Effects of foot and ankle devices on balance, gait and falls in adults with sensory perception loss: a systematic review

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EXECUTIVE SUMMARY

Background
Foot and ankle devices are being developed as a method of preventing people with sensory perception loss sustaining a fall. Such devices are believed to work by reducing the likelihood of a fall by improving the balance and gait of the user.

Objectives
The objective of the review was to evaluate the effectiveness of foot and ankle devices for the prevention of falls and the improvement of balance and gait in adults with sensory perception loss.

Inclusion criteria
Types of participants
Participants were community-dwelling adults with bilateral pathological sensory perception loss.

Types of intervention(s)/phenomena of interest
The current review evaluated any foot or ankle device, including but not restricted to, all types of footwear (therapeutic and retail), insoles (customized and prefabricated) and ankle-foot orthoses (AFOs).

Types of studies
In the absence of randomized controlled trials (RCT), the review considered experimental and epidemiological study designs, except case series, individual case reports and descriptive cross-sectional studies.

Outcomes
The primary outcome was number of falls. Secondary outcome measures were clinical or laboratory measures of balance or gait.

Search strategy
A search for published and unpublished literature from inception to March 2015 written in the English language was conducted across a number of major electronic databases. A three-step search strategy was developed using MeSH terminology and keywords to ensure all that relevant materials are captured.

Methodological quality
Methodological quality of included studies was assessed by two reviewers, who appraised each study independently, using standardized Joanna Briggs Institute (JBI) critical appraisal tools.

Data extraction
Quantitative data were extracted from the studies that were identified as meeting the criteria for methodological quality using the standardized JBI data extraction tools.

Data synthesis

Due to the heterogeneity of populations, interventions and outcome measures, meta-analyses were not possible and results are presented in narrative form.

Results

Nine trials (from 10 papers) involving 238 participants, (14 with multiple sclerosis and 16 with idiopathic peripheral neuropathy, 150 with diabetic neuropathy) and 58 controls were included in the review. No study reported falls as an outcome measure. The results of the included studies found that in people with sensory perception loss, postural sway improved with vibrating insoles and AFO, altering the softness and texture of the top cover had no effect on postural sway, wearing footwear over long distances or AFOs improved step-to-step consistency, and no foot and ankle device was reported to have a negative effect on the balance or gait of people with sensory perception loss. The methodological quality of the included studies was poor. No study used a randomized controlled trial (RCT) methodology. No study incorporated a follow-up period or tested the intervention within the context of the intended clinical environment.

Conclusion

There is limited evidence to suggest that footwear and insole devices can artificially alter postural stability and may reduce the step-to-step variability in adults with sensory perception loss. Varying the material properties of an insole does not notably affect static balance or gait.

Keywords Balance; falls; footwear; insoles; neuropathy

Background

Sensory perception loss in the lower limbs is commonly associated with a number of chronic conditions including diabetes, neurological and autoimmune diseases.[1-4] Peripheral neuropathy associated with diabetes is the most common cause of sensory perception loss, affecting up to 50% of individuals with the condition.[4] Altered somatosensory input can have major implications on postural control. At the feet, reduced information about the supporting surface or altered awareness of lower limb positioning can impair the ability to successfully respond to threats to balance. These sensory changes, commonly observed in aging populations, can be accelerated in adults with pathological loss of foot sensation,[3,5] increasing their risk of falls and injury.[6-8]

Falls are a major public health issue for adults with sensory perception loss. In people with diabetes, many of whom present with peripheral neuropathy, up to 39% of those aged over 65 years[8] and 35% of those above 55 years[9] are reported to fall annually. While pathological sensory loss cannot be reversed, one potential modifiable external fall risk factor is the interface between the foot or ankle and supporting surface. Foot and ankle devices including footwear, insoles and ankle-foot orthoses (AFOs) are all modalities that can be manipulated to alter this interface and potentially an individual's propensity to falling. Indeed, several studies show that wearing suboptimal footwear is an influential factor contributing to slips, trips and falls in older people.[10] Notably, inappropriate footwear has been reported in up to 75% of people who experience a fall-related hip fracture.[11]

Foot and ankle devices, including shoe insoles and AFOs have been shown to alter standing balance,[12] gait kinetics and kinematics[12-14] in healthy young,[13] aging,[12] rheumatoid arthritic[15] and diabetic neuropathic[14] populations. While their mechanism of action remains unclear, current theories suggest that footwear interventions may bring about their effects by way of providing mechanical support, shock attenuation and alterations in sensorimotor control, or a combination of all.[16,17] Mechanoreceptors located in the plantar surface of the feet provide important sensory information about changes in the position of foot pressure, which is used to inform maintenance of upright body position. However, plantar sensory thresholds are reduced with increasing age[18,19] and further compromised in those with pathological sensory perception loss.[3,20] As such, a wide range of shoe insole devices have been developed with a view to enhancing residual sensory information at the lower limbs for improving balance control and gait in insensate populations.[21-26] Insoles can be defined as any material construction positioned within a shoe, on which the foot rests.

Insoles can be pre-fabricated or custom-made devices and include a variety of profiles ranging from form-fitting to flat insoles.

To date, three systematic reviews have been conducted addressing the impact of insoles[12,27] and footwear features[10] on measures of balance and falls risk in aging populations, including those with peripheral nervous system disorders.[27] However, despite the major clinical and functional implications of sensory perception loss, the role of footwear interventions in this patient group has not been addressed using systematic review methodology. The prescription of therapeutic footwear and insoles plays a pivotal role in the management of people with peripheral neuropathy, as a means to reduce areas of high plantar pressures and prevent the development of foot ulceration.[28] While this preventative strategy aligns with recommendations from the National Institute for Health and Care Excellence guidelines[29] and a Cochrane review of the data,[30] the potential benefits (or otherwise) of such footwear interventions on balance, gait or falls risk remain unknown.

Laboratory and clinical-based measures of balance and gait have been used to explore the effects of wearing footwear interventions on postural control mechanisms.[12,31-33] During static balance tasks, such as standing quietly in a comfortable position (unperturbed), on a force platform, the magnitude and velocity of center of pressure (COP) movement in mediolateral and anterior-posterior axes have been extracted to quantify the effect of insoles and footwear.[12] Notably, COP velocity is reported to be one of the most sensitive measures in detecting between-condition differences in balance control.[34] Other traditional sway parameters, such as mean speed and amplitude of the COP, have been used in previous trials to predict falls.[35] Clinical assessments of mobility and functional task performance enable clinicians to observe balance control during demanding postural challenges that simulate those encountered in daily life.[36,37] Such balance tests include the functional reach and Berg Balance Scale, with the former reported to be a predictor of falls and sensitive to change following the introduction of an intervention.[38,39] Further, modifications in walking patterns have been associated with falls in aging populations.[40] Older fallers frequently adopt a more conservative gait pattern, showing marked reductions in velocity and step length, increased step width and variability.[41,42] Therefore,

spatiotemporal gait parameters commonly feature as primary outcome measures in studies evaluating the effect of an intervention on falls risk.[12,43,44]

The aim of this review was three-fold. First, the review aimed to highlight balance and gait deficits and falls risk for consideration by healthcare professionals when prescribing foot and ankle devices to people with loss of foot sensation. Second, this review set out to establish the therapeutic benefits (or otherwise) of foot and ankle devices on laboratory and clinical measures of balance, mobility and falls, within clinical populations with sensory perception loss. Third, the results of this review will be used to identify any footwear interventions and design features that have the capacity to alter balance, gait and reduce falls. This knowledge will be used to guide the future prescription and development of foot and ankle devices for people with pathological sensory perception loss. This review was conducted according to an *a priori* published protocol.[45]

Objectives

The primary and secondary objectives of this systematic review were to:

- Synthesize the best available evidence regarding the effects of foot and ankle devices on falls in adults with pathological, bilateral lower limb sensory perception loss.
- Evaluate the effect of foot and ankle devices on the surrogate secondary measures of falls risk, with regard to: (i) gait and (ii) balance in adults with pathological, bilateral lower limb sensory perception loss.
- Generate knowledge to inform the development of a new footwear device for people at increased risk of balance impairments and falls due to loss of foot sensation.

More specifically, the review content provides a summary of current evidence regarding the effect of foot and ankle devices (including therapeutic and retail footwear, pre-fabricated and custom-made insoles and AFO) on fall frequency or incidence, and clinical or laboratory measures of balance and gait, in adults with sensory perception loss.

Inclusion criteria
Types of participants

The current review considered studies that included participants who were community-dwelling adults

over the age of 18 years with bilateral sensory perception loss, defined as being unable to feel a 10 g monofilament at one or more sites on the plantar surface of the foot.[46]

Exclusion criteria

- People with foot ulceration at the time of the study.
- People with unilateral sensory perception loss.
- People from hospitals or care homes.
- People with an upper motor neuron injury (e.g. stroke survivors).
- People with age-related loss of foot sensation that did not originate from pathology.

Types of intervention(s)/phenomena of interest

The current review considered studies that evaluated the effect of any foot or ankle device on balance, gait or falls in adults with sensory perception loss. Foot or ankle devices were defined as any device placed in direct contact with the foot or ankle. This included therapeutic and non-therapeutic footwear, insoles designed to increase mechanical support or afferent sensory feedback, AFO and ankle braces used to restrict joint motion. In this review, studies were included if they presented one of the following comparisons: (i) foot or ankle device was compared to another foot or ankle device or (ii) foot or ankle device was compared to no intervention/control condition.

Studies that included any of the following interventions were excluded from the review:

- Industrial safety footwear.
- AFO that extends to the level of, or beyond, the knee joint.
- Foot ulcer offloading devices.

Outcomes

Studies that reported any measure of falls frequency or incidence were eligible for inclusion in the review. This review also considered studies that included any standardized clinical measures (e.g. Berg Balance Scale,[36] Functional Reach[37]) or laboratory-based assessment (e.g. COP movement[34]) of static or dynamic standing balance. Similarly, studies that measured gait by way of clinical tests (e.g. Timed Up and Go Test,[47] Dynamic Gait Index[48]) or laboratory assessments

(e.g. spatiotemporal gait parameters[41]) were included in the review.

Types of studies

The current review considered experimental and epidemiological study designs including randomized controlled trials, non-randomized controlled trials, quasi-experimental, before and after studies, prospective and retrospective cohort studies, case-control studies and analytical cross-sectional studies. Descriptive epidemiological study designs including case series, individual case reports and descriptive cross-sectional studies were excluded from the review.

Search strategy

The search strategy aimed to find both published and unpublished studies. A three-step search strategy was utilized in this review. An initial limited search of MEDLINE and EMBASE (OVID) was undertaken followed by analysis of the text words contained in the title and abstract, and of the index terms used to describe the articles. A second search using all identified keywords and index terms was undertaken across all included databases. Third, the reference list of all identified reports and articles was searched for additional studies. Studies published in the English language and published from inception to March 2015 were considered for inclusion in this review.

The sources to be searched includes:

MEDLINE, Embase (OVID), CINAHL, AMED (EBSCO), The Cochrane Central Register of Controlled Trials and the Joanna Briggs Institute (JBI) Database of Systematic Reviews and Implementation Reports.

The search for unpublished studies included:

Google Scholar, a thesis database (http://www.thesis.com), BIOSIS, Zetoc (http://zetoc.jisc.ac.uk.plymouth.idm.oclc.org/wzgw?db=etoc) and EThOS.

Initial MESH and key terms that were used were related to foot orthosis and insoles, footwear and shoes, ankle foot orthosis and ankle braces, postural balance and body sway, gait and walking pattern, stabilising and destabilising, accidental falls, older persons, nervous system disorders, diabetes and neuropathy.

An example of a full search strategy used in a major database is provided in Appendix I.

Method of the review

All studies selected for retrieval were assessed by two independent reviewers for methodological validity prior to inclusion in the review. A list of the full-text articles that were assessed for eligibility can be found in Appendix II. Each paper was assessed using standardized critical appraisal instruments from the Joanna Briggs Institute Meta-Analysis of Statistics Assessment and Review Instrument (JBI-MAStARI) (Appendix III). Where disagreements arose between the reviewers, these were resolved through discussion until agreement was reached. When it was unclear if study participants were assessed as having pathological sensory perception loss, the corresponding author of the article was contacted for clarification. In total, eight authors were contacted and six responded. When no response was received from an author, the corresponding article was excluded.

Data extraction

Quantitative data were extracted from papers included in the review using the standardized data extraction tool from JBI-MAStARI (Appendix IV). The data extracted included specific details about the interventions, populations, study methods and outcomes of significance to the review question and specific objectives.

Data synthesis

Quantitative data analysis by way of statistical pooling was not possible due to the wide and heterogeneous range of study methods and outcome measures used across the included studies. Therefore, the findings of this review are presented in narrative form, with general themes established in the discussion.

Results
Description of studies

The flowchart below (Figure 1) details identification and selection of studies. All citations, abstracts and papers were independently scanned by two investigators (JP and AH). The search produced 231 papers including three duplications. Three additional papers were identified from other sources: two from Google Scholar and one from BIOSIS. Screening by title of the remaining 231 citations excluded 154 records leaving 77 abstracts to screen. From this, 33 potential articles were identified. A further 21 papers were excluded on full-text review. Twelve papers underwent critical appraisal by the two investigators. Two were excluded because of quality issues. A total of 10 papers reporting on nine studies met the inclusion criteria and were included in the review. Appendix II summarizes the details of the retrieved studies, and Appendix V lists the studies that were excluded following assessment of the full-text article, together with the reason for exclusion. The primary reason retrieved studies were excluded from the review was study participants were not identified as having a pathological level of sensory perception loss.

Study characteristics

Study characteristics are reported in Appendix VI. A total of 238 participants (58 controls) were included in nine laboratory-based observational trials, 99 in the intervention group were male and 81 were female.[21,22,24,26,50-55] Two of the 10 articles included publications reporting on the same trial and participant group, and therefore the data contained were merged.[24,54] The number of participants recruited to the intervention group in each study ranged from 11 to 42. The mean (standard deviation) age within treatment groups ranged from 41.8 ± 7.3 to 69.5 ± 14.1 years. Six studies[21,22,26,51,53,55] recruited people with diabetic peripheral neuropathy, one study[50] reported on people with multiple sclerosis and two studies[24,52] used people with sensory perception loss of mixed pathology.

There were four comparisons made to foot and ankle devices including no foot and ankle device[26,50,52-54] barefoot,[51] standard diabetic insole[55] and the intervention (vibrating) insole turned off.[21,22] Five studies[21,22,26,50,56] reported testing various insole designs/concepts including insoles that vibrated,[21,22] insoles with a rough top surface (sandpaper),[50] offloading molded insoles with a novel anti-shear cover[55] and a comparison of two flat insoles with differing (hard and soft) shore values.[26] Three studies[24,52,53] reported testing AFOs. One offered mechanical support in the medial lateral direction,[24] the other two studies conducted by the same research group tested a single AFO intervention offering minimal ankle support in the sagittal plane but instead was designed to provide sensory stimulation via the shank to the lower leg.[52,53] One study used participants usual footwear as the intervention.[51]
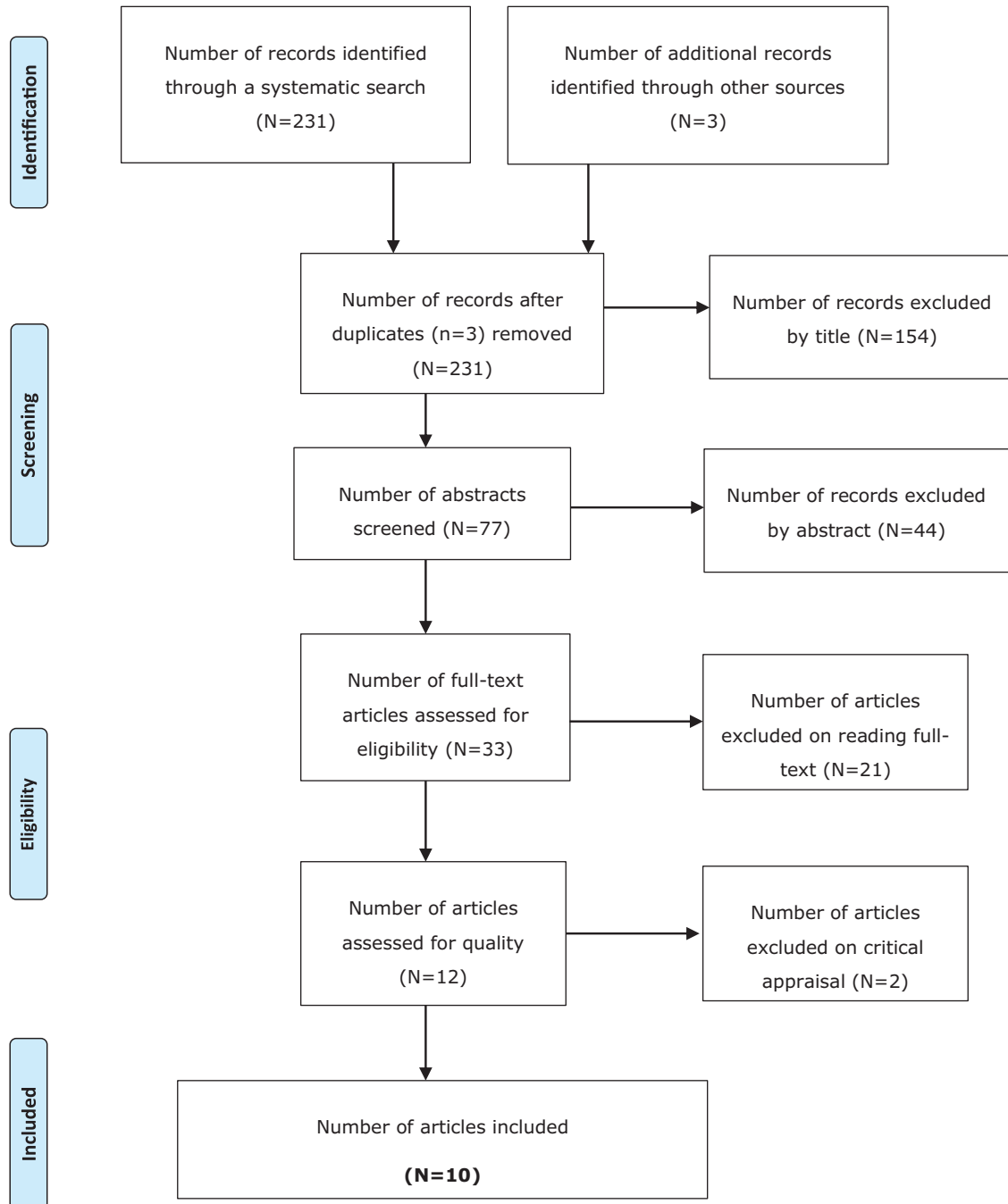
Figure 1: Flowchart of search and study selection process[49]

Table 1: Assessment of methodological quality

Citation	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9
Comparable cohort/case control studies									
Hijmans et al.[22]	Y	Y	Y	Y	Y	N/A	N/A	Y	Y
Kelleher et al.[50]	Y	Y	U	U	Y	N/A	N/A	Y	Y
Najafi et al.[51]	Y	U	Y	Y	Y	N/A	N/A	Y	Y
van Geffen et al.[26]	Y	U	U	Y	Y	N/A	N/A	Y	Y
Priplata et al.[21]	Y	U	U	Y	Y	N/A	N/A	Y	Y
%	100	40	40	80	100	N/A	N/A	100	100
Before and after studies									
Rao and Aruin[52]	U	Y	U	Y	N/A	N/A	N/A	Y	Y
Rao and Aruin[53]	U	Y	Y	Y	Y	N/A	N/A	N	N
Richardson et al.[54]	U	Y	Y	Y	U	N/A	N/A	Y	Y
Richardson et al.[24]	U	Y	Y	Y	Y	N/A	N/A	Y	Y
Wrobel et al.[55]	Y	Y	U	Y	Y	U	N/A	Y	Y
%	20	100	60	100	75	0	N/A	80	80

Detail of the questions included in the JBI-MAStARI critical appraisal checklists can be found in Appendix III.

Methodological quality

Assessment of methodological quality is reported in Table 1. Two studies were rejected after the review of full text because of quality issues. One study[25] used unreliable outcome measures. A second study[57] failed to adequately describe the allocation of the intervention group such that it was difficult to differentiate between participants wearing footwear with those in cast/offloading devices.

None of the studies reported falls as an outcome measure. Instead, five used parameters of balance measured in static stance,[21,22,26,52,53] and four studies used gait kinematic, spatial and temporal measures,[24,50,51,55] with one study including lower limb electromyography (EMG).[50] Parameters of balance included velocity of COP,[22] root mean square of COP velocity,[22,26] stabilogram radius and area,[21] range of COP excursion[21] and sensory organization test.[52,53] The main outcome measures in all studies excluding one were clearly described and recorded in a reliable way using objective assessment tools.[53] All the studies investigated the immediate effect of the foot or ankle device presented in a random order during a single data collection. None of the studies included a follow-up period. None of the studies

reported conducting a priori sample size analysis to recruit sufficient participants to identify a significant difference between groups. In all but one study, the sample size appeared deficient ($n < 40$).[24] While appropriate methods of statistical analysis were selected according to study design, parametric methods were consistently applied to sample sizes better suited to non-parametric analysis.

Five of the included studies were comparable cohort or case-control studies.[21,22,26,50,51] These five studies were conducted using a convenience sample of participants with sensory perception loss, although limited detail was given about the population from which they were drawn. Statistical tests of significance assumed baseline comparability of confounding factors between groups. Four of the five studies[21,22,50,51] attempted to address confounding factors between groups by recruiting a healthy control group that was matched for age and sex. One study recruited a control group of comparatively young (mean age 37 years) males used only as a point of reference and not included in the analysis.[26] Confounding factors between groups in this study were insufficiently addressed. In all studies, comparison of intervention effect was analyzed with the

participant acting as their own control. Blinding of the intervention to participants and researchers was therefore not possible. Four of the studies compared one intervention with a control condition, usually no intervention.[21,22,50,51] One study compared two 8-mm insole interventions (a soft foam insole shore value 15 and a hard multiform insole shore value 30) with the control.[26]

The other four studies were repeated measure studies.[24,52,53,55] Generally, insufficient information was reported regarding the source population of these four studies. All of the studies made clear the criteria for participant inclusion. One of the limitations of pre- and post-intervention design is that blinding to the intervention is not possible.[58] Three of the studies compared one intervention with a no intervention condition.[52,53,55] One study compared three interventions (AFO, walking cane and touching a vertical surface) with a no intervention condition.[24] Only data relating to the effects of the AFO are considered within the scope of this systematic review.

The information reported in all studies was sufficient to make some assessment of study outcome and included a reasonable description of interventions, main outcomes and findings.

Findings of the review

The studies included within this review were too heterogeneous to be combined for meta-analysis. Studies differed in terms of participant characteristics, intervention and outcome measures, therefore findings will be presented in a narrative form. A summary of the results, conclusions and characteristics of included studies can be found in Appendix VI.

Comparison 1: insoles with vibrating component activated versus insoles with vibrating component immobilized

Activated vibrating insoles (turned on) were compared with immobilized vibrating insoles (turned off) for people with diabetes and neuropathy in two studies,[21,22] including 32 people with diabetes and neuropathy and 27 healthy older adults. Both studies measured the effect of the insoles on postural sway. One study recorded mean and maximum stabilogram radius, area and range in the anterior-posterior and medial-lateral direction using a marker attached to the right shoulder, quiet standing with eyes closed only.[21] While the other used force plate stabiliometry to record root mean square COP velocity in anterior-posterior and medial-lateral directions with eyes open, eyes closed and while performing a dual task.[22]

Both studies reported increased sway in people with diabetes and neuropathy when compared to controls. One trial[21] reported a significant reduction in all sway parameters measured with eyes closed in both groups with vibration activated, although absolute values or the size of the difference were not fully reported. The other trial[22] found no difference between insole conditions with the exception of anterior-posterior sway in the group with diabetes and neuropathy. However, this difference was only evident when balance was challenged by simultaneously removing visual cues and diverting attention. Under these test conditions, the root mean square COP velocity in the anterior-posterior direction reduced from 24.3 to 20.4 mm/s when the vibration was activated.[22] Both studies provide evidence that vibrating insoles may reduce sway in people with diabetes and neuropathy when other compensatory balance strategies are compromised.

Comparison 2: insole top cover material type versus standard intervention for people with sensory perception loss

Insole top cover materials with different material properties, for example, softness or texture, were compared with standard offloading insole or no insole condition for people with sensory perception loss in three studies,[26,50,55] including 14 people with multiple sclerosis and sensation loss, 57 people with diabetes and peripheral neuropathy and 10 controls.

One study[50] compared flat shoes without socks while walking with and without fine leather insoles covered with grade p80 wet and dry sandpaper in 14 people with multiple sclerosis and sensory loss. The addition of the rough-textured insole made no difference to gait velocity or cadence, EMG activity or the majority of kinematic gait parameters. A significant increase in ankle joint dorsiflexion, and total hip and knee excursion angle was reported when textured insoles were worn. However, the recorded mean difference between conditions were small (measuring 0.6, 1.4 and 0.8 degrees, respectively).

A second study[26] compared an 8-mm thick foam insole, shore value 15 and a harder 8 mm multiform insole, shore value 30, with a no insole condition in 30 people with diabetes and neuropathy and 10 controls. No more detail about the insole material

tested was published. The authors reported increased anterior-posterior COP velocity in the people with diabetes and neuropathy, and in both groups with eyes closed, but not while performing a dual task. There was no difference in root mean square value of the anterior-posterior velocity of the COP in either group when the no insole, soft and hard insole conditions were compared.

A third study[55] compared a custom-made molded hard Ethylene-vinyl Acetate insole covered in a four-way stretch neoprene rubber and containing a sliding sandwich of silicone at the forepart, with a custom-made standard firm density Plastazote molded insole covered in PPT (a cross-linked polyethylene foam) in 27 people with diabetes and neuropathy. The authors reported on 12 different gait parameters recorded under single and dual task conditions and three static balance measures of sway conducted with eyes open and eyes closed. There was no difference in any of the gait or static balance measures between insoles with the exception of double stance time during gait initiation. Double stance time at gait initiation (defined as the acceleration phase occurring when moving from a standing position to walking) reduced from 32% to 28% of the gait cycle.

There is evidence to suggest that the properties of the top cover material (roughness, softness or horizontal stretch/shift) selected for insole fabrication does not have an effect on the static balance of people with sensory perception loss. There is limited evidence to suggest that roughness and horizontal stretch/shift of the top cover may alter a minority of specific gait parameters, although any reported detectible change appeared small, inconsistent and unpredictable.

Comparison 3: regular footwear versus barefoot for people with diabetes and neuropathy

A single study[51] compared regular footwear with walking barefoot, in 12 people with diabetes and neuropathy and eight controls matched for age, sex and body mass index. The authors reported on nine different gait parameters recorded while participants walked over short (7 m) and long (20 m) distances. Participants were asked to bring the shoes they wore most often during activities of daily living. Most chose to wear either Oxford type footwear (approximately 40%) or New Balance type footwear (approximately 60%) (personal correspondence with the author). There was no difference in any of the gait parameters when regular footwear was

worn over a short distance. Over the longer distance, the diabetic neuropathic group displayed a significantly greater double support time (20%) when compared to the elderly control group. The was no significant difference in any of the gait parameters when regular footwear was worn over a long distance with the exception of coefficient of variation of gait velocity. Over the longer distances, wearing shoes reduced the coefficient of variation of gait velocity in people with diabetes and neuropathy by 46% to a similar level to that seen in the controls when tested wearing shoes. There is limited evidence to suggest that wearing footwear over long distances increases the consistency of step-to-step velocity in people with diabetes and neuropathy to a level similar to that seen in elderly healthy people.

Comparison 4: ankle-foot orthosis versus no intervention for people with sensory perception loss

Ankle-foot orthosis was compared to no intervention in 65 people with peripheral neuropathy in three studies[24,52,53] reported in four publications.[24,52-54] Participants were diagnosed with a range of underlying long-term conditions; 49 were diagnosed with diabetes, nine suffered idiopathic sensory loss, three had connective tissue disease, two had neuropathy originating from the toxic effect of medication, one was diagnosed with hypothyroidism and one had a family history of neuropathy.

One study[52] compared a plastic semi-flexible sagittal plane AFO with no intervention in 11 people with sensory perception loss, seven of whom were diagnosed diabetic. The authors measured balance using the specifically designed dynamic postural system (EquiTest NeuroCom International Inc). The authors reported that the sensory organization scores calculated by the system significantly improved when the AFO was worn by 13% standing with eyes open, 35% standing with eyes closed, 39% standing on a rotating platform with eyes open and 59% standing on a rotating platform with eyes closed.

In a second study,[53] the same research team appeared to repeat their 2006 study with a group of 12 people with diabetes and neuropathy. The authors reported that the sensory organization scores calculated by the dynamic postural system improved significantly with eyes closed but not with eyes open. The improvement recorded when the AFO was worn when standing on a static platform

with eyes closed was 2%. The improvement recorded when the AFO was worn when standing on the rotating platform with eyes closed was 80%.

A third study[24] compared a medial-lateral AFO with no intervention in 42 people with peripheral neuropathy, (30 with diabetes) while walking over irregular terrain under low-light conditions. The authors reported a significant reduction in step width range (-28.4 mm), step width variability (-3.8 mm) and step time variability of (0.024 s) when the AFO was worn. Standard deviation (SD) was used as a measure of variability. However, it is unclear if the calculation was based on the SD of the total group score or the range of SDs taken from individual scores.

In a separate publication,[54] the same research team presents secondary analysis from their previous 2004 study using a sub-sample of 20 females. The authors reported that step length, as a fraction of body height, increased in this sub-group by 0.007 ($P < 0.001$) of 20 females when the AFO was worn. Comparisons of step length for the original total sample were not reported.

There is limited evidence to suggest that static balance and perturbed balance of people with sensory perception loss improves when a semi-flexible plastic sagittal plane AFO is worn; this improvement was greater when visual cues were removed. Evidence to suggest that medial-lateral AFO reduces step-to-step variability and increases step length of people with sensory perception loss is very weak.

Discussion

The aim of this review was to highlight balance and gait deficits, and falls risk as a consideration for healthcare professionals prescribing foot and ankle interventions to people with pathological loss of foot sensation. The review sought to establish the therapeutic benefits of footwear interventions on laboratory and clinical measures of balance, mobility and falls within insensate clinical populations. The results of this review were intended to inform the direction of the development of new interventions designed to enhance balance, gait and reduce falls in people with pathological sensory perception loss. Importantly, none of the included studies used the primary outcome (incidence or frequency) of falls as an outcome measure. A total of nine studies[21,22,24,26,50-53,55] reported secondary outcomes of balance and gait to assess the effectiveness of various foot and ankle devices in people with sensory perception loss. The

results of these nine studies imply that while footwear and insole devices have the potential to modify the balance and gait of people with sensory perception loss, varying the softness/hardness of the insole does not appear to have an effect. The results are discussed below.

The effect of foot and ankle devices on people with long-term chronic conditions and sensory perception loss

Four of the studies were designed to include a control group. In all of these studies, baseline balance and gait parameters were abnormal in participants with sensory loss when compared to controls.[21,22,26,51] However, a comparison of intervention effect size between the participant groups within the four studies found the response to be similar (or enhanced within the group with sensory loss), regardless of sensory perception threshold. More specifically, one study failed to detect a change in either participant group,[26] while a second found a comparable significant effect in both groups when the intervention was worn.[21] A further two studies reported a significant change in a single outcome measure for participants with sensory loss but not healthy controls.[22,51]

The majority of studies investigating the effect of foot and ankle devices intended to improve balance or gait, particularly through sensory enhancement, had excluded participants suffering sensory perception loss because the presumed mechanism of action was considered inapplicable.[23,59-62] In the absence of supporting evidence, such studies[59-62] presumed that insensate participants would be unable to detect the "novel" design features (textured covers or vibrating components) intended to enhance sensory feedback and thus render the device ineffective. The findings of this review appear to challenge that rational; conversely it appears that people with sensory perception loss may respond to foot and ankle devices and should be included in future research studies on the topic.

Therapeutic benefits of foot and ankle devices within clinical populations with sensory perception loss

Impairments in balance and gait performance are known risk factors for falls in aging and clinical populations.[35,41,42] Therefore, measures of postural sway during standing tasks, and changes in gait patterns reported by several included studies[34,35,40]

were considered surrogate measures of falls risk and therapeutic benefit in this review.

Change in gait patterns

The large variation in footwear and insole interventions prevented the pooling of study data. However, several of the included studies[24,26,50,51,54,55] investigated the effect of the various interventions on gait performance related measures. Thus, some dialogue about the effect of the devices on parameters of gait for people with sensory perception loss can be made. There is limited evidence that for people with sensory perception loss: (1) the roughness and horizontal stretch/shift of the insole top cover may alter a minority of specific gait parameters (double stance time at gait initiation, some sagittal plane joint angles);[50,55] (2) wearing standard footwear over long distances may increase the consistency of step-to-step velocity to a similar level to that seen in elderly healthy people;[51] and (3) medial lateral AFO may reduce step-to-step variability while increasing step length.[54] When considering the effect of the footwear and insole interventions investigated within these studies, some attention should be directed at the confounding effect of the wide range of host footwear worn by participants during data collection. Insoles worn within footwear cannot work in isolation but instead function in synergy with the footwear within which they are contained. Thus, while most of the trials focused on participants using standardized footwear,[24,26,50,54,55] the large variation in the footwear design between studies prevents any direct comparison of effect or pooling of study data. For example, one study chose the use of leather-lined sandals as the control,[26] to more closely reflect barefoot walking, while another provided athletic shoes with integral mechanical support and plantar cushioning.[24,54] A third study issued all participants with therapeutic extra-depth footwear incorporating a semi-ridged rocker sole[55] (a design feature known to impact upon gait). Yet another study asked participants to bring their own regular footwear to wear during data collection.[51] It is clear that an agreed protocol (including guidance on the standardizing of footwear worn during the investigation of foot and ankle devices) is needed before trial data can be pooled and definitive conclusions made about footwear and insole intervention choice.

While foot and ankle devices (particularly supportive footwear[51] and ankle bracing[24,54]), offering mechanical support, may improve some aspects of gait (e.g. step consistency) which are considered to be relevant to falls risk, the immediate benefit is likely to be marginal. Equally, based on the available evidence it would seem unlikely that people with sensory loss treated with foot and ankle devices would experience any immediate adverse change to their gait pattern, which would render them unsafe. It is possible that the footwear type and/or insole design features investigated (e.g. horizontal stretch/shift of top covers[55]) may be useful in the management of factors other than gait and balance, in people with loss of foot sensation, such as prevention of ulceration, and may be used without compromising gait stability.

Postural sway tests

While different types of foot and ankle orthosis were evaluated separately, an overall conclusion regarding the general effect of ankle and foot devices for people with sensory perception loss on postural sway can be discussed. There is some evidence that for people with sensory perception loss: (1) vibrating insoles may improve static balance when other compensatory balance strategies are compromised (e.g. eyes closed and dual task);[21,22] (2) the properties of the top cover material (roughness, softness or horizontal stretch/shift) selected for insole fabrication does not affect static balance;[21,26,50,55] and (3) a semi-flexible plastic sagittal plane AFO may improve static balance and perturbed balance and that this improvement is greater with visual ques removed.[52,53]

The results suggest that insole design can artificially alter the somatosensory awareness that contributes to the maintenance of postural stability in people with diabetes and neuropathy.[21,22,52] It appears the application of mechanical stimuli, by way of vibratory components,[21,22] have a more definite effect on static balance performance, than insoles that alter only the material composition of the top cover.[26] Thus, it may prove more effective to design insoles that stimulate the plantar receptors that detect vibration rather than those involved with light touch. In addition, the site of somatosensory stimulation may also be an important factor to consider in insole or orthotic design for people with loss of foot sensation. Interventions that extend across both the foot and ankle regions (e.g. AFOs)[52,53] appear to have a more pronounced effect

on balance measures than interventions that target only the plantar surface of the foot. The results of this systematic review suggest that the usefulness of footwear and insole interventions designed to enhance plantar sensory input may become more apparent when the residual sensory systems for balance control are manipulated, for example, by removing vision by closing the eyes. Under such conditions, individuals with loss of foot sensation appear to show greater reliance on and awareness of an altered somatosensory input, possibly as a consequence of induced sensory re-weighting.

Variations in insole design do not appear to have a large or consistent effect on the gait, over short distances, in people with sensory perception loss. The gait pattern is in part dependent on the planning, transmission and response of the descending motor command, confounded by a number of contributing variables including visual acuity, level of motivation and concentration, muscle strength and cognitive function. Thus, it is unsurprising to find the spatial and temporal parameters of gait are not a sensitive measure of the afferent feedback or mechanical support provided by interventions included in this review. There is insufficient evidence within the included studies to determine if the magnitude of effect of foot and ankle devices on balance and gait in people with sensory perception loss is clinically beneficial.

Limitations of the review

The findings of this review were limited because of the small number of studies meeting the inclusion criteria, the poor methodological quality of those studies, the inability to be able to pool the results and the inadequate sample size meaning most studies were underpowered. Moreover, only studies reported in English were included. This may have resulted in the exclusion of studies that were relevant and thus important for this review. Qualitative studies were excluded from the review, and these studies may have been able to contribute to the feasibility aspects of wearing/using the foot and ankle devices.

Conclusion
Implications for practice
Based on the evidence analyzed in the review, the following recommendations are considered important when prescribing foot and ankle devices for people with sensory perception loss. Levels of evidence and grades of recommendation have been assigned to each recommendation according to the JBI levels of evidence (Appendix VII). These recommendations should be interpreted with caution because the information provided by the studies included in this review was insufficient to determine with certainty if the observed effect might be reflected in clinical practice.

- The existing evidence does not reveal any disadvantage to balance or gait from using compliant covers in preference to hard covers for people with sensory perception loss. Thick cushioned covers should still be used on insoles to protect the feet of people at risk of neuropathic foot ulceration without increasing risk of falls (JBI level 3 evidence, Grade B recommendation).
- Foot and ankle devices can improve static balance and consistency of walking of people with sensory perception loss, most probably through a combination of mechanical support and increased somatosensory awareness. However, a clear recommendation regarding device selection cannot be made at this time (JBI level 3 evidence, Grade B recommendation).

Implications for research
The current review has identified several potential areas for future research to advance the development of foot and ankle interventions that enhance balance and gait and reduce falls risk in people with sensory perception loss. These are:

- Based on the available evidence, it is highly plausible that the mechanism by which foot and ankle devices affect the standing balance and gait kinematics of people with sensory perception loss is through a combination of mechanical support and adjustment of sensorimotor control. Thus, both approaches have the potential to play a role in reducing falls risk and should therefore be considered viable for future foot and ankle device development and design.
- The results of this review seem to suggest that the effect of foot and ankle devices on static balance may be enhanced when eyes are closed and people with sensory perception loss are forced to rely more on their somatosensory systems for postural balance control. This observation may have inferences to suggest how insoles might be

utilized as a training aid in the development of balance sensory re-training programs.

All of the included trials have methodological limitations that expose the trial findings to a high risk of bias. All of the trials were pre-clinical lab-based studies designed to test a hypothesis in a single data collection session. This research design precludes the use of falls as an outcome measure, instead forcing researchers to base conclusions on surrogate measures of balance and gait known to be associated with falls risk. None of the trials were of a randomized controlled trial design. Most studies were underpowered. Several studies did not use a control group, and none randomized the intervention or blinded to the procedure. All studies only looked at the immediate effect and most were laboratory-based proof of concept studies.

Despite this, further basic science is warranted to increase our understanding of:

- The pathophysiology of balance impairment and the potential for the manipulation of subsequent postural compensation strategies adopted by people with sensory loss.
- The mechanism of action of different intervention designs to determine which devices are actually bringing about their effects by way of an underlying sensory mechanism, as theorized (e.g. measuring electroencephalogram (EEG) activity and functional magnetic resonance imaging (fMRI) studies).

In addition to making a decision on best practice, interventions need to be tested in robust randomized controlled trials outside of the laboratory and within the clinical setting over an extended follow-up period. To ensure clinical relevance and utility, the follow-up period should be sufficient to capture differences in incidence or frequency of falls and explore aspects of intervention adherence.

Further clinical research is required using sound methodologies that examine different elements such as:

- Comparison of a range of devices with differing mode of action (mechanical support and altered sensorimotor control).
- Longevity, durability and user acceptability of foot and ankle devices.
- Long-term clinical effects of foot and ankle devices.

- Economic and health burden evaluation of footwear intervention.
- Patient perception of changes in fear of falls, balance confidence and quality of life.
- The effectiveness of devices in chronic long-term conditions, for example, people with diabetic sensory neuropathy or multiple sclerosis and groups with different levels of severity of sensory perception loss.

Outcome measures should include incidence or frequency of falls, intervention adherence levels and adverse effects (e.g. skin damage due to prolonged wear of a device). To increase the clinical relevance of clinical trials investigating this topic area and targeting people at increased risk of foot ulceration, a secondary outcome measure of peak pressure reduction as an indicator of foot ulcer risk is recommended.

Acknowledgements

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Appendix I: Search strategy

MEDLINE(Ovid)
Search February 2015
1. foot orthosis/
2. (insole$1 or inlay$1 or insert$1).kw,ti.
3. (footwear or shoe$1).kw,ti.
4. (ankle adj ortho*).mp. or (ankle adj brace).kw,ti. [mp = title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
5. (foot adj ortho*).mp. or (foot adj brace).kw,ti. [mp = title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
6. 1 or 2 or 3 or 4 or 5
7. postural balance/
8. posture.kw,ti.
9. ((body adj sway) or balance).kw,ti.
10. "center of pressure".kw,ti.
11. (stabilising or destabilising).kw,ti.
12. (gait or (walking adj pattern)).kw,ti.
13. 7 or 8 or 9 or 10 or 11 or 12
14. Accidental Falls/
15. "fall*".kw,ti.
16. 14 or 15
17. 13 or 16
18. exp nervous system disorders/
19. (diabet* or neuropath* or "multiple sclerosis" or "parkinsons disease").mp. [mp = title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
20. 18 or 19
21. 6 and 17 and 20

Appendix II: Studies selected for retrieval

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Appendix III: Appraisal instruments

MAStARI appraisal instrument

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)

_ _
_ _
_ _

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)

_ _
_ _
_ _

Appendix IV: Data extraction instrument
MAStARI data extraction instrument

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:
_____
_____
_____

Study results

Dichotomous data

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

Continuous data

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

Appendix V: Excluded studies and reasons for exclusion

1. Bregman D, De Groot V, Van Diggele P, Meulman H, Houdijk H, Harlaar J. Polypropylene ankle foot orthoses to overcome drop-foot gait in central neurological patients: a mechanical and functional evaluation. *Reason for exclusion:* Unable to contact author. Unclear if the three MS participants were neuropathic.

2. Cattaneo D, Marazzini F, Crippa A, Cardini R. Do static or dynamic AFOs improve balance? *Reason for exclusion:* Unable to contact author. participants not obviously tested for neuropathy.

3. Creylman V, Muraru L, Pallari J, Vertommen H, Peeraer L. Gait assessment during the initial fitting of customized selective laser sintering ankle foot orthoses in subjects with drop foot. *Reason for exclusion:* Pathology and therefore any neuropathy unilateral.

4. Dixon J, Hatton A, Robinson J, Gamesby-Iyayi H, Hodgson D, Rome K, Warnett R, Martin D. Effect of textured insoles on balance and gait in people with multiple sclerosis: an exploratory trial. *Reason for exclusion:* Majority of participants were not neuropathic.

5. Dufek J, Neumann E, Hawkins M, O'Toole B. Functional and dynamic response characteristics of a custom composite ankle foot orthosis for Charcot-Marie-Tooth patients. *Reason for exclusion:* Authors contacted: Did not check for sensory perception loss.

6. Farmer S, Pearce G, Whittall J, Quinlivan R, Patrick J. The use of stock orthoses to assist gait in neuromuscular disorders: a pilot study. *Reason for exclusion:* Age range from 14 years. Not neuropathic.

7. Grewal G, Bharara M, Talal R, Talal K, Armstrong D, Najafi B. Diabetic peripheral neuropathy and gait: does footwear modify this association? *Reason for exclusion:* Authors contacted: unable to differentiate data from participants with diabetic peripheral neuropathy wearing footwear and those in cast/offloading sandals. Excluded after critical appraisal as the allocation of the intervention group was unclear.

8. Guillebastre B, Calmels P, Rougier P. Assessment of appropriate ankle-foot orthoses models for patients with Charcot-Marie-Tooth disease. *Reason for exclusion:* No clear identification of pathological sensory loss. Not able to distinguish between neuropathic and non-neuropathic participants.

9. Jenkins M, Almeida Q, Spaulding S, van Oostveen R, Holmes J, Johnson A, Perry S. Plantar cutaneous sensory stimulation improves single-limb support time, and EMG activation patterns among individuals with Parkinson's disease. *Reason for exclusion:* Exclusion criteria not neuropathic.

10. Kalron A, Pasitselsky D, Greenberg-Abrahami M, Achiron. A. Do textured insoles affect postural control and spatiotemporal parameters of gait and plantar sensation in people with Multiple Sclerosis? *Reason for exclusion:* Inclusion criteria less than 5.07 monofilament thus not all participants meet neuropathic criteria.

11. Maki B, Perry S, Norrie R, McIlroy W. Effect of facilitation of sensation from plantar foot-surface boundaries on postural stabilization in young and older adults. *Reason for exclusion:* No pathological sensory perception loss.

12. McLoughlin J, Barr C, Sturnieks D, Lord S, Crotty M. Effect of wearing a dorsiflexion assist orthosis on mobility, perceived fatigue and exertion during the six-minute walk test in people with multiple sclerosis: a randomised cross-over protocol. *Reason for exclusion:* Protocol only. Author contacted; trial has now been completed and published but no measures of foot sensation were taken.

13. McLoughlin J, Lord S, Barr C, Crotty C, Sturnieks D. Dorsiflexion assist orthosis reduces the physiological cost and mitigates deterioration in strength and balance associated with walking in people with multiple sclerosis.
Reason for exclusion: Participants not tested for neuropathy.

14. Perry S, Radtke A, McIlroy W, Fernie G, Maki B. Efficacy and effectiveness of a balance-enhancing insole.
Reason for exclusion: Although vibration perception levels appear normal for elderly people. Not pathological sensory loss.

15. Priplata A, Niemi J, Harry J, Lipsitz L, Collins J. Vibrating insoles and balance control in elderly people.
Reason for exclusion: Not pathological sensation loss. Sensation loss within normal limits for elderly population.

16. Qiu F, Cole M, Davids K, Hennig E, Silburn P, Netscher H, Kerr G. Effects of textured insoles on balance in people with Parkinson's disease.
Reason for exclusion: Author contacted. Participants not assessed for sensation loss.

17. Ramdharry G, Marsden J, Day B, Thompson A. De-stabilizing and training effects of foot orthoses in multiple sclerosis.
Reason for exclusion: Author contacted. Participants not tested for neuropathy.

18. Ramdharry G, Pollard A, Marsden J, Reilly M, Comparing gait performance of people with Charcot-Marie-Tooth disease who do and do not wear ankle foot orthoses.
Reason for exclusion: Unclear if pathological sensation loss: light touch score would suggest neuropathy vibration at hallux would suggest not.

19. Sheffler L, Hennessey M, Knutson J, Naples G, Chae J. Functional effect of an ankle foot orthosis on gait in multiple sclerosis: a pilot study.
Reason for exclusion: Subjects were excluded for absent sensation in the ipsilateral lower limb.

20. Son J, Ashton-Miller J, Richardson J., Do ankle orthoses improve ankle proprioceptive thresholds or unipedal balance in older persons with peripheral neuropathy?
Reason for exclusion: Poor quality: Both reviewers considered outcome measures as unreliable. This study was excluded after critical appraisal.

21. Stevens V, Goodman K, Rough K, Kraft G. Gait impairment and optimizing mobility in multiple sclerosis.
Reason for exclusion: Discussion of the literature.

22. Wegener C, Wegener K, Smith R, Schott C, Burns J. Biomechanical effects of sensorimotor orthoses in adults with Charcot Marie Tooth disease.
Reason for exclusion: Authors contacted not all participants neuropathic.

23. de Morais Barbosa C, Barros Bertolo M, Marques Neto J, Bellini Coimbra I, Davitt M, de Paiva Magalhaes E. The effect of foot orthoses on balance, foot pain and disability in elderly women with osteoporosis: a randomized clinical trial.
Reason for exclusion: Exclusion criteria were reduced tactile and thermal foot sensibility.

Appendix VI: List of study findings/conclusions/characteristics of included studies
MAStARI

Reference	Methods/outcome measure	Participants	Intervention	Findings/conclusions	Notes
Hijmans et al.[22]	Repeated measure random order case comparison study Force plate stabilometry Mean velocity of COP displacement in mm/s Root mean square of anterior posterior and medial lateral COP vel	Group A: People with diabetes and neuropathy. $n = 17$ 8/9 M/F 52.1 years $\pm$ 6 between 40 and 60 years Group B: People without diabetes. $n = 15$ 7/8 M/F 51.8 yrs $\pm$ 5.6 Exclusion Group A: ulceration, amputation unable to stand without an aid, musc disorder, visual impairment Exclusion Group B: DM, monofilament, tuning fork 0	Intervention: Vibrating insoles set at 90% of the tactile threshold for each individual (or maximum amplitude (120 V) where the threshold could not be reached The vibration insoles consist of a cork sole with three built-in piezo-electric elements at MTP1, MTP5 and the heel. The sole was then covered with a thin leather layer Control: Vibrating insoles turned off × 5 60 s trials 1st and 5th with eyes open. Other 3 with 1. Eyes closed 2. Dual task 3. Both presented in random order Vibration turned on for 30 s off for 30 s. Fist 5 s discarded	Both groups sway increased with eyes closed and dual task ($P = 0.01$) Addition of vibration made no diff to non-diabetic group for all conditions Addition of vibration made no diff to diabetic neuropathic group except eyes closed plus dual task when velocity of COP displacement decreased and the root mean square displacement of COP vel AP (not ML) decreased from 24.3 $\pm$ 3.3 to 20.4 $\pm$ 20.4 mm/s ($P = 0.05$) Use of vibration insoles may only be helpful for people with diabetes and neuropathy unable to use other compensatory strategies	A total of 71% of subjects with neuropathy used the max amplitude of vibration (120 V) but not sufficient to reach the sensory detection threshold Participants were below 60 years to guard against sensory loss due to normal aging being a feature of the control group Outcome measures chosen were static measures of balance not necessarily representative of dynamic function Only the immediate effect of the insole on COP measures investigated no longitudinal investigation undertaken Authors contacted to supply mean velocity of COP displacement data not available from the publication. Author replied not able to locate the information

(Continued)					
Reference	**Methods/outcome measure**	**Participants**	**Intervention**	**Findings/conclusions**	**Notes**
Kelleher et al.[50]	Repeated measure random order case comparison study\n\nEMG. kinematic and kinetic parameters during gait\n\nSagittal plane ankle, knee and hip angles\n\nGait velocity (m/s), cadence (steps/min), ground reaction force (N/kg)\n\nEMG activity; tibialis anterior, medial gastrocnemius lateral gastrocnemius soleus (% peak amplitude)	Group A: Fourteen people with either relapsing-remitting or secondary progressive MS and sensation loss. 41.8 ± 7.3. Male to female ratio 4:3\n\nGroup B: Same group without insoles\n\nGroup C: 10 healthy age and weight matched volunteers walking without insoles and used only as a point of reference\n\nMS Participants were included if they could walk 25 ft. in 20 s or less with or without unilateral support\n\nSensation loss threshold was determined using a forced-choice technique at three locations on the plantar aspects of both feet; the heel medial and lateral forefoot. The tactile threshold was defined as the lightest filament that could be felt more than 50% of the time\n\nSensory threshold at medial forefoot: MS group 5.71 ± 0.85, Control group $3.77 = /-0.25$	Intervention: Fine leather insoles with grade p80 wet and dry sandpaper adhered to the top, in flat shoes without socks\n\nControl: No insoles\n\nParticipants walked a distance of 6 m at a self-selected walking velocity. Gait trials were repeated until three trials with a clean strike of the force plate were achieved for each leg with and without insoles. Trials with and without insoles were randomized	There was no significant difference in gait velocity or cadence between groups A and B\n\nThere were no differences between Group A and B in kinematic parameters except an increase in ankle joint dorsiflexion from 13.3 ± 5.3 to 13.9 ± 13.9 degrees ($P < 0.05$), and increase in total knee excursion angle from 67.5 ± 6.1 to 68.9 ± 6.1 degrees ($P = 0.05$) and total hip excursion angle from 42.0 ± 6.5 to 42.8 ± 5.7 degrees ($P < 0.05$)\n\nThere were no differences between Group A and B in EMG activity except an increase in lateral gastrocnemius during the first phase of gait (heel strike to the first peak of vertical GRF) from 25.94 ± 12.95 to 27.93 ± 13.41 and increase in medial gastrocnemius during phase 3 of gait (swing) from 15.19 ± 7.79 to 16.37 ± 8.93 ($P < 0.05$)\n\nThe increase in EMG activity of the shank muscles was non-significant with the exception of lateral gastrocnemius in phase one of gait. Thus the authors conclusions regarding changes in muscle activity with the introduction of a textured insole must be considered with caution\n\nIncrease in sagittal plane joint angles with the introduction of the insole were largely non-significant. Where a significant difference was found the change was small, 2 degrees or less. An insole effect this small may not have clinical relevance and thus must be considered with caution	Unaware if the authors controlled for footwear\n\nThere is only one set of data presented for the control group. The control group data is not used in the analysis but inserted as reference data only. It appears that only no insole data was collected for the control group

	Methods/outcome measure	Participants	Intervention	Findings/conclusions	Notes
(Continued)					
Reference					
Najafi et al.[51]	Repeated measure random order case comparison study 9 gait parameters collected using the LEGSys device 1. Gait initiation velocity, 2. Average stride velocity during steady state walking, 3. Coefficient of variation of stride velocity during steady state walking, 4. Average range of motion of centre of mass during each stride in the Medio-lateral direction, 5. Average range of motion of centre of mass during each stride in the anteroposterior direction 6. Average double support phase as a percentage of stride time 7. Average stride time 8. Average stride length 9. Number of steps required to achieve gait steady state	Group A: Twelve people with diabetes, 66 years ± 12, diagnosed as having diabetes for at least 5 years and neuropathic for at least 3 years as determined by vibratory perception threshold testing (>25 V) and monofilament Group B: Eight recruited from the same outpatients clinic. Age 60 ±6 years. VPT of <25 V. Able to walk 10 min without a walking aid. Matched for age sex and BMI People were excluded with foot ulceration or orthopedic or surgical problems influencing gait or were unable to walk without a waking aid or had history of non-diabetes related peripheral neuropathy	Intervention: Participants regular shoes. Mainly prescribed diabetic shoes according to guideline of prescribed diabetic shoes in USA Control: Barefoot Group B: also were asked to wear their regular shoes. Subjects were asked to bring the regular shoes, they wear most often during activities of daily living but not sandal/flip flop or high heels Most chose to wear either oxford type footwear (approximately 40%) or new balance type footwear (approximately 60%) Participants were asked to walk at a self-selected speed for a short distance 7 m and a long distance 20 m barefoot and in their regular shoes. Each trial was performed twice and the testing order was randomized.	Most differences in barefoot and shoe conditions were comparable between Group A and B Over short walking distances these differences did not reach a level of significance Over a longer distance wearing shoes reduced the coefficient of variation of gait velocity in Group A by 46%, from 4.04 ± 2.2 to 2.2 ±1.3% (P = 0.02) to a level similar to that seen in Group B when tested wearing shoes Over the longer distance double support time was 20% (P = 0.03) greater in group A (barefoot; 25.5 ± 7.0, shoe 26.0 ± 4.9) when compared to Group B (barefoot 20.3 ± 5.1, shoe 20.9 ± 4.9) both with and without shoes Gait unsteadiness may be improved in people with diabetes and neuropathy by wearing shoes This improvement may only be apparent over longer walking distances (>20 m)	Data collected dynamically outside the confines of the gait laboratory Footwear was not standardized but rather participants wore their regular shoes

	Methods/outcome				
Reference	measure	Participants	Intervention	Findings/conclusions	Notes
Priplata et al.[21]	Repeated measure random order case comparison study Postural sway measured using a marker attached to right shoulder used to record shoulder displacement Parameters included mean and max stabilogram radius, area of stabilogram, range of antero-posterior and medial-lateral discursion	Group A; 15 patients with moderate diabetic neuropathy vibration perception threshold between 20 and 40 Hz. (9 female and 6 male age range 38-81 years mean age 60 ± 11years (SD) Group B; 12 healthy elderly subjects from a previous study. (8 female and 4 male age range 68-78 years mean age 73 ± 3 years	Intervention: Viscoelastic silicone insole with pre-sensory threshold vibrating elements turned on Control: Vibrating insoles turned off Participants asked to stand with eyes closed to remove visual cues. 30 s stance. 10 trials 5 with/ without noise 2 min seated break middle of test	Sway parameters decrease with noise ($P < 0.05$) No differential effect between patient groups (people with diabetes and neuropathy and the elderly) Reduction in postural sway during the application of noise appears greater in individuals with larger baseline postural sway Wearing vibrating insoles appears to reduce sway in people with eyes closed even in those with diabetes and moderate sensory perception loss	Participant groups were not matched for age or sex 20-40 V moderate PDN defined by American Diabetes Association Expert Committee. Also exclude patients with severe neuropathy who would have functional loss of peripheral nerve function Reflective marker to the right shoulder unusual method of recording sway. Authors claim that data captured in this way highly correlated with foot centre of pressure displacement data Limited transferability of finding to clinical practice Only eyes closed condition recorded. Effect of insoles with eyes open unknown Insoles not yet designed for in shoe use Detailed data sets and pairwise comparisons not published

(Continued)					
Reference	Methods/outcome measure	Participants	Intervention	Findings/conclusions	Notes
Rao and Aruin[52]	Repeated measure random order case comparison study Static and dynamic balance measured using the dynamic postural system (EquiTest, Neuro-Com International Inc.) This system consists of a series of tests performed on a platform while displacement of the centre of gravity is measured and automatically compared to a database of healthy controls	Group A: Eleven people with sensory perception loss. M/F 6/5. Age 56.1 ± 7.7 years with a range of 46-68 years Mean time since peripheral neuropathy diagnosed 11.0 ± 9.9 years with a range of 1-35 years Seven patients were diabetic, four had neuropathy not associated with diabetes Neuropathy determined using monofilaments applied to three dorsal and two plantar foot zones. Correct detection of light touch by a filament in three out of five trials was considered to be that subjects sensory threshold. Average score for the group 4.6 ± 1.19	Intervention: Ankle-foot orthosis. AFO consisted of a single continuous piece of plastic 4.5 mm thick extending to the sulcus of the toes and 25 mm distal to the fibular head providing auxiliary sensory cures and additional mechanical support Control: No ankle-foot orthosis Sensory organization test 4 tests including eyes open and closed with the platform stationary and rotating in the anterior posterior direction Each test is given a score out of 100. A higher score signifies less sway Motor Control Test 4 tests including medium and large forward and backward perturbations of the platform Latency equals time in milliseconds between the onset of translation and the onset of the subjects active response and the support surface movement and strength, the amount of force generated by each leg during the automatic postural response	All four sensory organization test scores increased when by a significant amount when the AFO was worn (P < 0.01). Standing still with eyes open the score increased from 80.41 ± 5.65 to 91.41 ± 1.12 when the AFO was worn, the increase with eyes closed was 48.86 ± 8.52 to 66.23 ± 7.19. Standing on the rotation platform with eyes open the score increased from 53.00 ± 8.23 to 73.68 ± 5.77 when the AFO was worn, the increase with eyes closed was 20.00 ± 7.2 to 31.90 ± 7.52 There was a significant difference in latency but not muscle strength when the AFO and no AFO conditions were compared Authors suggest that the increase in sensory organization test scores and while wearing the AFO indicates an improvement in static postural balance Furthermore the improvement in latency score suggests a possible improved response to a perturbation	Participants acted as their own controls Changes in strength did not reach statistical significance when the with and without AFO conditions were compared Authors did not appear to test for neuropathy proximal to the foot therefore an assumption is made that sensation is intact in the lower extremity Only immediate effect of AFO investigated Difficult to give scale or meaning to the degree of improvement seen with the addition of the AFO because the apparatus used is unusual and the outcome recorded without recognizable measurement units

(Continued)					
Reference	Methods/outcome measure	Participants	Intervention	Findings/conclusions	Notes
Rao and Aruin[53]	Repeated measures, within-subjects comparison: Sensory organization test and response to platform perturbations, with and without intervention	Group A: Twelve adults with diabetes and peripheral neuropathy. Age 69.5 ± 14.1 years. M/F 9:3 Included with clinically confirmed diabetes, peripheral neuropathy and loss of muscle stretch reflexes. All able to walk independently (with or without assistive device) and stand unassisted for 5 min. No other major medical conditions that can affect balance	Intervention: Ankle-foot orthoses (worn bilaterally) providing auxiliary sensory information to the calf via the shank of the brace and to the middle of the tibia via calf straps but without mechanical support Control: No ankle-foot orthoses Sensory organization test as previously described Motor control test. Data for latency but not strength presented	Post-hoc analysis showed a significant improvement in sensory organization scores with the addition of the AFO when participants were tested standing still with eyes closed (85.29 +/10.97 without AFO, 86.80 ± 0.88 with AFO) and sway referenced support with eyes closed 21.16 ± 6.40 without AFO and 38.29 ± 7.29 with AFO), but not eyes open ($P < 0.05$) There was no significant difference in latency scores when participants wore the AFO ($P = 0.20$) Applying auxiliary sensory information to the calf and tibia appears to improve standing balance in people with diabetic neuropathy with eyes closed, but not with eyes open and does not appear to improve reactive responses to platform perturbations	Participants wore standardized footwear Participants acted as their own controls Changes in strength did not reach statistical significance when the with and without AFO conditions were compared Authors did not appear to test for neuropathy proximal to the foot therefore an assumption is made that sensation is intact in the lower extremity Only immediate effect of AFO investigated Difficult to give scale or meaning to the degree of improvement seen with the addition of the AFO because the apparatus used is unusual and the outcome recorded without recognizable measurement units

			(Continued)		
Reference	Methods/outcome measure	Participants	Intervention	Findings/conclusions	Notes
Richard-son et al.[54]	Repeated measures, within-subjects comparison Step length	Group A: Twenty women with peripheral neuropathy not necessarily of diabetic origin. Mean age 64.5 (SD ± 9.7) years Mean BMI 32.1 ± 6.9 Subgroup of a previous study 2004	Intervention: 10 walking trials (over an irregular surface) wearing a medial/lateral ankle brace. (Active Ankle Systems Inc Louisville. KY) consisting of foam lined shells secured to the medial and lateral aspects of the ankle and lower leg Control: 10 walking trials with no intervention (over a smooth and irregular surface)	Available published data relating to the effect of the AFO is limited to step length as a fraction of body height while walking on irregular surface Step length increased when the AFO was worn from 0.269 ± 0.044 to 0.276 ± 0.045 ($P < 0.001$) The intervention gave lateral ankle support suggesting that greater frontal plane stability allowed step length to increase	The only data presented for the effect of the intervention is for step length. While this was statistically significant, the between-condition difference was very small (question clinical significance) Further analyses were performed to explore correlations between step time variability and step length when using the interventions (on the irregular surface, and smooth [control no interventions] surface) This study compared the ankle brace condition with a walking cane and touching a vertical surface. Analysis of these additional interventions are outside the scope of this review and therefore will not be included Unclear if the AFO was providing sensory function, improved mechanical support or both Participants were not blind to the intervention

	Methods/outcome				
Reference	measure	Participants	Intervention	Findings/conclusions	Notes
Richardson et al.[24]	Repeated measure random order case comparison study Gait parameters including step-width variability and range, step-time variability, and speed Variability measured using SD and range. Mean number of steps between 40 and 50	Group A: 42 people with peripheral neuropathy (20 female) mean age 65.9 (SD ± 9.7) years Mean BMI 32.1 ± 6.9 Peripheral neuropathy was presumed caused by diabetes mellitus ($n = 30$) idiopathic ($n = 5$) connective tissue disease ($n − 3$) toxic effect of medication ($n = 2$) hypothyroidism ($n = 1$) familial ($n = 1$)	Intervention: 10 walking trials (over an irregular surface) wearing a medial/lateral ankle brace. (Active Ankle Systems Inc Louisville. KY) consisting of foam lined shells secured to the medial and lateral aspects of the ankle and lower leg Control: 10 walking trials with no intervention (over a smooth and irregular surface)	When participants wore the AFO step width variability reduced from 41.o ± 1.5 to 37.2 ± 1.3 mm ($P = 0.0024$). Step width range reduced from 192.7 ± 7.4 to 164.3 ±7.4 mm ($P = 0.038$). Step time variability reduced from 0.073 ± 0.005 to 0.049 ± 0.005 s ($P < 0.001$) No significant difference in gait speed with the addition of an AFO The AFO may have improved dynamic balance in the frontal plane	This study compared the ankle brace condition with a walking cane and touching a vertical surface. Analysis of these additional interventions are outside the scope of this review and therefore will not be included Unclear if the AFO was providing sensory function, improved mechanical support or both Participants were not blind to the intervention

	Methods/outcome measure	Participants	Intervention	Findings/conclusions	Notes
Reference					
(Continued)					
Wrobel et al.[55]	Cross-sectional, repeated measures, within subjects comparison (standard insoles vs dynamic foot orthoses) Gait and balance parameters including Gait initiation (steps), stride velocity SV at gait initiation (m/s), SV during steady state (m/s), stride length STL at gait initiation (m) STL (m), gait cycle time GCT at gait initiation (s), GCT (s), centre of mass COM anterior posterior (defined by sacrum range of motion during each stride), COM medial lateral degrees Double stance phase DS at gait initiation (%), DS at gait steady state (%) Gait variability (%)	Group A: 27 subjects with diabetes (type I or type II) and neuropathy presenting for prescription of shoe and insoles fitting. Mean age 65.1 years M/F 52%/48% Participants were included if they had diabetes, peripheral neuropathy and either pre-ulcerative callus or history of foot ulcer	Intervention: Dynamic foot orthoses: With rolling link mechanism at the distal third of the foot to reduce sliding friction and torque at the metatarsal heads in addition to decreasing compressive forces. Rubbatex neoprene rubber top cover with 4-way stretch darlex on both sides. Silicone layer that slides on firm density Ethylene-vinyl Acetate base material lined with ballistic nylon Control: Fabricated using firm density plastazote and PPT bi-lam All subjects given standardized extra depth shoes with semi rigid rocker sole and a lightweight sock Both insoles worn during level-ground walking (single- and dual-task conditions [counting backwards]), tandem stance (eyes open and eyes closed) randomized	There was a significant reduction in double stance at gait initiation when the diabetic insole was compared to the standard insole. 31.6 ± 2.4 with standard insole reducing to 28.3 ± 1.3 with diabetic insole a reduction of -3.3 (10.4%) ($P = 0.05$) The introduction of the diabetic insole showed a non-significant trend toward improved gait parameters when compared with the standard insole There was no difference in balance parameters between insoles with eyes closed Unable to determine how the insoles used in this study affected balance and gait parameters as no baseline (no insole) data published	This study compared new intervention with standard insole to investigate whether the new insole had a destabilizing effect. Thus data for a no insole condition is not recorded Unclear as to the mechanism of action of the dynamic foot orthoses. Freely moving top cover of the DFO could have assisted propulsion and therefore reduced double stance phase. Possible mechanical action. However, authors indicate that the DFOs had a contoured arch which may contribute to this finding. Sensory effect? Only one significant finding out of 24 gait variables (across both tasks): reduced double stance phase during single task gait conditions. $P = 0.05$. To be interpreted with caution Participants not blinded to the insoles. Washout and acclimatization periods given between insoles

(Continued)					
Reference	Methods/outcome measure	Participants	Intervention	Findings/conclusions	Notes
van Geffen et al.[26]	Repeated measures, within-subjects comparison (3 insole/sandal conditions) and Case control, between-subjects comparison Force plate: Root mean square value of the AP velocity	Group A: 30 patients with diabetes mellitus and neuropathy. Mean age 62.5 (SD 11.3) years. M/F 18/12 Excluded: Plantar ulcers, severe visual or cognitive problems unable to stand without support Group B: 10 males with no disease affecting posture Mean age 37yrs SD 7.9	Intervention 1: 8 mm thick, Shore A value, 15 degrees (insoles worn in sandals) Intervention 2: 8 mm think, Shore A value, 30 degrees (insoles worn in sandals) Control: Standardized sandals (1 cm sole thickness, leather lining, 1 cm heel rise) No insole condition Postural stability assessed under all sandal/insole conditions, during quiet double-limb standing: (i) eyes open, no dual task; (ii) eyes closed, no dual task; (iii) eyes open, dual task; (iv) eyes closed, dual task. (Dual task = mental arithmetic) Although first 15 pts tested with soft insole first second 15 pts with hard insole first	DPN higher RMS of the AP velocity than controls Both groups AP velocity increased with EC but not dual task Both group no change in AP velocity when barefoot soft and hard conditions compared Insole softness/hardness made no difference of AP velocity	Patients were not blinded to the insoles Only one COP measure analyzed (AP velocity) – changes may have occurred in the ML direction? Control group were younger than those with diabetic neuropathy Data suggests possible learning effect over the repeated trials Unclear as to whether or not the diabetic patients had prior exposure/use of insoles

AFO, ankle-foot orthosis; AP, anterior posterior; BMI, body mass index; COP, centre of pressure; DFO, dynamic foot orthosis; DM, Diabetes Mellitus; EC, eyes closed; GRF, ground reaction force; ML, medial/lateral; MS, Multiple Sclerosis; MTP, metatarsal phalangeal joint; Musc, Musculoskeletal; PDN, peripheral diabetic neuropathy; RMS, root mean square; SD, standard deviation; Vel, velocity; VPT, vibration perception threshold.

Appendix VII: JBI levels of evidence

Levels of evidence	Feasibility F (1-4)	Appropriateness A (1-4)	Meaningfulness M (1-4)	Effectiveness E (1-4)	Economic evidence
1	Meta-synthesis of research with unequivocal synthesized findings	Meta-synthesis of research with unequivocal synthesized findings	Meta-synthesis of research with unequivocal synthesized findings	Meta-analysis(with homogeneity) of experimental studies (e.g. RCT with concealed randomization) OR. One or more large experimental studies with narrow confidence intervals	Meta-synthesis (with homogeneity) of evaluations of important alternative interventions comparing all clinically relevant outcomes against appropriate cost measurement, and including a clinically sensible sensitivity analysis
2	Meta-synthesis of research with credible synthesized findings	Meta-synthesis of research with credible synthesized findings	Meta-synthesis of research with credible synthesized findings	One or more smaller RCTs with wider confidence intervals OR. Quasi-experimental studies (without randomization)	Evaluations of important alternative interventions comparing all clinically relevant outcomes against appropriate cost measurement, and including a clinically sensible sensitivity analysis
3	(a) Meta-synthesis of text/opinion with credible synthesized findings (b) One or more single research studies of high quality	(a) Meta-synthesis of text/opinion with credible synthesized findings (b) One or more single research studies of high quality	(a) Meta-synthesis of text/opinion with credible synthesized findings (b) One or more single research studies of high quality	(a) Cohort studies (with control group) (b) Case-controlled (c) Observational studies (without control group)	Evaluations of important alternative interventions comparing a limited number of appropriate cost measurement, without a clinically sensible sensitivity analysis
4	Expert opinion	Expert opinion	Expert opinion	Expert opinion, or physiology bench research, or consensus	Expert opinion, or based on economic theory