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Footwear and insole design features to prevent foot ulceration in people with diabetes: A systematic review protocol

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Review title

Footwear and insole design features to prevent foot ulceration in adults with diabetes: A systematic review protocol

Review question/objective

The aim of this systematic review is to identify the key design features of footwear and insoles which are used to offload the plantar surface of the foot to prevent foot ulceration in adults with diabetes.

More specifically, the objectives are to identify the key design features of footwear and insoles to offload the plantar surface of the foot 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

Background

Diabetes is a disease with devastating multi-factorial complications which causes an economic burden to healthcare providers.[1] The global prevalence of diabetes was reported at 336 million people in 2011 and is expected to rise to 552 million by 2030.[2] In the United Kingdom (UK) around 1.2 million adults (5.7% of the adult population) are diagnosed with diabetes. This figure is anticipated to grow by a further 1.4% over the next 15 years.[3] It is expected that 25% of people with diabetes will develop a foot ulcer at some point.[4] Foot ulceration is a limb and life threatening condition known to precede 80% of all diabetic lower limb amputations.[5]

Diabetic foot amputation is associated with poor quality of life and high rates of mortality.[6] Following primary foot amputation, the five-year mortality rate is in the region of 44%.[1] Estimates of the National Health Services (NHS) annual expenditure for the treatment of the diabetic ulcerated foot were approximately £591 million,[1] whilst indirect costs associated with loss of productivity, sickness and informal care in the UK were estimated at £14 billion for 2010-2011.[7]

Approximately 30% of people with diabetes will develop peripheral neuropathy.[4] Diabetic peripheral neuropathy (DPN) is a risk factor for the development of foot ulceration. There are three types of DPN: sensory, motor and autonomic. Sensory neuropathy is a loss of the body's protective feedback mechanism in response to pain or touch.[8] Motor neuropathy can cause changes in joint mobility and strength, foot structure/deformity and plantar foot pressures[9-12] whilst autonomic neuropathy contributes to plantar tissue quality loss.[13-15] Areas at increased susceptibility of ulceration are often in the forefoot region, where the combination of loss of protective sensory feedback, tissue ischemia and elevated plantar pressure loading can result in ulceration.[16]

Elevated dynamic plantar pressures during locomotion are known to contribute to the development of diabetic foot ulcers when in the presence of neuropathy.[17] Reducing high plantar loads or foot pressures is therefore one mechanism by which foot ulceration maybe prevented.[18-19] Recommendations for the prevention of diabetic foot ulcer are multidisciplinary and holistic in their approach. However, offloading footwear and insoles has been recognized as one important element of the foot ulcer prevention strategy.

An initial search of the literature published prior to September 2016 was completed using the following databases: AMED, EMBASE, MEDLINE, BNI, CINAHL, the Cochrane Database of Systematic Reviews and PROSPERO databases, and the Joanna Briggs Institute Database of Systematic Reviews and Implementation Reports. This initial literature search suggests that there is a general consensus that footwear and insoles are effective in reducing the load under the foot and preventing ulceration .[20-23,26] However an evaluation of the specific design features and modes of action that function to alter the load under the foot has not been comprehensively reported. Paton et al (2011)

focused on the effectiveness of insoles used in Randomized Controlled Trial's (RCT's) before 2008 but did not include the specification or design of the insoles used within the comparative studies.[21] The reviews by Bus et al (2015) and van Netten et al (2016) presented a more comprehensive analysis of factors for preventing foot ulceration and re-ulceration in the at-risk patient with diabetes.[22,23] Their findings highlighted only one study which emphasised the design features of footwear and insoles using a prescription algorithm[24] and one study that used in-shoe pressure measurements to inform the footwear.[25] Heuch and Gomersall's (2016) systematic review identified three studies of poor quality evidence to support methods of offloading for preventing primary diabetic foot ulceration only. Whilst the components of the insole and footwear used to offload were presented from the studies, the key design features and mode of action were not identified, as was the lack of exploration of offloading on those with a past history of ulceration.[26]

None of the reviews to date have included robust studies which investigate the effectiveness of particular design features for insole and footwear manufacture. Without this important clinically relevant information, those tasked with providing insoles for people with diabetes are unable to determine which insole and footwear type or design is best for preventing foot ulceration. This should be related to the design features of the footwear or insole, and should include details associated with the profile/shape, material properties, integrated modifications and fabrication.[27,28] A scoping of the existing literature, using identical databases as in the initial search, reveals a large variety of design features for insoles and footwear that merits further exploration.

Therefore the purpose of this systematic literature review is to bridge the existing gap in the literature and identify the key design features of footwear and insoles used to offload the plantar surface of the foot to prevent foot ulceration in people with diabetes. It is anticipated that this information will inform a protocol for the clinical design of therapeutic insoles and footwear within a RCT to offload the foot and reduce ulcer risk in people with diabetes and neuropathy.

Inclusion and exclusion criteria

Types of participants

This review will consider studies that include adults over 18 years with type 1 or type 2 diabetes, regardless of duration of diabetes, history of previous foot ulceration or other co-morbidities, without any amputation or Charcot arthropathy. It will exclude studies of people with current foot ulceration on entry to the study.

Types of intervention(s)

Studies will be considered that evaluate the effectiveness of any footwear and/or insole design features intended to offload the plantar surface of the diabetic foot for ulcer prevention.

Studies will be included if they make one of the following comparisons:

1. Footwear and/or insole design feature compared to another therapeutic footwear and/or insole design feature
2. Footwear and/or insole design feature compared to no intervention

Footwear and/or insole design features will be defined as any identifiable and distinguishing characteristic integral to the footwear or insole device. These may include, but are not limited to: footwear outsole profile variations (heel height, rocker modifications), footwear upper style variations (boots, shoes, sandals), insoles/orthoses profile variations (with/without arch support, metatarsal bars, 1st ray cut-outs, kinetic wedges, internal and external posting), differences in insole/orthosis material properties (rigid or soft devices), shaped padding applied to the foot (plantar covers, ring pads), and variations in the design and stiffness of ankle foot orthosis used to restrict ankle joint dorsiflexion (rigid/semi-rigid). Excluded will be studies that investigate offloading devices intended for the treatment of foot ulceration as the indications and rationale for use are not consistent with the objectives of this systematic review.

Types of outcomes

This review will consider studies that include either of the following

primary outcome measures of foot ulceration incidence or frequency

and/or secondary outcome measures of:

- Any standardized kinetic or kinematic outcome measure indicating loading or offloading the plantar foot: such as plantar pressure (eg reduction in mean peak pressure, reduction in pressure time integral, increase in total contact area, and changes in the dynamic measures of centre of pressure trajectory or velocity).
- Any standardized clinical measure indicating loading/offloading of the plantar foot: such as callus/lesion reduction.
- Any side effects/adverse events as a result of the design features

Types of studies

This review will consider both experimental and epidemiological study designs including randomized controlled trials, non-randomized controlled trials, quasi-experimental, before and after case series studies, prospective and retrospective cohort studies and analytical cross sectional studies for inclusion.

This review will exclude qualitative studies, case reports and systematic reviews.

Search strategy

The search strategy aims to find both published and unpublished studies. A three-step search strategy will be utilized. An initial limited search of MEDLINE and CINAHL will be undertaken followed by analysis of the text words contained in the title and abstract, and of the index terms used to describe the article. A second search using all identified keywords and index terms will then be undertaken across all included databases. Thirdly, the reference list of all identified reports and articles will be searched for additional studies. A research librarian will assist in designing search terms for various databases. Studies published in English will be considered for inclusion in this review. Studies published from inception to present will be considered for inclusion in this review.

The databases to be searched include:

AMED (EBSCO), CINAHL, MEDLINE, EMBASE, Cochrane Central Register of Controlled Trials. Joanna Briggs Institute Database of Systematic Reviews, and PROSPERO will be will be used to check the reference list of relevant systematic reviews to ensure all appropriate papers are included in the search.

The search for unpublished studies and gray literature will include:

EThOS, Pearl, Web of Science, Google Scholar, SIGLE

Initial keywords and MeSH terms to be used will be:

1. diabet*
2. diabetes mellitus [MeSH]
3. foot feet
4. neuropath*
5. ulcer*
6. pressure [MeSH]
7. gait
8. walking
9. time
10. offload*
11. off-load*
12. insole*
13. orthos*
14. orthotic devices [MeSH]
15. therapeutic footwear
16. shoes[MeSH]
17. footwear
18. rocker

Assessment of methodological quality

Two independent reviewers (RC / JP) will assess papers selected for retrieval. The reviewers will initially scan the titles and abstracts to exclude papers that do not align with the inclusion criteria. Full text articles will be obtained for papers that meet the inclusion criteria or where uncertainty exists. The full text articles will then be read and those that fulfil the inclusion criteria will be assessed for methodological validity prior to inclusion in the review. Papers selected for retrieval will be assessed using standardized critical appraisal instruments from the Joanna Briggs Institute System for the Unified Management, Assessment and Review of Information (JBI SUMARI) (Appendix I). Any disagreements that arise between the reviewers will be resolved through discussion, or with two other reviewers (JF / JML).

Data extraction

The data will be extracted by two independent reviewers. Data will be extracted from papers included in the review using the standardized data extraction tool from JBI SUMARI (Appendix III). The data extracted will include specific details about the footwear and/or insole design features, populations, study methods and outcomes of significance to the review question and specific objectives. If there is information missing in relevant studies, the corresponding author will be contacted and given the opportunity to clarify the information.

Data synthesis

Quantitative data will, where possible be pooled in statistical meta-analysis using JBI SUMARI. All results will be subject to double data entry. Effect sizes expressed as odds ratio (for categorical data) and weighted mean differences (for continuous data) and their 95% confidence intervals will be calculated for analysis. Heterogeneity will be assessed statistically using the standard Chi-square and also explored using subgroup analyses based on the different study designs included in this review. Where statistical pooling is not possible the findings will be presented in narrative form including tables and figures to aid in data presentation where appropriate.

Conflicts of interest

There is no conflict of interest to declare.

Acknowledgements

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Appendix I: Appraisal instruments

SUMARI Appraisal instrument

JBI Critical Appraisal Checklist for Randomised Control / Pseudo-randomised Trial

Reviewer _____ Date _____

Author _____ Year _____ Record Number _____

	Yes	No	Unclear	Not Applicable
1. Was the assignment to treatment groups truly random?	☐	☐	☐	☐
2. Were participants blinded to treatment allocation?	☐	☐	☐	☐
3. Was allocation to treatment groups concealed from the allocator?	☐	☐	☐	☐
4. Were the outcomes of people who withdrew described and included in the analysis?	☐	☐	☐	☐
5. Were those assessing outcomes blind to the treatment allocation?	☐	☐	☐	☐
6. Were the control and treatment groups comparable at entry?	☐	☐	☐	☐
7. Were groups treated identically other than for the named interventions	☐	☐	☐	☐
8. Were outcomes measured in the same way for all groups?	☐	☐	☐	☐
9. Were outcomes measured in a reliable way?	☐	☐	☐	☐
10. Was appropriate statistical analysis used?	☐	☐	☐	☐
	☐	☐	☐	☐

Overall appraisal: Include ☐ Exclude ☐ Seek further info. ☐

Comments (Including reason for exclusion)

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JBI Critical Appraisal Checklist for Descriptive / Case Series

Reviewer _____ Date _____

Author _____ Year _____ Record Number _____

	Yes	No	Unclear	Not Applicable
1. Was study based on a random or pseudo-random sample?	☐	☐	☐	☐
2. Were the criteria for inclusion in the sample clearly defined?	☐	☐	☐	☐
3. Were confounding factors identified and strategies to deal with them stated?	☐	☐	☐	☐
4. Were outcomes assessed using objective criteria?	☐	☐	☐	☐
5. If comparisons are being made, was there sufficient descriptions of the groups?	☐	☐	☐	☐
6. Was follow up carried out over a sufficient time period?	☐	☐	☐	☐
7. Were the outcomes of people who withdrew described and included in the analysis?	☐	☐	☐	☐
8. Were outcomes measured in a reliable way?	☐	☐	☐	☐
9. Was appropriate statistical analysis used?	☐	☐	☐	☐

Overall appraisal: Include ☐ Exclude ☐ Seek further info ☐

Comments (Including reason for exclusion)

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JBI Critical Appraisal Checklist for Comparable Cohort/ Case Control

Reviewer _____ Date _____

Author _____ Year _____ Record Number _____

	Yes	No	Unclear	Not Applicable
1. Is sample representative of patients in the population as a whole?	☐	☐	☐	☐
2. Are the patients at a similar point in the course of their condition/illness?	☐	☐	☐	☐
3. Has bias been minimised in relation to selection of cases and of controls?	☐	☐	☐	☐
4. Are confounding factors identified and strategies to deal with them stated?	☐	☐	☐	☐
5. Are outcomes assessed using objective criteria?	☐	☐	☐	☐
6. Was follow up carried out over a sufficient time period?	☐	☐	☐	☐
7. Were the outcomes of people who withdrew described and included in the analysis?	☐	☐	☐	☐
8. Were outcomes measured in a reliable way?	☐	☐	☐	☐
9. Was appropriate statistical analysis used?	☐	☐	☐	☐

Overall appraisal: Include ☐ Exclude ☐ Seek further info. ☐

Comments (Including reason for exclusion)

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330 **JBI Critical Appraisal Checklist for Analytical Cross Sectional Studies**

Reviewer _____ Date _____

Author _____ Year _____ Record Number _____

	Yes	No	Unclear	Not applicable
1. Were the criteria for inclusion in the sample clearly defined?	☐	☐	☐	☐
2. Were the study subjects and the setting described in detail?	☐	☐	☐	☐
3. Was the exposure measured in a valid and reliable way?	☐	☐	☐	☐
4. Were objective, standard criteria used for measurement of the condition?	☐	☐	☐	☐
5. Were confounding factors identified?	☐	☐	☐	☐
6. Were strategies to deal with confounding factors stated?	☐	☐	☐	☐
7. Were the outcomes measured in a valid and reliable way?	☐	☐	☐	☐
8. Was appropriate statistical analysis used?	☐	☐	☐	☐

Overall appraisal: Include ☐ Exclude ☐ Seek further info ☐

Comments (Including reason for exclusion)

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JBI Data Extraction Form for Experimental / Observational Studies

Reviewer _____ Date _____

Author _____ Year _____

Journal _____ Record Number _____

Study Method

RCT ☐ Quasi-RCT ☐ Longitudinal ☐

Retrospective ☐ Observational ☐ Other ☐

Participants

Setting

Population

Sample size

Group A _____ Group B _____

Interventions

Intervention A

Intervention B

Authors Conclusions:

Reviewers Conclusions:

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Appendix II: SUMARI Data extraction instruments

Study results

Dichotomous data

Outcome	Intervention ( ) number / total number	Intervention ( ) number / total number

Continuous data

Outcome	Intervention ( ) number / total number	Intervention ( ) number / total number