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Orthotic interventions to improve standing balance in somatosensory loss

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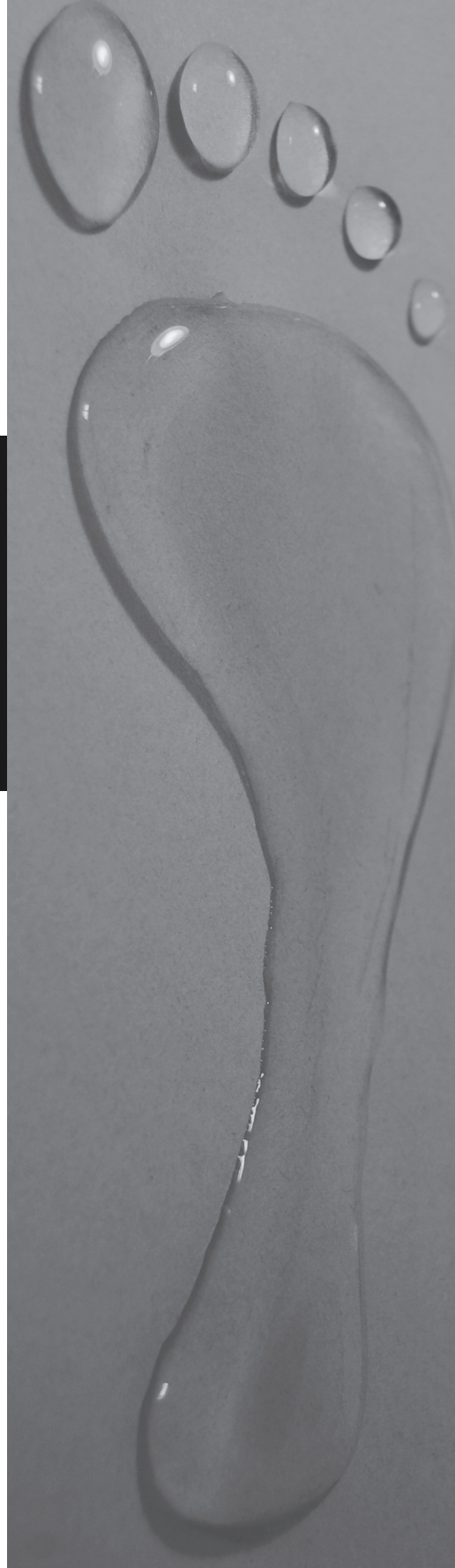
A systematic review of the
effects of shoes and other
ankle or foot appliances on
balance in older people and
people with peripheral
nervous system disorders

2

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ABSTRACT

The objective of this paper is to identify and review all publications on effects ankle and/or foot appliances (AFA) on balance in older people (≥ 60 years) and patients with peripheral nervous system disorders (PNSD). These two groups account for the majority of the population with deteriorated balance due to peripheral somatosensory feedback problems. To provide a context for understanding and interpreting the studies that have been published to date, we will briefly summarize current theories on the role of somatosensory mechanisms in control of balance and how balance can be affected by AFA. A systematic literature review is presented in which publications were searched in Medline, Embase and Recal.

In total 146 papers were identified and 18 were selected based on title and abstract for qualitative assessment by two independent reviewers. Based on assessment of the total articles, seven of the 18 papers fulfilled predetermined qualitative criteria and were selected for detailed review. No definitive conclusions can be drawn concerning the effects of AFA on balance in older people or in patients with PNSD because of the small number of studies and the weak level of evidence. The available literature seems to indicate that a training program may be helpful in ensuring the effectiveness of an appliance. Insoles with tubing or vibrating elements may improve balance, whereas thick or soft soles may deteriorate balance. The effects of these different types of insoles or soles are consistent with theories about somatosensory mechanisms that play a role in control of balance. More and better quality research is needed to support the prevalent use of appliances in these populations.

INTRODUCTION

The focus of this review is on balance in older people and people with peripheral nervous system disorders (PNSD) and on the effects of ankle and/or foot appliances (AFA), such as therapeutic shoes, inlays, and ankle foot orthoses (AFO) on balance. Both older people and people with PNSD (e.g. (diabetic) neuropathies, hereditary motor and sensory neuropathies (HMSN), nerve compression syndromes) show a decline in control of balance, resulting in an increased risk for falling [1–5]. Together, these groups account for the majority of the population with deteriorated balance due to somatosensory feedback problems, without a specific disorder of the central nervous system (CNS). Diabetic neuropathy is the most common PNSD [6]. About one-third of the diabetic population suffers from neuropathy. The incidence increases with both age and disease duration [6]. In older people, about 30% fall at least once a year and about 15% fall more than once a year [7]. Many potential modifiable risk factors for falling are described in literature of which mediolateral sway was the strongest associated with recurrent falls [7]. Mediolateral sway may be improved by AFA, however no data are available concerning the effects of AFA on fall frequency and the number of AFA prescribed yearly.

After an overview of current theories concerning the role of somatosensory mechanisms in control of balance, a systematic review concerning the effects of AFA on balance in older people and people with PNSD will be presented. Based on evidence for the effects of AFA on balance found in the systematic review, the validity of the theories concerning control of balance are discussed.

Somatosensory mechanisms

Several sensory systems play a role in control of balance. The somatosensory, visual and vestibular systems are important in the detection of balance perturbations and control of balance [8]. As part of the somatosensory system, probably both the tactile and the proprioceptive system play a role in balance control. The tactile system provides the CNS with information concerning the sense of touch, detected by Meissner's corpuscles, Pacinian corpuscles, Merkel's disks and Ruffini endings [9]. The proprioceptive system provides the CNS with information concerning joint angles and changes in these angles, detected by muscle spindles, Golgi tendon organs and joint afferents [9].

Tactile stimuli, detected by cutaneous mechanoreceptors in the soles of the feet provide the CNS with information concerning pressure distribution at the soles of the feet [10]. Change in pressure is often related to a change in upright position. Studies in which plantar cutaneous mechanoreceptors are stimulated by a vibration are used to investigate the role of the tactile system [10;11]. When vibratory stimuli are applied to a specific portion of the contact area e.g. one foot, anterior zones of both feet or posterior zones of both feet, the centre of pressure (COP) moves in the opposite direction, therefore, the sole of the

feet can be seen as a “dynamometric map” [10]. However, these vibrations could possibly affect intrinsic foot proprioceptors as well, so the postural responses could be the result of tactile stimuli as well as proprioceptive sensation. On the other hand, if foot sole afferents are anesthetized specifically, without the confounding effect of proprioception, balance is impaired [12]. Therefore, feedback from cutaneous afferents is an important mechanism in the maintenance of balance.

The proprioceptive system provides the CNS with information concerning changes in joint angles. Proprioceptors in muscle spindles, tendons, ligaments and joint capsules play a part in this system [13]. The exact role of the proprioceptive information from the feet and ankles in control of balance and the detection of balance perturbation remains unclear. It seems that proprioceptive information from the legs is not required to trigger most automatic postural responses [14], however proprioceptive training is thought to improve balance due to an improvement of proprioceptive feedback from ankles and feet. A proprioceptive training program cannot specifically target ankle proprioception alone [15]. Therefore, it is questionable that improvement of balance due to proprioceptive training is evidence for the role of ankle proprioception in the control of balance. Despite this lack of evidence, it is stated that balance improves due to the “proprioceptive effects” of an AFO [16]. Possibly normal proprioception from ankle and/or foot plays only a minor role in balance control, but extra proprioceptive input due to the application of an AFO may have a positive effect on balance control. This view is supported by the finding of no significant effects of ankle ligaments anesthesia on joint position sense, whereas, an AFO does have a positive effect on joint position sense [17]. These findings suggest that ankle ligament mechanoreceptors contribute little to ankle joint proprioception and application of an AFO may increase afferent feedback from cutaneous receptors in skin of the ankle, resulting in improved ankle proprioception.

In older people, balance performance deteriorates due to changes in the neural, sensory and musculoskeletal system [18], independent from geriatric pathologies [19]. The sensitivity of foot position declines with age as well, mainly due to decline in plantar tactile sensitivity [20]. Additionally, balance is associated with larger attention demands when people get older [21]. The inability to assign sufficient attention to postural control during dual tasks, seems to contribute to imbalance and falls in this population.

In patients with PNSD, like neuropathy due to diabetes mellitus, both tactile and proprioceptive information is not conducted to the CNS as in healthy people. This loss of sensory perception has detrimental effects on postural stability [1], resulting in an increased risk for falling [2].

Appliances to the ankle and/or foot

Falls in older people are often related to footwear [22;23]. Both a narrow basis of support

and high heels increase the risk for falling. Footwear is a modifiable environmental factor that may play a part in preventing falls. Both tactile and proprioceptive mechanisms can be influenced by therapeutic shoes or shoe modifications, which may result in improvement of balance and a reduced risk for falling [17;24–26]. Greater compression at the ankle may improve balance due to increased feedback from cutaneous receptors in the foot and ankle, improving joint position sense [17;26].

Foot orthoses can have both positive and negative effects on the detection of tactile input from the bottom of the foot. Soft soles can distribute pressure under the soles, which has a positive effect on pain, but it also may result in a deterioration of the detection of pressure changes at the soles, which has a negative effect on balance [27]. In contrast, firm inlays and inlays with tubing at the plantar surface boundaries, may improve balance [18]. Lately some new techniques like randomly vibrating insoles or magnetic insoles that may improve tactile and proprioceptive feedback from the foot and ankle and therefore may improve balance have been described [28;29].

The exact relation between balance and AFA remains unclear. To analyse the evidence concerning the effects of AFA on balance and falls in people with deterioration of somatosensory feedback from ankles and feet (older people and patients with PNSD), a systematic review of literature was performed.

METHODS

To identify publications concerning the effects of AFA on balance or falls in older people or people with PNSD (regardless of age), a search was performed in Medline, Embase, and Recal databases from 1989 until the end of 2004. A search using MESH terms and free text words was performed using search terms related to “shoe”, “foot orthosis”, and “ankle foot orthosis”, “older people” and “PNSD” and “balance” and “fall”. No language restrictions were applied. In Appendix A, the Medline search strategy is presented as an example. Titles and abstracts of the papers identified by these searches were read by the first author. Observational, cross-sectional, case control and cohort studies, case series and randomized controlled trials (RCTs) in which the effects of AFA on balance or falls in older people (age ≥ 60) or patients with a PNSD were assessed, were selected. Also balance studies in which a group of older people or a group of patients with PNSD was compared with another group were selected. Review articles, single-case studies and abstracts, not connected to a full paper, were excluded. The references of the selected papers were examined and the relevant titles published between 1989 and the end of 2004 were added to the initially selected papers.

Subsequently, all papers selected, based on title and abstract, were assessed by two reviewers (JH, JG) independently by examining the whole article on its methodological quality using an assessment form (Table 1). Because no general quality scoring systems for observational

Table 1. Assessment form

| | |
|-----|---|
| 1a) | Are the inclusion criteria described? |
| 1b) | Does the included (sub-)population consist of older people (age of the youngest subject ≥ 60 years)? |
| 1c) | Does the included (sub-)population consist of patients with peripheral nervous system disorders? |
| 2) | Are the exclusion criteria described? |
| 3a) | Does the paper describe prospective research? |
| 3b) | Does the paper describe an observational study? (At least a baseline measurement (T0), an intervention, and a measurement after (or during) the intervention (T1)) |
| 3c) | Are the results of T0 and T1 published? |
| 4) | How many subjects are included? |
| 5a) | Are any measurements performed? (for example: force or movement registration or questionnaire) |
| 5b) | Does at least one of the measurements refer to balance or falling? |
| 6a) | Is an intervention described? |
| 6b) | Does the intervention involve application of an appliance to the foot or ankle? |
| 7) | Are the descriptive statistics concerning gender published? |
| 8) | Are the descriptive statistics concerning age published? |

studies only for RCTs are available, a specific assessment form for quality scoring was developed in line with other quality scoring systems for observational studies [30].

Inter observer agreement between the scores on the assessment form of the two reviewers, was determined by calculating Cohen's Kappa. During a consensus meeting, in which the reviewers compared the results of the assessment procedure, they discussed disagreement until consensus was reached. If consensus could not be reached, a third reviewer (PD) passed a binding judgement. When the answers on question 1a or 2 and 1b or 1c, and 3a, 3b, 3c, 5a, 5b, 6a, 6b, 7 and 8 were positive, the study was included for detailed review.

The methodological value of the included studies was assessed based on the study design and population. This level of evidence, derived from "Oxford Centre for Evidence-based Medicine Levels of Evidence" (May 2001) describes the methodological quality of the study (Table 2).

Table 2. Oxford Centre for evidence-based medicine levels of evidence (May 2001)

| Level of evidence | Study type |
|-------------------|--|
| level 1a | Systematic reviews of RCTs |
| level 1b | RCTs with a narrow confidence interval (large sample size and a homogeneous group) |
| level 2a | Systematic reviews of cohort studies |
| level 2b | Cohort studies and low quality RCTs |
| level 3a | Systematic reviews of case control studies |
| level 3b | Case control studies |
| level 4 | Case series (including poor quality cohort and case control studies) |
| level 5 | Expert opinions |

RESULTS

In Medline, 110 papers were found. In Embase and Recal respectively, 21 and 15 additional papers were found. A flow chart of the literature search is presented in Figure 1. Due to the use of different databases, many duplicate papers were found. In total, 146 papers were identified. Based on title and abstract, 17 papers were selected. One paper [31] was added after examining the references of the selected papers, resulting in 18 papers to be assessed.

Inter observer agreement expressed as Cohen's Kappa was .86 (95% CI: .79–.92). The third independent reviewer passed a binding judgement on one item. Based on the assessments of the reviewers, seven papers were included for detailed review [18;27;29;31–34]. Only one paper described the effects of AFA on balance in patients with PNSD [32]. The other six papers described the effects of AFA on balance in older people [18;27;29;31;33;34]. An outline of the included studies is presented in Table 3.

Two of the 18 selected papers were excluded because no inclusion or exclusion criteria were described [35;36]. Two papers were excluded because people under 60 were included (this was not mentioned in the abstract) [28;37]. One study was excluded because the measurements did not refer to balance or falling [21]. Finally, six papers were excluded based on more than one reason (e.g. wrong population, no inclusion or exclusion criteria, no observational prospective study and no measurements referring to balance or falling) [38–43].

DISCUSSION

Only seven papers met the inclusion criteria for detailed review. One study described the effects of AFA in patients with PNSD and six described these effects in older people. None

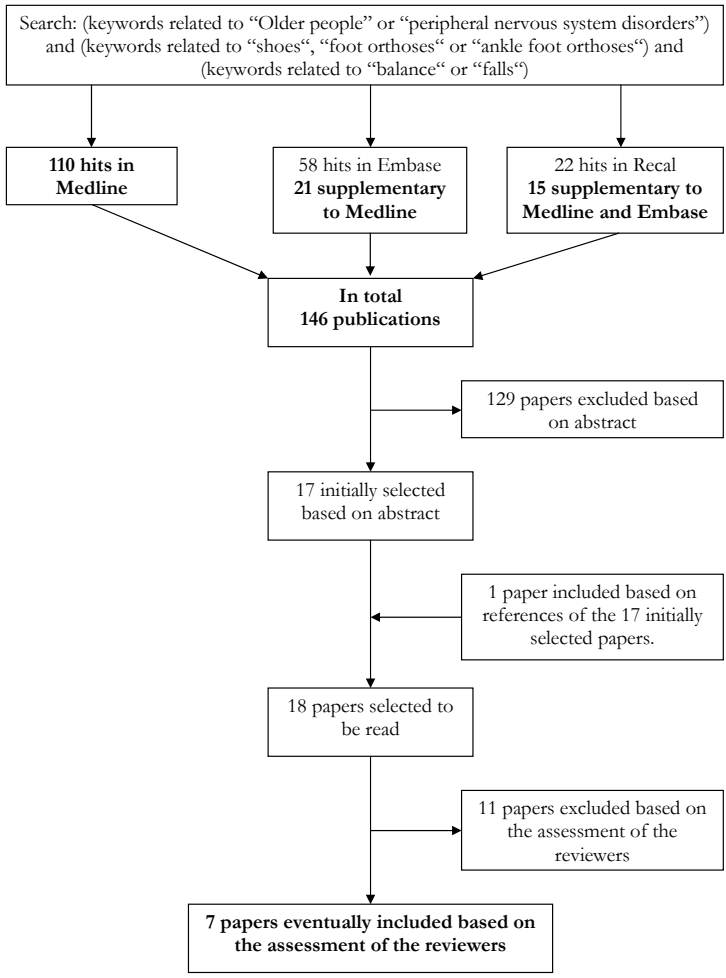


Figure 1. Flowchart of the review process.

of the studies described the effects of AFOs. Therefore, this discussion only accounts for the effects of insoles and shoes on balance. No randomized-controlled trials with large sample sizes were found (largest sample size was 26). Only two studies used follow-up measurements to evaluate the effects of AFA on balance after some weeks or months [32;34]. The results of the included studies cannot be pooled because of the differences in intervention and outcome measurements and the weak level of evidence. Based on the small number of studies and the weak level of evidence of these studies, no definitive conclusions can be drawn about the effects of shoes and insoles on balance in older people and patients with PNSD. The only definitive conclusion that can be drawn is that the quantity and quality of the research on the effects of AFA on balance is low. Only some preliminary conclusions,

Table 3. Outline of the included papers.

| Author | Subjects | Study type and LoE | Intervention | Follow-up | Outcome measures | Conclusions |
|-------------------------------------|--|--|---|-------------------|--|---|
| Peripheral nervous system disorders | | | | | | |
| Geurts, 1992 | 10 patients with HMSN (type I and II); age 12-44 | Case series, LoE 4 | New orthopedic footwear and individual training program | 2-4 months | Velocity and displacements of COP during stance with eyes open, blurred vision, eyes closed and dual task. | Marked loss of balance during dual tasks. After training program this loss did no longer exist. |
| Older people | | | | | | |
| Lindemann, 2002 | 26 older women; age 67-99 | Cross-over, randomized, controlled, LoE 2b | senior sport shoe with 1 or 2 cm heel elevation; 2 hours/day | 5 weeks | Mean velocity of the COP during stance (eyes closed), maximum gait speed and percentage double support time. | No differences in static balance and gait between habitual shoes and senior sports shoes with either 1 or 2 cm heel elevation. |
| Maki, 1999 | 14 older people with moderate insensitivity; age 65-73 & 7 young | Cross-over, controlled, LoE 3b | flexible rubbing, applied to plantar surface boundaries of the feet | immediate effects | Stepping reactions (position and distance) and COP displacements after platform perturbations. | Tubing at the boundaries of the plantar surface of the foot can improve reactions on postural perturbations. |
| Priplata, 2003 | 12 older people; mean age 73 (SD 3) & 15 young | Cross-over, randomized, controlled, LoE 2b | vibrating gel-based insoles | immediate effects | Whole-body postural sway, measured by motion capture of a marker on the right shoulder. | Randomly vibrating insoles could reduce impairments in balance control. |
| Robbins, 1992 | 25 older men; mean age 69 (SD 1.1) & 13 young | Cross-over, randomized, controlled, LoE 2b | shoes with different sole thickness and hardness | immediate effects | Balance failure (number of falls from a beam per 100 m). | Walking with footwear with thick, soft midsoles or barefooted, destabilizes. |
| Robbins, 1997 | 13 older men; mean age 72.6 (SD 4.5) & 13 young | Cross-over, randomized, controlled, LoE 2b | shoes with different sole thickness and hardness | immediate effects | Balance failure (number of falls from beam per 100 m); rearfoot angle; perceived maximal supination. | Foot position awareness declines when shoes with thick and soft midsoles are used. |
| Waked, 1997 | 13 older men; mean age 72.6 (SD 4.5) | Cross-over, randomized, controlled, LoE 2b | shoes with different sole thickness and hardness | immediate effects | Balance failure (number of falls from beam per 100 m); rearfoot angle; perceived maximal supination. | Strong correlation between foot position awareness and stability. Thick and soft soles induce instability and declines foot position awareness. |

HMSN = hereditary motor and sensory neuropathy SD = standard deviation

LoE = level of evidence

COP = center of pressure

based on a low level of scientific evidence can be drawn. These preliminary conclusions should be regarded with caution.

Peripheral nervous system disorders

One study (10 patients) describes the effects of new orthopedic footwear on balance (e.g. COP displacements and velocity) directly after application and after a training period of 2–4 months. A marked loss of sway control in anterior posterior direction before the training program was found due to the application of orthopedic footwear [32]. After the training program, this loss was no longer present. This seems to indicate that a central adaptation process takes place after application of new orthopedic shoes to patients with HMSN, based on the time needed to get used to immobilization of the ankle [32]. During this adaptation process, a temporary increase in attention demands can be expected. An individually tailored training program might facilitate this learning process. Especially in the case that the ankle is immobilized by footwear and a roll-off correction is applied, a switch from ankle strategy towards a hip strategy is needed (because the ankle musculature cannot be used for control of balance when the ankle is immobilized).

Older people

Both the application of mechanical noise to the plantar surface of the feet by vibrating insoles and application of tubing at the plantar surface boundaries of the feet seem to improve balance in older people [18]. Application of vibrating insoles reduced sway due to a proposed mechanism called stochastic resonance. Via this counterintuitive mechanism, mechanical or electrical noise can enhance the detection and transmission of weak signals. The mechanical noise, applied by the vibrating insoles to the soles of the feet can improve the detection of a change in pressure distribution under the soles. Earlier detection results in earlier reaction on a change in upright position, hence in a better control of balance [29]. The insoles with tubing consisting of a sole on which a flexible polyethylene tube with an outer diameter of 3 mm was attached, positioned at the plantar surface boundaries of the feet improved the stepping reactions after platform perturbations based on the facilitation of sensation from the boundaries of the plantar surface [18].

In the studies concerning standardized shoes it appeared that both thick (16–27 mm) and soft (Shore A15) insoles had a negative effect on static and dynamic balance performance, potentially due to the reduced foot position awareness caused by shoes with thick and soft soles [27;31;34]. It should be noted that these standardized shoes may be prescribed because of the positive effects on peak pressure, comfort or prevention or healing of wounds. However, when these standardized shoes are prescribed, the negative effects on balance and the potential increased risk for falling should be taken into account. In contrast to the previously described studies, Lindemann *et al.* (2003) found no effect of shoe sole thickness

on COP [33]. These differences can be caused by the difference in outcome measures. Because no gold standard for measuring balance is available, it is arguable which of the used measures is the best to evaluate the effects of standardized shoes on balance in older people. Additionally, these studies used different interventions. Robbins and Waked compared midsoles with varying thickness and hardness [27;31;34], and Lindemann *et al.* (2003) compared the effects of the differences in heel height [33]. Moreover, the standardized shoe used by Lindemann *et al.* (2003) was a senior sports shoe [33]. Although the shore values (indication of hardness of the sole) of the shoe were not provided, based on the picture and description of the shoes, the soles of the standardized shoe appear soft. A soft sole may cancel out the positive effects of a lower heel.

Theoretically, AFA should aim to improve sensory information by influencing the tactile system and/or the proprioceptive system. Some of the included studies clearly show that improvement of tactile feedback results in improvement of balance and deterioration of tactile feedback results in deterioration of balance and therefore support the theory described in the introduction [18;27;29;31;32].

Facilitation of tactile sensation due to tubing or vibrating insoles improved balance, while worsening of tactile sensation due to the application of soft soles deteriorated balance. In the study on patients with HMSN it became clear that balance can be affected by footwear in a completely other way [32]. Ankle immobilization has a negative effect on balance performance immediately after application because another motor control mechanism (hip strategy instead of ankle strategy) is needed for control of balance.

Balance problems are a major contributor to the risk of falling. Because aging deteriorates balance, the population is growing older and the elderly population is growing, it is likely that greater numbers of people will fall due to difficulties in postural control. Moreover diabetes mellitus is growing in prevalence and many patients with diabetes suffer from peripheral neuropathy, which has a negative effect on balance in people, resulting in increased fall rates. Prevention of these falls may reduce numerous fractures and other trauma. Therefore, if possible, environmental factors should be manipulated in such a way that the chance of falling is reduced. More research is needed to identify these environmental factors of which AFA may be part.

The outcomes of the seven included studies were difficult to compare because many different outcome measures were used to measure balance. One suggestion for future research, in order to facilitate comparisons across studies, an agreed upon general measure for balance, for example COP displacement and velocity, should be used. Specific outcome measures, such as the number of falls from a beam per 100 m, can be ancillary measures, however these should be coupled with a general outcome measure. In only two of the seven included studies, both the immediate and the long term effects of an AFA on balance were assessed.

In future research it is important to investigate both the immediate effects and the effects of AFA when the users had time to get used to the appliance, because the application of an AFA can have a short term destabilizing effect and a long term stabilizing effect.

Important in future research is investigating the effects of AFA step by step. Changing only one of the properties of a standardized shoe instead of comparison with habitual footwear would give more insight in the underlying mechanisms. When a standardized shoe is compared with a habitual shoe, it is difficult to attribute the effects of the intervention to one of the features of the standardized shoe.

This review has shown that more research and development concerning usable AFA that improve balance and reduce falling is needed. Research concerning new appliances, such as those that provide compression at the ankle which may improve proprioception thus resulting in improvement of balance and reduction of fall risk, is essential. Furthermore, extension of current research is needed. A promising development that warrants further exploration is the improvement of plantar sensation by insoles with tubing or vibrating insoles.

Appendix A. Search in Medline (1989–2004).

| | |
|-----|--|
| #1 | explode “Aged”/ all subheadings the thesaurus term is exploded with: <i>Aged, 80 and over</i> <i>Frail Elderly</i> |
| #2 | elder* |
| #3 | older* |
| #4 | explode “Peripheral-Nervous-System-Diseases”/ all subheadings <i>the thesaurus term is exploded with:</i> <i>Acrodynia</i> <i>Amyloid Neuropathies</i> <i>Brachial Plexus Neuropathies</i> <i>Complex Regional Pain Syndromes</i> <i>Diabetic Neuropathies</i> <i>Guillain-Barre Syndrome</i> <i>Isaacs Syndrome</i> <i>Mononeuropathies</i> <i>Nerve Compression Syndromes</i> <i>Neuralgia</i> <i>Neuritis</i> <i>Neurofibromatosis</i> <i>Pain Insensitivity, Congenital</i> <i>Peripheral Nervous System Neoplasms</i> <i>Polyneuropathies</i> |
| #5 | neuropathy |
| #6 | #1 or #2 or #3 or #4 or #5 |
| #7 | “Shoes”/ all subheadings |
| #8 | explode “Orthotic-Devices”/ all subheadings the thesaurus term is exploded with: <i>Braces</i> |
| #10 | foot orthos* |
| #13 | foot orthot* |
| #14 | afo |
| #15 | footwear |
| #16 | shoe* |
| #17 | (#16 in ti) or (#16 in mjme) or(#16 in mime) or (#16 in ab) |
| #18 | inlay* |
| #19 | insole* |
| #20 | #7 or #8 or #10 or #13 or #14 or #15 or #17 or #18 or #19 |
| #21 | “Musculoskeletal-Equilibrium”/ all subheadings |
| #22 | “Posture”/ all subheadings |
| #23 | postur* |
| #24 | balance* |
| #25 | #24 or #23 or #22 or #21 |
| #26 | #6 and #25 and #20 |

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