ones in reducing plantar pressure. We first searched published articles cited from Web of Science, Medline via OVID, CINAHL, SCOPUS, INFORMIT, Cochrane Central and EMBASE via OVID. Then we filtered observational studies reporting experimental effect of pressure-relieving insoles/shoes. Meanwhile, we set up primary outcome as overall mean peak plantar pressure (MPP) and secondary outcomes as MPP at various plantar regions and MPP at insoles/shoes with various structure designs. Our results show that pressure-relieving products (shoes/insoles) did lower the amplitude of pressure concentration; effect of custom-made and pre-fabricated products on pressure-relieving were similar. These findings suggested that no matter pressure-relieving products were custom-made or prefabricated standard one, if they were designed targeting to increase overall plantar contact areas, such as designed based on plantar model, or to provide extra arch supports or plug-in structures to transfer pressure concentration, they were all useful in diabetic foot care to prevent occurrence of ulceration. Overall, it is recommended that diabetic patients shall wear pressure-relieving insoles/shoes while walking.

KEY WORDS: diabetes mellitus, footwear, foot ulcer, plantar pressure

EFICACITATEA ÎNCĂLȚĂMINTEI / BRANȚURILOR ÎN REDUCEREA PRESIUNII PLANTARE ÎN CAZUL DIABETICILOR: O META-ANALIZĂ

REZUMAT. Întrucât rapoartele actuale au demonstrat o prevalență mai mare a ulcerelor piciorului la pacienții diabetici care suferă de complicații ale piciorului, prevenirea apariției ulcerațiilor a fost ținta principală în îngrijirea piciorului. În urma consensului clinic s-a introdus o varietate de produse pentru ameliorarea presiunii la pacienții cu diabet zaharat, iar clinicienii au prescris aceste produse pacienților și le-au recomandat utilizarea acestora în viața de zi cu zi. Cu toate acestea, datele disponibile încă sunt controversate și este incert dacă aceste produse ar putea reduce efectiv presiunea plantară sau nu. Prin urmare, această meta-analiză a avut ca scop mai întâi să treacă în revistă toate constatările relevante din baza de date actuală și, în al doilea rând, să determine dacă branțurile / încălțămintea cu funcție de reducere a presiunii pot ameliora cu adevărat presiunea plantară și care sunt diferențele dintre produsele personalizate (încălțăminte / branțuri) și cele standard în ceea ce privește reducerea presiunii plantare. S-au căutat mai întâi articole indexate în Web of Science, Medline via OVID, CINAHL, SCOPUS, INFORMIT, Cochrane Central și EMBASE via OVID. Apoi s-au filtrat studiile observaționale care raportează efectul experimental al branțurilor / încălțămintei cu funcție de reducere a presiunii. Între timp, s-a stabilit ca rezultat primar media generală a maximelor de presiune plantară (MPP) și ca rezultate secundare, MPP în diferite regiuni plantare și MPP la branțuri / încălțăminte cu diferite modele structurale. Rezultatele arată că produsele de reducere a presiunii (încălțăminte / branțuri) au scăzut amplitudinea concentrației de presiune, iar efectul produselor personalizate și prefabricate în ceea ce privește ameliorarea presiunii a fost similar. Aceste constatări au sugerat că, indiferent dacă produsele de reducere a presiunii au fost fabricate la comandă sau prefabricate standard, dacă au fost concepute pentru a crește suprafața de contact în zona plantară, cum ar fi cele proiectate pe baza modelului plantar, sau pentru a oferi suport plantar suplimentar sau structuri „plug-in" pentru a transfera concentrația de presiune, toate produsele au fost utile în îngrijirea piciorului diabetic pentru a preveni apariția ulcerațiilor. În general, se recomandă ca pacienții cu diabet zaharat să poarte branțuri / încălțăminte pentru ameliorarea presiunii în timpul mersului.

CUVINTE CHEIE: diabet, încălțăminte, ulcerul piciorului, presiunea plantară

EFFICACITÉ DES CHAUSSURES / SEMELLES DE DÉCHARGE SUR LA RÉDUCTION DE LA PRESSION PLANTAIRE DU PIED DIABÉTIQUE : UNE MÉTA-ANALYSE

RÉSUMÉ. Étant donné que les rapports actuels ont démontré une prévalence plus élevée des ulcères du pied chez les patients diabétiques qui souffrent de complications du pied, la prévention des ulcères du pied était la principale cible des soins des pieds. Le consensus clinique a introduit une variété de produits anti-pression pour les patients diabétiques et les cliniciens ont prescrit ces produits à leurs patients et les ont recommandés dans la vie quotidienne. Cependant, les données disponibles étaient encore controversées et la question de savoir si ces produits pouvaient effectivement réduire la pression plantaire ou non était incertaine. Ainsi, cette méta-analyse visait d'abord à résumer tous les résultats pertinents de la base de données actuelle et, d'autre part, à explorer si les semelles / chaussures de décharge peuvent vraiment soulager la pression plantaire et quelles sont les différences entre les produits personnalisés (chaussures / semelles) et les produits standard pour réduire la pression plantaire. On a d'abord recherché des articles cités à partir de Web of Science, Medline via OVID, CINAHL, SCOPUS, INFORMIT, Cochrane Central et EMBASE via OVID. Ensuite, on a filtré les études observationnelles rapportant l'effet expérimental des semelles / chaussures de décharge. Pendant ce temps, on a défini le résultat principal en tant que pic de pression plantaire moyenne

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(MPP) globale et les résultats secondaires en tant que MPP dans diverses régions plantaires et MPP au niveau des semelles / chaussures avec différentes conceptions de structure. Les résultats montrent que les produits de soulagement de la pression (chaussures / semelles) ont réduit l›amplitude de la concentration de pression ; l'effet des produits sur mesure et préfabriqués sur le soulagement de la pression était similaire. Ces résultats suggèrent que peu importe que les produits de soulagement de la pression soient fabriqués sur mesure ou préfabriqués en standard, s'ils ont été conçus pour augmenter les zones de contact plantaires globales, telles que les produits conçus sur la base d'un modèle plantaire, ou pour fournir des supports plantaires supplémentaires ou des structures enfichables pour transférer la concentration de pression, ils étaient tous utiles dans les soins du pied diabétique pour éviter l'apparition d'ulcères. Dans l'ensemble, il est recommandé aux patients diabétiques de porter des semelles / chaussures anti-pression tout en marchant.
MOTS CLÉS : diabète, chaussure, ulcère du pied, pression plantaire

INTRODUCTION

More than 0.5 billion patients worldwide are diagnosed with diabetic mellitus (DM), which severely lowers the quality of life and even threatens the life of patients. DM cannot be cured and can only be controlled in a general level; however, poor control measures can result in complications, such as nephropathy and diabetic foot, which contribute to other serious consequences [1].

Diabetic foot, usually found in the lower limbs, is characterised by diabetic sensory neuropathy, limited joint activity, poor immune function, peripheral artery disease, foot ulcer and Charcot joint disease [2]. These complications provide an ideal environment for unrecognised tissue injury, which leads to ulceration [3]. Currently, the prevalence of foot ulcer ranges from 4% to 10% in the DM group, and the annual incidence by population ranges from 1.0% to 4.1% [4]. Furthermore, foot ulcers are the main cause of amputation, and the possibility of ulceration is 10–30 times higher in patients with DM than in healthy individuals [5, 6]. In fact, one person is amputated every 30 s in the world because of diabetes [7].

Clinical consensus approved that abnormal pressure and pressure concentration are highly correlated with ulceration [8, 9]. Those abnormal pressures might be attributed to foot deformities, wearing unsuitable shoes or trauma caused by accident. Sites with abnormal pressure then develop muscle/soft tissue constrains, which might further deteriorate as pressure ulcers and even amputations. According to existing literature, the foot pressure of patients with diabetes is higher than that of people without diabetes [10-13]. In particular, ulcer sites, either the new one or with previous ulcer history, are recorded with high pressure distribution [10, 13]. Hence, avoiding high pressure load and implementing pressure relief are the primary tasks in diabetic foot care.

Protective shoes and insoles are prescribed to patients with DM because they lower pressure amplitudes and thus avoid foot ulcers [14]. However, a descriptive study following ulcerated patients over 2 years found that re-ulceration occurs in 72% of patients who resumed wearing their own footwear compared with 26% of patients who continued wearing prescribed footwear [15]. Other studies disclosed the positive effectiveness of various protective shoes/insoles on pressure relief [16-18]. Thereby, the International Consensus for Diabetic Foot [19] suggested that wearing correct shoes/insoles is a direct and effective protocol in diabetic foot care. However, a few controversial outcomes were observed in the literature [20]. In specific, (1) whether or not pressure-relieving products (shoes/insoles) actually lower the pressure concentration under feet and (2) whether or not customised products (shoes/insoles) are superior to standard pressure-relieving ones remain uncertain.

Therefore, this study assessed the current literature by meta-analysis and then quantitatively evaluated the pressure-relieving effect of shoes and insoles and those with varied design characteristics, such as custom made or standard one.

METHODS

Search Strategy and Quality Assessment

The following databases published until 18th March 2019 were selected: Web of Science (1994–2018), Medline via OVID (1994–2018), CINAHL (1994–2018), SCOPUS (1994–2018), INFORMIT, Cochrane Central (2000–2018) and EMBASE via OVID (1994–2018). A primary author conducted the searching action; thereafter, this author repeatedly searched in August 2019 to identify any new articles of relevance. Keywords were elected according to a meeting among authors of this study: 'diabetes*', 'diabetic foot', 'shoe*', 'pressure*', 'insole', 'ulcer', 'relieving', 'offload*', 'random', 'custom-made' and 'prevention'.

Two blinded authors applied the tools in Review Manager (Version 5.3, Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2014) for risk of bias assessment. A quality assessment tool was also adapted from validated measures with addition of questions specific to the pressure-relieving function of shoes/insoles [21]. Quality scores of ≥45, 30–45, 20–30 and ≤20 were defined as excellent, good, fair and poor, respectively [10]. A primary author checked both records of risk of bias and quality of studies for consistency.

Study Selection

Studies were included in the meta-analysis if they met all the below inclusion criteria. Potential studies identified for inclusion were reviewed independently by two authors using those inclusion criteria. Group discussions were held to resolve any disagreements in the inclusion of studies.

- An observational study;
- Subjects included had no current ulcers or ulcers in their feet already recovered;
- The study was reported in or available in the English language;
- Plantar pressure values were reported in two groups: one included pressure-relieving shoes/insoles, including custom-made and standard products, and the other included control products.
- Plantar pressure values were reported as the mean peak plantar pressure (MPP) in any acceptable pressure unit (KPa, N/kg^2 or similar);
- Overall plantar pressure or regional ones, such as fore foot, mid foot and rear foot were reported
- Experimental shoes or insoles were reported with details.
- Studies were excluded if they meet any of the following criteria:
- Other pressure-relieving protocols rather than insoles/shoes, such as callus debridement and podiatry.
- Foot pressure data did not provide extractable mean and standard deviation (SD);
- Foot pressure data were not provided by sufficiently large samples. Studies only reported one person's data;
- No randomised experiments were conducted in the study;
- Only pressure plate measures were reported, as pressure plate recorded the pressure distribution of outsoles.
- Full-text manuscripts could not be acquired.

Primary and Secondary Outcomes

Three primary outcomes were set up: overall MPP, MPP in pressure-relieving insoles and MPP in pressure-relieving shoes. Then, seven secondary outcomes were nominated: MPP at the fore foot, MPP at the mid foot, MPP at the rear foot, MPP in custom-made insoles, MPP in standard pressure-relieving insoles, MPP in custom-made shoes and MPP in standard pressure-relieving shoes. We defined that the toes, MTH1-5, hallux were included into fore foot regions and the heel was divided into rear foot regions.

Data Extraction and Synthesis

Data extraction was first completed by one primary author, and the extracted data were checked by another primary author for any omissions. At first, descriptive data such as age, sample size, types and structures of shoes/insoles were recorded for each study. Afterwards, numerical data (mean and SD) for each plantar pressure variable were carefully identified and extracted. When studies assessed insoles/shoes with a variety of structure designs or modifications and more than one comparison were reported, each comparison was extracted and included for analysis. Considering that plantar pressure data were measured and reported in terms of feet unit, we extracted each foot data. Anatomical locations were unspecified, and we defaulted that all the included studies have a unified criterion for anatomical definition.

Statistical Methods

Standardised mean differences (SMD) were calculated by Cohen's d [22] and then input in meta-analyses. Results were expressed as SMD with 95% confidence intervals (95%CI) and p-values. Furthermore, weighted means (according to the sample size factor) were randomly calculated for reported variables. The Z test and I2 statistics were used to assess statistical heterogeneity between studies. I2 with values of 25%, 50% and 75% were considered as low, moderate and high heterogeneity, respectively [23]. All meta-analysis models were executed by the primary author using the software package of Review Manager.

RESULTS

Search Results

The flowchart of literature filtering is shown in Figure 1, and 18 studies were retained for further analysis [20, 24-40].

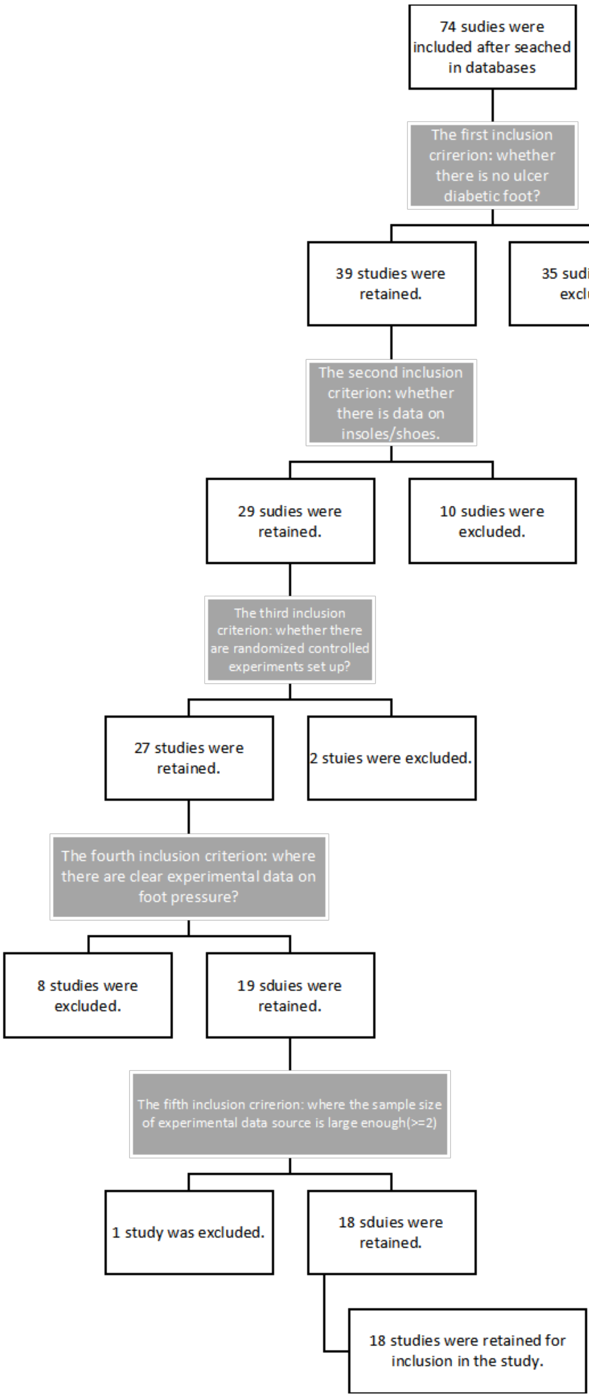
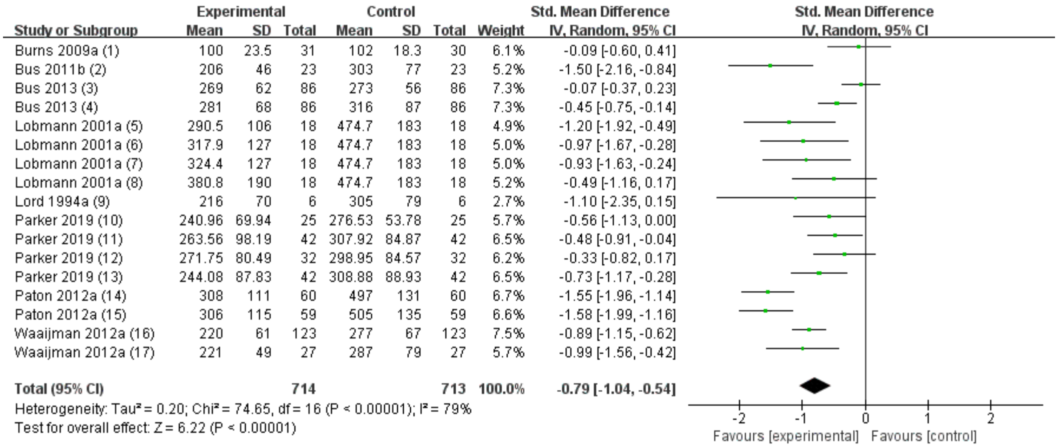


Figure 1. Flowchart of filtering of literature

Primary Outcomes

Overall MPP was reported by all 17 comparisons from 8 studies. Meta-analysis combining the data from 17 comparisons (pressure-relieving insoles n = 714; standard control insoles n = 713) suggested that pressure-relieving shoes/insoles significantly reduced the MPP for patients with diabetes in comparison with the control ones (SMD = −0.74, 95% CI = −1.00–(−0.49), Z = 5.70, P < 0.0001). The heterogeneity between studies was high (I2 = 80%) (Figure 2).



Footnotes
(1) Custom orthoses Vs Sham
(2) fully customized footwear Vs custom molded insoles in an extradepth shoe
(3) Improved footwear Vs Usual care
(4) Improved footwear Vs Usual care
(5) 2 weeks after insole protection Vs Baseline
(6) 8 weeks after insole protection Vs Baseline
(7) 6 months after insole protection Vs Baseline
(8) 1 year after insole protection Vs Baseline
(9) molded inserts Vs flat inserts
(10) Traditional Supply Chain: Orthotic Vs Control
(11) Traditional Supply Chain: Orthotic Vs Control
(12) Digital Supply Chain: Orthotic Vs Control
(13) Digital Supply Chain: Orthotic Vs Control
(14) Custom-made functional insole: Baseline Vs after 6-months
(15) Custom-made group Vs Prefabricated group
(16) custom-made insoles in custom-made shoes Vs custom-made insoles in offthe-shelf extra-depth shoes
(17) custom-made insoles in custom-made shoes Vs custom-made insoles in offthe-shelf extra-depth shoes

Figure 2. Forest plot of the overall Peak Plantar Pressure (MPP)

Pressure-relieving insoles significantly reduced the MPP for patients with diabetes in comparison with the control shoes (SMD = −1.19, 95%CI = −1.45–(−0.93), Z = 9.01, P < 0.00001, I2 = 87%). Similarly, pressure-relieving insoles significantly reduced the MPP for patients with diabetes in comparison with the control insoles (SMD = −0.42, 95% CI = −0.55–(−0.29), Z = 6.35, P < 0.00001, I2 = 85%).

Secondary Outcomes

MPP at Various Plantar Regions

MPP at the forefoot was significantly lowered (SMD = −0.70, 95% CI = −0.85–(−0.54), Z = 8.79, P < 0.00001). The heterogeneity between studies was high (I2 = 85%).

MPP at the rear foot was also significantly attenuated by pressure-relieving insoles (SMD = −1.00, 95% CI = −1.27–(−0.74), Z = 7.41, p < 0.00001, I2 = 73%).

Although a slight pressure-relieving effect on the mid foot area was observed in contrast with the control insoles (SMD = 0.00, 95% CI = −0.18–0.19, Z = 0.03, P = 0.97), heterogeneity between studies was low (I2 = 46%).

MPP at Various Shoes

MPP with custom-made shoes was divided by three studies, and four comparisons were reported. Meta-analysis combining the data from four comparisons (pressure-relieving shoes n = 211; standard control shoes n = 211) implied that with the favour of custom-made shoes, the

MPP with custom-made shoes was significantly lowered (SMD = −0.75, 95% CI = −1.33–(−0.17), Z = 2.52, P = 0.01). The heterogeneity between studies was high (I2 = 86%) (Figure 3).

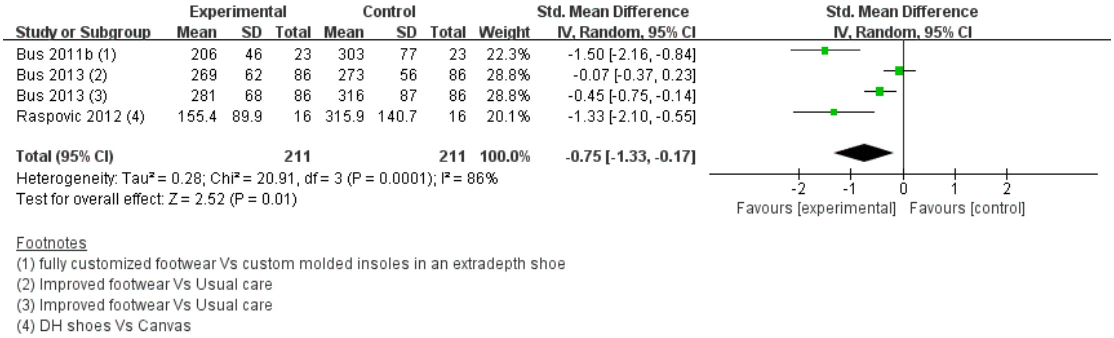
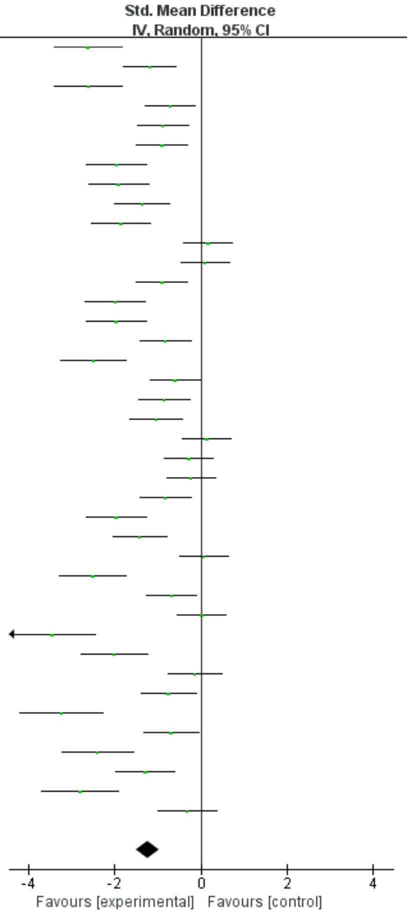


Figure 3. Forest plot of the Peak Plantar Pressure (MPP) in custom-made pressure-relieving shoes

The same tendency was also found for standard pressure-relieving shoes and meta-analysis combining data 49 comparisons from three studies (pressure-relieving insoles n = 1096; standard control insoles n = 1096) indicated that the MPP under the standard insoles was also slightly attenuated by pressure-relieving insoles (SMD = −1.34, 95% CI = −1.60–(−1.07), Z = 9.89, $p < 0.00001$, I2 = 87%) (Figure 4).

Study or Subgroup	Experimental Mean	Experimental SD	Experimental Total	Control Mean	Control SD	Control Total	Weight	Std. Mean Difference IV, Random, 95% CI
Bus 2009a (1)	157	40	24	364	102	24	2.4%	-2.63 [-3.42, -1.84]
Bus 2009a (2)	136	36	24	240	116	24	2.6%	-1.19 [-1.81, -0.57]
Bus 2009a (3)	157	41	24	364	102	24	2.4%	-2.62 [-3.41, -1.83]
Bus 2009a (4)	168	80	24	240	116	24	2.6%	-0.71 [-1.30, -0.13]
Bus 2009a (5)	220	50	24	262	43	24	2.6%	-0.89 [-1.48, -0.29]
Bus 2009a (6)	153	67	24	240	116	24	2.6%	-0.90 [-1.50, -0.31]
Bus 2009a (7)	173	46	24	262	43	24	2.5%	-1.97 [-2.67, -1.27]
Bus 2009a (8)	135	43	24	272	90	24	2.5%	-1.91 [-2.60, -1.22]
Bus 2009a (9)	166	59	24	272	90	24	2.5%	-1.37 [-2.00, -0.74]
Bus 2009a (10)	203	65	24	364	102	24	2.5%	-1.85 [-2.54, -1.17]
Bus 2009a (11)	112	39	24	104	50	24	2.6%	0.18 [-0.39, 0.74]
Bus 2009a (12)	108	30	24	104	50	24	2.6%	0.10 [-0.47, 0.66]
Bus 2009a (13)	152	72	24	240	116	24	2.6%	-0.90 [-1.49, -0.30]
Bus 2009a (14)	131	41	24	272	90	24	2.5%	-1.98 [-2.68, -1.28]
Bus 2009a (15)	129	46	24	272	90	24	2.5%	-1.97 [-2.67, -1.27]
Bus 2009a (16)	96	47	24	138	53	24	2.6%	-0.82 [-1.42, -0.23]
Bus 2009a (17)	165	43	24	364	102	24	2.4%	-2.50 [-3.27, -1.73]
Bus 2009a (18)	110	38	24	138	53	24	2.6%	-0.60 [-1.18, -0.02]
Bus 2009a (19)	218	58	24	262	43	24	2.6%	-0.85 [-1.44, -0.25]
Bus 2009a (20)	137	76	24	240	116	24	2.6%	-1.03 [-1.64, -0.43]
Bus 2009a (21)	111	45	24	104	50	24	2.6%	0.14 [-0.42, 0.71]
Bus 2009a (22)	122	61	24	138	53	24	2.6%	-0.28 [-0.84, 0.29]
Bus 2009a (23)	125	59	24	138	53	24	2.6%	-0.23 [-0.80, 0.34]
Bus 2009a (24)	217	62	24	262	43	24	2.6%	-0.83 [-1.42, -0.24]
Bus 2009a (25)	127	48	24	272	90	24	2.5%	-1.98 [-2.68, -1.28]
Bus 2009a (26)	195	50	24	262	43	24	2.5%	-1.41 [-2.05, -0.78]
Bus 2009a (27)	107	39	24	104	50	24	2.6%	0.07 [-0.50, 0.63]
Bus 2009a (28)	153	57	24	364	102	24	2.4%	-2.51 [-3.28, -1.74]
Bus 2009a (29)	108	32	24	138	53	24	2.6%	-0.67 [-1.26, -0.09]
Bus 2009a (30)	105	39	24	104	50	24	2.6%	0.02 [-0.54, 0.59]
Nagel 2009a (31)	153.4	39.9	20	420.5	99.3	20	2.1%	-3.46 [-4.47, -2.45]
Nagel 2009a (32)	194.4	38.3	20	306.7	67.4	20	2.4%	-2.01 [-2.78, -1.23]
Nagel 2009a (33)	146.8	38.5	20	154	58.8	20	2.6%	-0.14 [-0.76, 0.48]
Nagel 2009a (34)	117.4	33.4	20	154	58.8	20	2.5%	-0.75 [-1.39, -0.11]
Nagel 2009a (35)	160.9	50.2	20	420.5	99.3	20	2.2%	-3.23 [-4.20, -2.26]
Nagel 2009a (36)	121.3	28.8	20	154	58.8	20	2.5%	-0.69 [-1.33, -0.05]
Nagel 2009a (37)	176.2	34.1	20	306.7	67.4	20	2.3%	-2.39 [-3.23, -1.56]
Nagel 2009a (38)	224.4	57.1	20	306.7	67.4	20	2.5%	-1.29 [-1.98, -0.60]
Nagel 2009a (39)	191.8	54.2	20	420.5	99.3	20	2.3%	-2.80 [-3.70, -1.91]
Raspovic 2012 (40)	273	127.1	16	315.9	140.7	16	2.5%	-0.31 [-1.01, 0.39]
Total (95% CI)			**916**			**916**	**100.0%**	**-1.24 [-1.52, -0.96]**

Heterogeneity: $Tau^2 = 0.70$; $Chi^2 = 287.63$, df = 39 ($P < 0.00001$); $I^2 = 86\%$
Test for overall effect: $Z = 8.64$ ($P < 0.00001$)



Footnotes
(1) Rattenhuber Talus FOS Vs Control shoe
(2) Thanner Cabrio FOS Vs Control shoe
(3) Thanner Cabrio FOS Vs Control shoe
(4) Fior&Gentz Hannover FOS Vs Control shoe
(5) Thanner Cabrio FOS Vs Control shoe
(6) Mabal cast shoe Vs Control shoe
(7) Mabal cast shoe Vs Control shoe
(8) Fior&Gentz Hannover FOS Vs Control shoe
(9) Mabal cast shoe Vs Control shoe
(10) Mabal cast shoe Vs Control shoe
(11) Fior&Gentz Luneburg FOS Vs Control shoe
(12) Fior&Gentz Hannover FOS Vs Control shoe
(13) Fior&Gentz Luneburg FOS Vs Control shoe
(14) Thanner Cabrio FOS Vs Control shoe
(15) Rattenhuber Talus FOS Vs Control shoe
(16) Rattenhuber Talus FOS Vs Control shoe
(17) Fior&Gentz Hannover FOS Vs Control shoe
(18) Mabal cast shoe Vs Control shoe
(19) Fior&Gentz Luneburg FOS Vs Control shoe
(20) Rattenhuber Talus FOS Vs Control shoe
(21) Mabal cast shoe Vs Control shoe
(22) Fior&Gentz Luneburg FOS Vs Control shoe
(23) Fior&Gentz Hannover FOS Vs Control shoe
(24) Rattenhuber Talus FOS Vs Control shoe
(25) Fior&Gentz Luneburg FOS Vs Control shoe
(26) Fior&Gentz Hannover FOS Vs Control shoe
(27) Rattenhuber Talus FOS Vs Control shoe
(28) Fior&Gentz Luneburg FOS Vs Control shoe
(29) Thanner Cabrio FOS Vs Control shoe
(30) Thanner Cabrio FOS Vs Control shoe
(31) Post-operative shoe (POS) Vs Off-the-shelf footwear (OSF)
(32) VACOdiaped-Plus (low-cut) Vs Off-the-shelf footwear (OSF)
(33) VACOdiaped-Plus (low-cut) Vs Off-the-shelf footwear (OSF)
(34) Post-operative shoe (POS) Vs Off-the-shelf footwear (OSF)
(35) VACOdiaped (high-cut) Vs Off-the-shelf footwear (OSF)
(36) VACOdiaped (high-cut) Vs Off-the-shelf footwear (OSF)
(37) VACOdiaped (high-cut) Vs Off-the-shelf footwear (OSF)
(38) Post-operative shoe (POS) Vs Off-the-shelf footwear (OSF)
(39) VACOdiaped-Plus (low-cut) Vs Off-the-shelf footwear (OSF)
(40) Standard shoes Vs Canvas

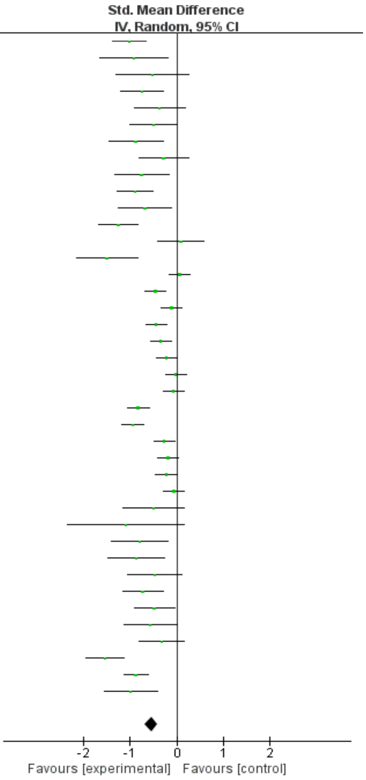
Figure 4. Forest plot of the Peak Plantar Pressure (MPP) in standard pressure-relieving shoes

MPP at Various Insoles

The insoles can be classified into custom-made and standard ones. The MPP under the custom-made insoles was divided by 10 studies, and 33 comparisons were reported. Meta-analysis combining data from 33 comparisons (pressure-relieving insoles n = 2894; standard control insoles n = 3056) implied that the MPP under custom-made insoles was significantly lowered (SMD = −0.48, 95% CI = −0.61–(−0.34), Z = 6.73, P < 0.00001). The heterogeneity between studies was high (I2 = 84%) (Figure 5).

	Experimental			Control				Std. Mean Difference
Study or Subgroup	**Mean**	**SD**	**Total**	**Mean**	**SD**	**Total**	**Weight**	**IV, Random, 95% CI**
Arts 2015a (1)	209	55	67	271	66	67	2.7%	-1.01 [-1.38, -0.65]
Arts 2015a (2)	209	37	16	241	30	16	1.6%	-0.93 [-1.66, -0.19]
Arts 2015a (3)	235	70	13	284	108	13	1.5%	-0.52 [-1.31, 0.26]
Arts 2015a (4)	221	50	39	258	48	39	2.4%	-0.75 [-1.21, -0.29]
Arts 2015a (5)	239	53	26	258	50	26	2.1%	-0.36 [-0.91, 0.19]
Arts 2015a (6)	268	72	30	306	79	30	2.2%	-0.50 [-1.01, 0.02]
Arts 2015a (7)	212	40	25	251	47	25	2.0%	-0.88 [-1.46, -0.30]
Arts 2015a (8)	264	78	27	283	52	27	2.2%	-0.28 [-0.82, 0.25]
Arts 2015a (9)	238	53	24	281	59	24	2.0%	-0.75 [-1.34, -0.17]
Arts 2015a (10)	212	52	58	260	54	58	2.7%	-0.90 [-1.28, -0.52]
Arts 2015a (11)	210	48	25	250	66	25	2.1%	-0.68 [-1.25, -0.11]
Arts 2015a (12)	212	51	52	280	56	52	2.5%	-1.26 [-1.68, -0.84]
Burns 2009a (13)	102	18.3	30	100	23.5	31	2.3%	0.09 [-0.41, 0.60]
Bus 2011b (14)	206	46	23	303	77	23	1.8%	-1.50 [-2.16, -0.84]
Hellstrand 2014 (15)	259	114	142	250	137	154	3.2%	0.07 [-0.16, 0.30]
Hellstrand 2014 (16)	127	65	142	163	88	154	3.1%	-0.46 [-0.69, -0.23]
Hellstrand 2014 (17)	193	86	142	202	85	154	3.2%	-0.11 [-0.33, 0.12]
Hellstrand 2014 (18)	189	85	143	238	130	154	3.2%	-0.44 [-0.67, -0.21]
Hellstrand 2014 (19)	206	118	143	250	137	154	3.2%	-0.34 [-0.57, -0.11]
Hellstrand 2014 (20)	144	83	143	163	88	154	3.2%	-0.22 [-0.45, 0.01]
Hellstrand 2014 (21)	98	47	143	99	69	154	3.2%	-0.02 [-0.24, 0.21]
Hellstrand 2014 (22)	95	44	142	99	69	154	3.2%	-0.07 [-0.30, 0.16]
Hellstrand 2014 (23)	178	64	143	242	88	154	3.1%	-0.82 [-1.06, -0.59]
Hellstrand 2014 (24)	171	57	142	242	88	154	3.1%	-0.95 [-1.19, -0.71]
Hellstrand 2014 (25)	251	118	143	283	119	154	3.2%	-0.27 [-0.50, -0.04]
Hellstrand 2014 (26)	217	95	142	238	130	154	3.2%	-0.18 [-0.41, 0.05]
Hellstrand 2014 (27)	259	95	142	283	119	154	3.2%	-0.22 [-0.45, 0.01]
Hellstrand 2014 (28)	197	89	143	202	85	154	3.2%	-0.06 [-0.29, 0.17]
Lobmann 2001a (29)	380.8	190	18	474.7	183	18	1.8%	-0.49 [-1.16, 0.17]
Lord 1994a (30)	216	70	6	305	79	6	0.8%	-1.10 [-2.35, 0.15]
Owings 2008a (31)	200	46	23	245	63	23	2.0%	-0.80 [-1.40, -0.20]
Owings 2008a (32)	127	38	23	168	53	23	2.0%	-0.87 [-1.48, -0.27]
Owings 2008a (33)	178	59	23	211	79	23	2.0%	-0.47 [-1.05, 0.12]
Parker 2019 (34)	244.08	87.83	42	308.88	88.93	42	2.5%	-0.73 [-1.17, -0.28]
Parker 2019 (35)	263.56	98.19	42	307.92	84.87	42	2.5%	-0.48 [-0.91, -0.04]
Parker 2019 (36)	240.96	69.94	25	276.53	53.78	25	2.1%	-0.56 [-1.13, 0.00]
Parker 2019 (37)	271.75	80.49	32	298.95	84.57	32	2.3%	-0.33 [-0.82, 0.17]
Paton 2012a (38)	308	111	60	497	131	60	2.6%	-1.55 [-1.96, -1.14]
Waaijman 2012a (39)	220	61	123	277	67	123	3.1%	-0.89 [-1.15, -0.62]
Waaijman 2012a (40)	221	49	27	287	79	27	2.1%	-0.99 [-1.56, -0.42]
Total (95% CI)			**2894**			**3056**	**100.0%**	**-0.55 [-0.68, -0.42]**

Heterogeneity: $Tau^2 = 0.12$; $Chi^2 = 204.87$, df = 39 (P < 0.00001); $I^2 = 81\%$
Test for overall effect: Z = 8.39 (P < 0.00001)



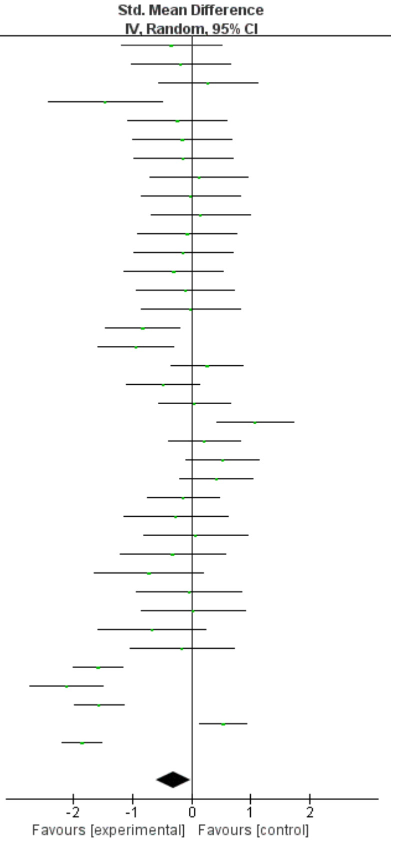
Footnotes
(1) fully custom-made footwear Vs semi-custom-made footwear
(2) fully custom-made footwear Vs semi-custom-made footwear
(3) fully custom-made footwear Vs semi-custom-made footwear
(4) fully custom-made footwear Vs semi-custom-made footwear
(5) fully custom-made footwear Vs semi-custom-made footwear
(6) fully custom-made footwear Vs semi-custom-made footwear
(7) fully custom-made footwear Vs semi-custom-made footwear
(8) fully custom-made footwear Vs semi-custom-made footwear
(9) fully custom-made footwear Vs semi-custom-made footwear
(10) fully custom-made footwear Vs semi-custom-made footwear
(11) fully custom-made footwear Vs semi-custom-made footwear
(12) fully custom-made footwear Vs semi-custom-made footwear
(13) Custom orthoses Vs Sham
(14) fully customized footwear Vs custom molded insoles in an extradepth shoe
(15) 55 shore EVA insoles Vs prefabricated insoles
(16) 55 shore EVA insoles Vs prefabricated insoles
(17) 55 shore EVA insoles Vs prefabricated insoles
(18) 35 shore EVA insoles Vs prefabricated insoles
(19) 35 shore EVA insoles Vs prefabricated insoles
(20) 35 shore EVA insoles Vs prefabricated insoles
(21) 35 shore EVA insoles Vs prefabricated insoles
(22) 55 shore EVA insoles Vs prefabricated insoles
(23) 35 shore EVA insoles Vs prefabricated insoles
(24) 55 shore EVA insoles Vs prefabricated insoles
(25) 35 shore EVA insoles Vs prefabricated insoles
(26) 55 shore EVA insoles Vs prefabricated insoles
(27) 55 shore EVA insoles Vs prefabricated insoles
(28) 35 shore EVA insoles Vs prefabricated insoles
(29) 1 year after insole protection Vs Baseline
(30) molded inserts Vs flat inserts
(31) insoles X in the rigid shoes Vs insoles X in the fflexible shoes
(32) insoles Z in the rigid shoes Vs insoles X in the fflexible shoes
(33) insoles Y in the rigid shoes Vs insoles X in the fflexible shoes
(34) Digital Supply Chain: Orthotic Vs Control
(35) Traditional Supply Chain: Orthotic Vs Control
(36) Traditional Supply Chain: Orthotic Vs Control
(37) Digital Supply Chain: Orthotic Vs Control
(38) Custom-made functional insole: Baseline Vs after 6-months
(39) custom-made insoles in custom-made shoes Vs custom-made insoles in offthe-shelf extra-depth shoes
(40) custom-made insoles in custom-made shoes Vs custom-made insoles in offthe-shelf extra-depth shoes

Figure 5. Forest plot of the Peak Plantar Pressure (MPP) in custom-made pressure-relieving insoles

Similarly, the MPP under the standard insoles was also slightly attenuated (SMD = −0.43, 95% CI = −0.78–(−0.09), Z = 2.46, p = 0.01, I2 = 85%) on the basis of 28 comparisons (pressure-relieving insoles n = 553; standard control insoles n = 537) from four studies (Figure 6).

	Experimental			Control				Std. Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI
Ashry 1997a (1)	264.2	106	11	299.6	94.6	11	2.5%	-0.34 [-1.18, 0.50]
Ashry 1997a (2)	143.6	64.1	11	155.4	64	11	2.5%	-0.18 [-1.01, 0.66]
Ashry 1997a (3)	276.5	51.6	11	261.7	51.6	11	2.5%	0.28 [-0.56, 1.12]
Ashry 1997a (4)	176.1	60.5	11	261.7	51.6	11	2.4%	-1.46 [-2.43, -0.50]
Ashry 1997a (5)	252.7	116.7	11	280.7	112.2	11	2.5%	-0.24 [-1.07, 0.60]
Ashry 1997a (6)	262.7	110.2	11	280.7	112.2	11	2.5%	-0.16 [-0.99, 0.68]
Ashry 1997a (7)	285.6	97.4	11	299.6	94.6	11	2.5%	-0.14 [-0.98, 0.70]
Ashry 1997a (8)	268.5	52.5	11	261.7	51.6	11	2.5%	0.13 [-0.71, 0.96]
Ashry 1997a (9)	154.6	72.8	11	155.4	64	11	2.5%	-0.01 [-0.85, 0.82]
Ashry 1997a (10)	164.8	52.4	11	155.4	64	11	2.5%	0.15 [-0.68, 0.99]
Ashry 1997a (11)	212.3	38.3	11	215.6	50.8	11	2.5%	-0.07 [-0.91, 0.77]
Ashry 1997a (12)	209.3	33.7	11	215.6	50.8	11	2.5%	-0.14 [-0.98, 0.70]
Ashry 1997a (13)	251.7	68	11	280.7	112.2	11	2.5%	-0.30 [-1.14, 0.54]
Ashry 1997a (14)	288.7	105.9	11	299.6	94.6	11	2.5%	-0.10 [-0.94, 0.73]
Ashry 1997a (15)	215	38	11	215.6	50.8	11	2.5%	-0.01 [-0.85, 0.82]
Bus 2004c (16)	189	45	21	239	71	21	2.8%	-0.83 [-1.46, -0.19]
Bus 2004c (17)	188	42	21	245	73	21	2.8%	-0.94 [-1.58, -0.30]
Bus 2004c (18)	121	25	21	113	33	21	2.8%	0.27 [-0.34, 0.88]
Bus 2004c (19)	255	81	21	302	109	21	2.8%	-0.48 [-1.09, 0.13]
Bus 2004c (20)	201	83	21	197	91	21	2.8%	0.05 [-0.56, 0.65]
Bus 2004c (21)	118	23	21	90	28	21	2.8%	1.07 [0.42, 1.72]
Bus 2004c (22)	153	28	21	145	44	21	2.8%	0.21 [-0.39, 0.82]
Bus 2004c (23)	120	47	21	96	42	21	2.8%	0.53 [-0.09, 1.14]
Bus 2004c (24)	130	54	21	110	38	21	2.8%	0.42 [-0.19, 1.03]
Bus 2004c (25)	183	35	21	190	58	21	2.8%	-0.14 [-0.75, 0.46]
Guldemond 2007b (26)	216	50.8	11	231	58.9	9	2.5%	-0.26 [-1.15, 0.62]
Guldemond 2007b (27)	138	43.5	11	135	43.2	9	2.5%	0.07 [-0.81, 0.95]
Guldemond 2007b (28)	190	61.6	11	210	58.4	9	2.5%	-0.32 [-1.21, 0.57]
Guldemond 2007b (29)	164	63.5	11	210	58.4	9	2.4%	-0.72 [-1.63, 0.20]
Guldemond 2007b (30)	181	96.5	11	185	83.8	9	2.5%	-0.04 [-0.92, 0.84]
Guldemond 2007b (31)	136	39.8	11	135	43.2	9	2.5%	0.02 [-0.86, 0.90]
Guldemond 2007b (32)	192	53	11	231	58.9	9	2.4%	-0.67 [-1.58, 0.24]
Guldemond 2007b (33)	170	92.7	11	185	83.8	9	2.5%	-0.16 [-1.04, 0.72]
Paton 2012a (34)	306	115	59	505	135	59	3.0%	-1.58 [-1.99, -1.16]
Viswanathan 2004a (35)	6.8	6.1	32	16.2	1.3	32	2.8%	-2.11 [-2.72, -1.49]
Viswanathan 2004a (36)	6.2	3.9	59	16.3	8.2	59	3.0%	-1.56 [-1.98, -1.15]
Viswanathan 2004a (37)	40.7	20.5	50	29.2	22.1	50	3.0%	0.54 [0.14, 0.93]
Viswanathan 2004a (38)	6.9	3.6	100	16.2	6.1	100	3.1%	-1.85 [-2.18, -1.52]
Total (95% CI)			**763**			**747**	**100.0%**	**-0.30 [-0.59, -0.02]**

Heterogeneity: Tau² = 0.67; Chi² = 251.67, df = 37 (P < 0.00001); I² = 85%
Test for overall effect: Z = 2.07 (P = 0.04)



Footnotes
(1) Arch Pad Vs Plastizote
(2) Metatarsal-Arch Pad Vs Plastizote
(3) Metatarsal Pad Vs Plastizote
(4) Metatarsal-Arch Pad Vs Plastizote
(5) Metatarsal Pad Vs Plastizote
(6) Arch Pad Vs Plastizote
(7) Metatarsal Pad Vs Plastizote
(8) Arch Pad Vs Plastizote
(9) Metatarsal Pad Vs Plastizote
(10) Arch Pad Vs Plastizote
(11) Metatarsal-Arch Pad Vs Plastizote
(12) Arch Pad Vs Plastizote
(13) Metatarsal-Arch Pad Vs Plastizote
(14) Metatarsal-Arch Pad Vs Plastizote
(15) Metatarsal Pad Vs Plastizote
(16) CMI Vs Flat insole
(17) CMI Vs Flat insole
(18) CMI Vs Flat insole
(19) CMI Vs Flat insole
(20) CMI Vs Flat insole
(21) CMI Vs Flat insole
(22) CMI Vs Flat insole
(23) CMI Vs Flat insole
(24) CMI Vs Flat insole
(25) CMI Vs Flat insole
(26) Standard arch support Vs Basic
(27) Standard arch support Vs Basic
(28) Standard arch support Vs Basic
(29) Extra arch support Vs Basic
(30) Standard arch support Vs Basic
(31) Extra arch support Vs Basic
(32) Extra arch support Vs Basic
(33) Extra arch support Vs Basic
(34) Prefabricated insole: Baseline Vs after 6-months
(35) molded footwear: follow up Vs first visit
(36) polyurethane foam-insoled footwear: follow up Vs first visit
(37) prescribed sandals: follow up Vs first visit
(38) MCR insoles: follow up Vs first visit

Figure 6. Forest plot of the Peak Plantar Pressure (MPP) in standard pressure-relieving insoles

DISCUSSION

In this study, we used a meta-analysis to evaluate 18 studies and 346 comparisons between pressure-relieving products (shoes/insoles) and standard ones. Then, we analysed the overall MPP, MPP at various plantar regions and MPP at insoles/shoes with various structure designs. Our findings confirmed several positive agreements that pressure-relieving products (shoes/insoles) really lower the amplitude of pressure concentration. In addition, the pressure-relieving effects of custom-made and prefabricated products were similar.

Abnormal peak pressure is considered a major cause of diabetic foot ulcer; thus, pressure relief is a fundamental measure in diabetic care [19, 41, 42]. According to foot biomechanics, foot is the only body part contacting with the ground, where a large amount of ground reaction forces is concentrated on. Two principles are followed in lowering plantar pressure: one is increasing contact areas, and the other is transferring the peak pressure from risk areas to relatively safe ones, such as areas with occurrence of foot deformities, abnormal gait, wearing wrong shoes or shoes with foreign bodies (e.g. scree) [25].

In the first situation, current studies directly approved that plantar pressures are significantly reduced by using pressure-relieving products [43, 44], where experiment shoes and insoles performed closely. Moreover, two types of product designs were available: one was custom made [45, 46], and the other was prefabricated standard or modular assembled [31, 35]. Usually, the custom-made ones use static or dynamic foot impressions in a foam box or by digital 3D scan, from which a positive plaster cast of the plantar surface is created [28]. The custom-made shoes or insoles were developed based on the patient's plantar surface. This style of products has the largest contact area with the foot; thus, the overall MPP can be distributed.

In the second situation, extra structure designs were provided to both shoes and insoles. Standard pressure-relieving products provide extra structures, such as arch support, heel cup, wedges, metatarsal pad and hollow treatment [18, 47, 48], and they also aim to achieve pressure exchange. By contrast, standard pressure-relieving products (SMD = −1.34 for shoes and SMD = −0.43 for insole) performed superior than custom-made ones (SMD = −0.75 for shoes and SMD = −0.48 for insole). Thereby, we postulated that efficient pressure-relieving measures should first consider shoes before insoles. These findings once again support the description in international consensus for diabetic foot [19]: wearing the pressure-relieving shoes/insoles can effectively reduce plantar pressure and avoid ulceration.

By considering the heterogeneity of our results, majority of findings displayed a moderate-to-high heterogeneity (I2 > 70%). The I2 value at the mid foot was lower than 50% because this area beard extra loading by the arch support structure which transferred pressure from other parts of plantar regions. The high heterogeneity further supported validity of this meta-analysis [10].

Risk of bias for the included studies was assessed. The overall agreement between the two quality assessors was good, with the variation of scores ranging from zero to three points. In general, all studies used an appropriate study design and accounted for potential confounders. However, one study did not report data on a primary outcome measure for at least 85% of the participants, none of the studies calculated the power of the sample and only two studies identified the presence of PAD or excluded those with PAD. The highest score for the method- and participant-specific questions was given to the study which addressed issues such as number of steps used in measurements, number of walking trials and the measurement of factors which potentially affected plantar pressure, such as diabetes duration and type of diabetes [29].

This study has some limitations. In a single study, researchers reported two measures between pressure-relieving and control products. One was two or more types of pressure-relieving shoes versus control shoes (See [31, 32]); the other was continuing modification for custom-made insoles (See [34, 49]). Regarding the two conditions, we counted each measure as individual record and input each of them in the meta-analysis. This method might introduce bias by increasing the sample size.

CONCLUSION

This meta-analysis confirmed that pressure-relieving shoes/insoles perform well in lowering plantar pressure distribution. Pressure-relieving products, regardless if they are custom made or pre-fabricated, can prevent ulceration and help in diabetic foot care if they are designed to increase overall plantar contact areas or to provide extra arch supports or plug-in structures to transfer pressure concentration.

Acknowledgement

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Conflict of Interest Statement

There are no conflicts of interest with other authors and institutions. No subjects or animals were included in this study. Neither participants nor informed consent were included in the study.

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