

University of Groningen

Orthotic interventions to improve standing balance in somatosensory loss

Hijmans, Juha Markus

IMPORTANT NOTE: You are advised to consult the publisher's version (publisher's PDF) if you wish to cite from it. Please check the document version below.

Document Version

Publisher's PDF, also known as Version of record

Publication date:
2009

[Link to publication in University of Groningen/UMCG research database](#)

Citation for published version (APA):

Hijmans, J. M. (2009). *Orthotic interventions to improve standing balance in somatosensory loss*. s.n.

Copyright

Other than for strictly personal use, it is not permitted to download or to forward/distribute the text or part of it without the consent of the author(s) and/or copyright holder(s), unless the work is under an open content license (like Creative Commons).

The publication may also be distributed here under the terms of Article 25fa of the Dutch Copyright Act, indicated by the "Taverne" license. More information can be found on the University of Groningen website: <https://www.rug.nl/library/open-access/self-archiving-pure/taverne-amendment>.

Take-down policy

If you believe that this document breaches copyright please contact us providing details, and we will remove access to the work immediately and investigate your claim.

Downloaded from the University of Groningen/UMCG research database (Pure): <http://www.rug.nl/research/portal>. For technical reasons the number of authors shown on this cover page is limited to 10 maximum.

Orthotic Interventions to Improve Standing Balance in Somatosensory Loss

The publication of this thesis was generously supported by:

Biometrics BV

Centrum voor Revalidatie, Universitair Medisch Centrum Groningen

D.H. Heijne Stichting / Basko Healthcare

Loth Fabenim

OIM Orthopedie

School of Behavioral and Cognitive Neurosciences

Stichting Beatrixoord Noord-Nederland

Hijmans, Juha M.

Orthotic Interventions to Improve Standing Balance in Somatosensory Loss

Dissertation University of Groningen, the Netherlands – With ref. – With
summary in Dutch.



FSC

Mixed Sources

Product group from well-managed
forests, controlled sources and
recycled wood or fibre

Cert no. CU-COC-811465
www.fsc.org

© 1996 Forest Stewardship Council

Printed by: Gildeprint, Enschede

Cover photo: Marleen van Dijk

ISBN: 978-90-367-3794-4

© J.M. Hijmans, Groningen, the Netherlands, 2009.

All rights reserved. No part of this publication may be reproduced or transmitted in any form or by any means, electronical or mechanical, including photocopy, recording or any information storage or retrieval system, without the prior written permission of the copyright owner.

RIJKSUNIVERSITEIT GRONINGEN

Orthotic Interventions to Improve Standing Balance in Somatosensory Loss

Proefschrift

ter verkrijging van het doctoraat in de
Medische Wetenschappen
aan de Rijksuniversiteit Groningen
op gezag van de
Rector Magnificus, dr. F. Zwarts,
in het openbaar te verdedigen op
woensdag 13 mei 2009
om 16.15 uur

door
Juha Markus Hijmans
geboren op 5 december 1978
te Enschede

Promotores : Prof. dr. K. Postema
: Prof. dr. J.H.B. Geertzen

Copromotores : Dr. W. Zijlstra
: Dr. ir. A.L. Hof

Beoordelingscommissie : Prof. dr. J.E.J. Duysens
: Prof. dr. L. Peeraer
: Prof. dr. J.S. Rietman

ISBN : 978-90-367-3794-4

Paranimfen

: Cornelis van de Kamp

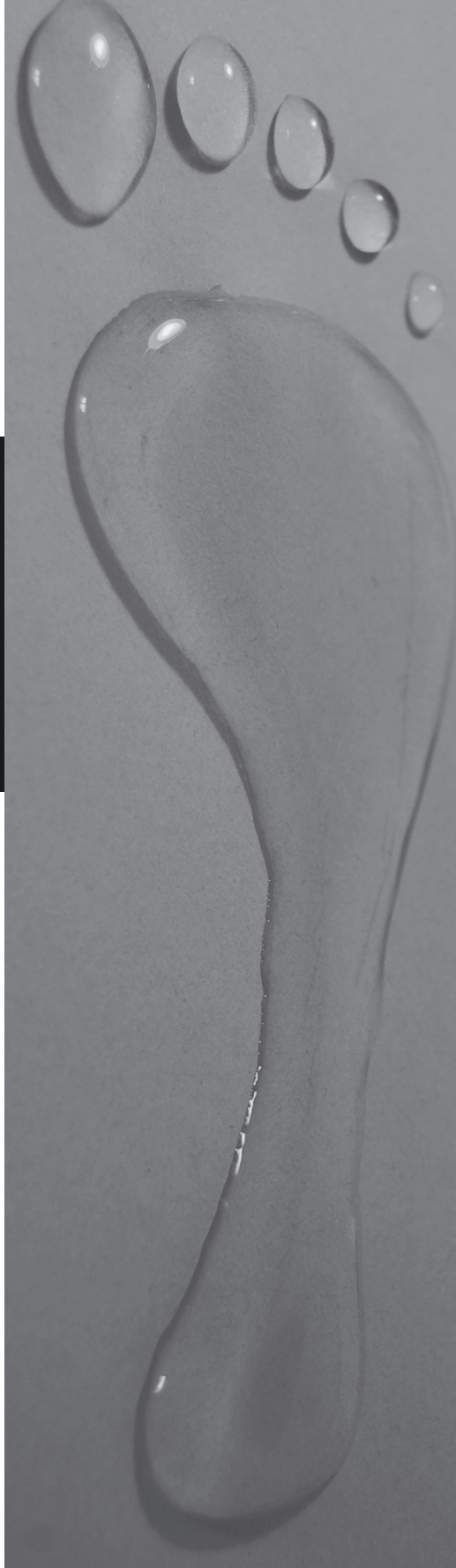
: Sjouke Zijlstra

CONTENTS

Chapter 1	Introduction	9
Chapter 2	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 <i>Gait & Posture 25 (2007) 316–323</i>	23
Chapter 3	Foot and ankle compression improves joint position sense but not bipedal stance in older people <i>Gait & Posture 29 (2009) 322–325</i>	41
Chapter 4	Effects of vibrating insoles on standing balance in diabetic neuropathy <i>Journal of Rehabilitation Research & Development 45 (2008) 1442–1450</i>	55
Chapter 5	Development of vibrating insoles <i>International Journal of Rehabilitation Research 30 (2007) 343–345</i>	73
Chapter 6	Properties of noise to improve standing balance in people with diabetic neuropathy. A single case design <i>Submitted</i>	83
Chapter 7	General discussion	97
	Summary	117
	Samenvatting	123
	Dankwoord	129
	Curriculum Vitae	134
	Publications	135

Introduction

1



INTRODUCTION

Older people and people with peripheral nervous system disorders (PNSD) (e.g. neuropathies, nerve compression syndromes) show a similar decline in the control of posture [1-5]. Both groups are at risk of falling [1]. More than 30% of the older people (over 65 years of age) fall at least once a year and 50% of these fall more than once [6-9]. Diabetic neuropathy (DN) is the most common PNSD [10]. Together, these groups (older people and DN) account for the majority of the population with deteriorated balance due to somatosensory loss, although in older people somatosensory loss is not the only explanation of the deteriorated balance [10;11]. Postural control in people with somatosensory loss is impaired because of decreased tactile and proprioceptive feedback from the lower limbs [1-3]. Possibly, tactile and proprioceptive sensation from the lower limbs can be improved with an orthotic intervention of the ankle and foot. By increasing tactile or proprioceptive sensation from the lower limb, balance is thought to improve concurrently. In this thesis orthotic interventions to improve standing balance in people with somatosensory loss are studied.

Somatosensory loss

Falling in older people is related to increased postural sway, mainly in mediolateral (ML) direction [12;13]. It can be expected that improvement of postural control leads to a decreased risk of falling. Research concerning possibilities to improve balance is therefore of great importance. Balance impairment in older people is a result of degeneration of multiple systems. Mechanical, motor and sensory deteriorations all contribute to balance problems that occur with aging [14;15]. One of the reasons for loss of balance is decreased somatosensory input from the lower limbs [12;16], mainly a result of increased thresholds for fast adapting type II receptors [17].

Diabetes mellitus (DM) leads to the development of DN in about 30% of the cases [10;18;19]. Prolonged disease duration, older age and poor glycemic control lead to an increased chance to develop DN [10;18;19]. Patients with type II DM have a higher risk of developing DN [10]. DN is present in about 50% of patients with type II DM over the age of 60 [10]. The main cause of the DN is axonal degeneration and demyelination. Due to severe microvascular changes a reduced nerve blood flow and consequently reduced oxygenation is present [20]. Some of the symptoms of DN are increased thresholds for joint position sense (JPS), tactile and vibrotactile sensation [21-23]. Large diameter fibres mainly conduct somatosensory information [24;25], however, medium-size afferent fibres seem to play the most important role in standing balance control [26-28]. It has been shown that in DN a range of fibre types can be selectively affected [29;30].

A wide range of diagnostic tools are described in the literature to assess somatosensation in DN, healthy people, and other groups, although disagreement exists about the best measurement to be used [31-38]. Impaired tactile sensation of the plantar surface of the

feet may lead to deteriorated balance, as changes in pressure distribution are detected less accurately [39]. In contrast with older people who have an increased sway mainly in ML direction, in DN this is mainly in anteroposterior direction. Most studies focus on standing balance, which has been shown to deteriorate with the severity of the sensory loss [40]. Balance seems to be less affected during dynamic conditions, possibly due to anticipatory strategies [26].

Postural control

In normal stance, the body is not stationary. Rather, during quiet stance the body is constantly moving with the direction of the movement constantly changing. Postural control refers to maintaining the centre of gravity (CoG) within the base of support (BoS) [41]. CoG in this case is defined as the vertical projection of the centre of mass (CoM) on the support surface [42]. The postural control system has two main functions: first a mechanical antigravity function and secondly it serves as a reference frame for perception and action with respect to the external world [14]. Because in this thesis quiet stance is studied, mainly the first function is referred to. Posture is thought to be controlled by both open loop (without the use of feedback) and closed loop mechanisms (with the use of feedback) [43].

Approximately two thirds of the human body weight is located above two thirds of the body height. Postural control is therefore a challenging task [42;44]. In order to control posture, we rely heavily on our sensory feedback systems. Three main sensory feedback systems can be distinguished for postural control, the visual, vestibular and somatosensory system [43;45]. During normal stance, somatosensory information provides the most sensitive information; standing balance is therefore thought to be controlled mainly by somatosensory information [46-48].

Visual system

The main type of visual information in relation to postural control is the motion of the person or the environment detected by the retina [49]. As the projection of an object increases on the retina, either the object is moving towards the person or the person is moving towards the object [49]. When a person is standing still, yet at the same time moving towards an object, the central nervous system has to react to stop the movement towards the object and change it in a movement in the opposite direction [50]. The importance of the visual system in postural control increases when other sensory systems are impaired [49;51]. Consequently, conflicting visual cues, darkness, or visual impairment results in an even greater loss of balance in conjunction with reduced function of the vestibular or somatosensory system.

Vestibular system

The vestibular organ can be seen as a measuring device for movements of the head in space with six degrees of freedom [52]. It can be divided in two subsystems, the semi-circular and

the otolith system [52]. The otolith system, responsible for the detection of translational accelerations, plays a role in postural control, particularly in the selection of an appropriate postural movement strategy when balance is perturbed and in postural reactions to trunk movements [53-55]. The semi-circular subsystem, responsible for the detection of angular acceleration, is not accurate in detecting low frequency angular accelerations and therefore its role in detecting sway during quiet stance seems to be limited [45]. During quiet stance the role of the vestibular system seems to be limited [56]. This is in line with Mergner's model, suggesting that vestibular information plays only a role in postural control when the support surface is regarded as unstable [52].

Somatosensory system

The somatosensory system plays an important role in postural control [57]. It has been shown that posture can be controlled based on somatosensory information alone [46], and the somatosensory system is thought to be the most automatic feedback system [58]. The somatosensory system can be separated in two parts, the tactile and the proprioceptive system [57;59]. Both play a role in postural control [59].

The tactile system provides the CNS with information concerning the sense of touch. Tactile stimuli, detected by cutaneous mechanoreceptors (Meissner's corpuscles, Pacinian corpuscles, Merkel's disks and Ruffini endings) in the plantar surface of the feet provide the CNS with information concerning pressure distribution [24]. Changes in pressure distribution are often related to changes in upright position.

Studies in which plantar cutaneous mechanoreceptors are stimulated by vibration are used to investigate the role of the tactile system [60;61]. 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 CNS reacts, resulting in movement of the centre of pressure (COP) in the opposite direction. When the afferents in the plantar foot are anesthetized by cooling, ischemic blocking or anesthetics, balance deteriorates, mainly in anteroposterior direction [46;62-71]. It is suggested that plantar sensation plays a role mainly in the magnitude and not the time-dependant structure of sway [64]. With increasing somatosensory loss, balance seems to deteriorate gradually [71]. Moreover, when tactile sensation is improved by peripheral nerve decompression or phototherapy, balance seems to improve [72;73].

The proprioceptive system provides the CNS with information concerning movement and position of body segments. Proprioceptors in muscles, tendons, ligaments and joint capsules (muscle spindles, Golgi tendon organs and joint afferents) play a part in this system [24]. The exact role of the proprioceptive information in control of posture 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 [74]. Balance seems to improve due to the "proprioceptive effects" of an ankle foot orthosis (AFO) [75;76]. It is possible that

normal proprioception from the ankle and foot plays only a minor role in postural control if information from all other sensory systems is available. However, extra proprioceptive input may have a positive effect on postural control when it is impaired [76].

Multisensory integration

Multisensory integration of the sensory systems described above is involved in human postural control [14]. Degeneration of one of the sensory systems used for feedback concerning balance is often compensated [55;69;77]. Therefore, during normal circumstances, the effects of the degeneration of one of the sensory systems might not be apparent. The role of the different sensory systems is re-weighted, with the relative role of the intact systems increased [77-82]. There are limits in compensatory possibilities though. When the compensating systems are challenged (e.g. when it is dark or standing on a soft surface), postural control becomes increasingly difficult, resulting in an increased risk of falling [83].

Attention

Although not a sensory system, attention also plays an important role in postural control [84;85]. Attention can be seen as the information processing capacity of an individual [85]. Research concerning the role of attention in postural control is rather new. The precise role of attention on balance is still not clear. It is known, however, that as people get older or acquire certain pathologies, the attention demands for balance increase. Attentional demands for the control of posture are usually studied using a dual task. When a dual task is presented, the CNS has to use a reasonable part of the information processing capacity for this task, meaning that limited capacity is available for the balance task [85] resulting in a deterioration of balance when this is not fully automated [83].

Manipulation and disorders of the sensory systems

In the literature, two important methods for studying the role of the different systems on balance are described. The first is the manipulation of the system. Vision is easily manipulated by closing the eyes, decreasing the intensity of light, blurring the vision, or by presenting optical illusions [49]. The vestibular system can be manipulated by galvanic vestibular stimulation (GVS) [86-88]. Using GVS the CNS is provided with sway information without the actual presence of sway. In this way the reaction on vestibular detection of sway can be studied. The somatosensory system can be manipulated in different ways. Anesthesia can decrease or eliminate somatosensory feedback from either the plantar surface of the foot, the ankle, or both [46;62-71]. The tactile system can also be manipulated by decreasing tactile input from the plantar surface of the foot by having subjects stand on foam [83;89]. Another method often used to study the role of somatosensation in the control of posture is the application of muscle vibration which can induce a proprioceptive illusion [90]. The CNS receives input about the presence of certain rotation of a limb without the actual occurrence of the rotation. The postural effects of each of these manipulations explain the

relative roles of the different sensory systems.

A second method of studying the role of the different sensory systems on balance is to examine people with specific disorders of one of the systems. Similar to decreasing feedback experimentally, when examining specific patient groups, the effect of the absence of certain feedback can be studied. In this group however, people usually compensate for their sensory loss. When information from one of the systems is decreased or absent, the remaining systems become more important. Therefore, people with vestibular or somatosensory loss depend heavily on visual information for postural control.

In this thesis, the focus will be on balance in people with somatosensory loss and on possibilities to improve balance by enhancing somatosensory feedback with ankle and foot appliances.

Outline of the thesis

In this thesis, first theories and current knowledge concerning the balance improving possibilities of ankle and foot appliances were studied in a review (*Chapter 2*). Promising interventions with balance improve possibilities in people with somatosensory loss were identified. Following, these interventions that have either been shown to be effective or that in theory might be effective to improve balance were further studied. *Chapter 2* presents an overview of theories concerning the role of the somatosensory system on balance followed by a systematic review about the effects of appliances on the ankle and foot on balance in people with somatosensory loss. The research presented in *Chapter 3 to 6*, in which different appliances to the lower limbs were developed and their effects on balance were investigated, was guided by the results from the review. *Chapter 3* describes the effects of ankle and foot compression on JPS and balance. From theories based on previous research in ankle instability, it seems that compression of the ankle and foot may lead to improvement of JPS due to additional tactile information from the skin of the ankle referring to the angle or angular change of the ankle. Improvement of JPS is thought to improve balance only in people with both proprioceptive and balance difficulties, which is often present in older people. In the following chapters, research and development of vibrating insoles is presented. In *Chapter 4* the effects of vibrating insoles on balance in people with DN are tested. Vibrating insoles provide mechanical noise to the plantar foot in order to improve tactile feedback concerning pressure distribution at the plantar surface of the feet. Although noise is usually associated with decreased signal information, in some cases it can improve signal detection. The mechanism behind this is called stochastic resonance, described as a counterintuitive mechanism whereby the addition of noise to a non-linear system can enhance the detection of weak stimuli or enhance the information content of a signal. *Chapter 5* describes the development of vibrating insoles. The most effective mechanical properties, components and configuration are investigated. In *Chapter 6* the most effective

characteristics of the noise signal to improve balance in patients with DN are studied in a single case design. The outcomes of the research presented in this thesis and their impact will be discussed in *Chapter 7*.

REFERENCES

1. Richardson JK, Hurvitz EA. Peripheral neuropathy: A true risk factor for falls. *Journals of Gerontology Series A: Biological Sciences and Medical Sciences* 1995;50(4):M211-M215.
2. Simmons RW, Richardson C, Pozos R. Postural stability of diabetic patients with and without cutaneous sensory deficit in the foot. *Diabetes Research & Clinical Practice* 1997;36(3):153-60.
3. Simoneau GG, Ulbrecht JS, Derr JA, Becker MB, Cavanagh PR. Postural instability in patients with diabetic sensory neuropathy. *Diabetes Care* 1994 Dec;17(12):1411-21.
4. Ducic I, Short KW, Dellon AL. Relationship between loss of pedal sensibility, balance, and falls in patients with peripheral neuropathy. *Annals of Plastic Surgery* 2004 Jun;52(6):535-40.
5. Corriveau H, Prince F, Hebert R, Raiche M, Tessier D, Maheux P, Ardilouze JL. Evaluation of postural stability in elderly with diabetic neuropathy. *Diabetes Care* 2000;23(8):1187-91.
6. American Geriatrics Society. Guideline for the prevention of falls in older persons. *Journal of the American Geriatrics Society* 2001;49(5):664-72.
7. Campbell AJ, Borrie MJ, Spears GF, Jackson SL, Brown JS, Fitzgerald JL. Circumstances and consequences of falls experienced by a community population 70 years and over during a prospective study. *Age & Ageing* 1990;19(2):136-41.
8. Rubenstein LZ. Falls in older people: epidemiology, risk factors and strategies for prevention. *Age & Ageing* 2006;35:ii37-ii41.
9. Horak FB, Shupert CL, Mirka A. Components of postural dyscontrol in the elderly: a review. *Neurobiology of Aging* 1989;10(6):727-38.
10. Young MJ, Boulton AJ, MacLeod AF, Williams DR, Sonksen PH. A multicentre study of the prevalence of diabetic peripheral neuropathy in the United Kingdom hospital clinic population. *Diabetologia* 1993;36(2):150-4.
11. Konrad HR, Girardi M, Helfert R. Balance and aging. *Laryngoscope* 1999;109(9):1454-60.
12. Melzer I, Benjuya N, Kaplanski J. Postural stability in the elderly: a comparison between fallers and non-fallers. *Age & Ageing* 2004;33(6):602-7.
13. Raymakers JA, Samson MM, Verhaar HJ. The assessment of body sway and the choice of the stability parameter(s). *Gait & Posture* 2005;21(1):48-58.
14. Massion J. Postural control system. *Current Opinion in Neurobiology* 1994;4(6):877-87.
15. Speers RA, Kuo AD, Horak FB. Contributions of altered sensation and feedback responses to changes in coordination of postural control due to aging. *Gait & Posture* 2002;16(1):20-30.

16. Richardson JK. Factors associated with falls in older patients with diffuse polyneuropathy. *Journal of the American Geriatrics Society* 2002;50(11):1767-73.
17. Wells C, Ward LM, Chua R, Inglis JT. Regional variation and changes with ageing in vibrotactile sensitivity in the human footsole. *Journals of Gerontology Series A-Biological Sciences & Medical Sciences* 2003;58(8):680-6.
18. Boru UT, Alp R, Sargin H, Kocer A, Sargin M, Luleci A, Yayla A. Prevalence of peripheral neuropathy in type 2 diabetic patients attending a diabetes center in Turkey. *Endocrine Journal* 2004;51(6):563-7.
19. Valensi P, Giroux C, Seeboth-Ghalayini B, Attali JR. Diabetic peripheral neuropathy: effects of age, duration of diabetes, glycemic control, and vascular factors. *Journal of Diabetes Complications* 1997;11(1):27-34.
20. Tesfaye S, Malik R, Ward JD. Vascular factors in diabetic neuropathy. *Diabetologia* 1994;37(9):847-54.
21. Lafond D, Corriveau H, Prince F. Postural control mechanisms during quiet standing in patients with diabetic sensory neuropathy. *Diabetes Care* 2004;27(1):173-8.
22. Lafond D, Mouchnino L, Prince F. Tactile stimulation of insoles and balance control in elderly people. *Lancet* 2004;363(9402):84.
23. Simoneau GG, Derr JA, Ulbrecht JS, Becker MB, Cavanagh PR. Diabetic sensory neuropathy effect on ankle joint movement perception. *Archives of Physical Medicine & Rehabilitation* 1996;77(5):453-60.
24. Bray JJ, Cragg PA, Macknight ADC, Mills RG. *Sensory systems. Human physiology.* Oxford: Blackwell Science; 1999. p. 128-42.
25. Gilman S. Joint position sense and vibration sense: anatomical organisation and assessment. *Journal of Neurology, Neurosurgery & Psychiatry* 2002;73(5):473-7.
26. Nardone A, Grasso M, Schieppati M. Balance control in peripheral neuropathy: are patients equally unstable under static and dynamic conditions? *Gait & Posture* 2006;23(3):364-73.
27. Nardone A, Schieppati M. Group II spindle fibres and afferent control of stance. Clues from diabetic neuropathy. *Clinical Neurophysiology* 2004;115(4):779-89.
28. Nardone A, Tarantola J, Miscio G, Pisano F, Schenone A, Schieppati M. Loss of large-diameter spindle afferent fibres is not detrimental to the control of body sway during upright stance: evidence from neuropathy. *Experimental Brain Research* 2000;135(2):155-62.
29. Heimans JJ, Bertelsmann FW, Van Rooy JC. Large and small nerve fiber function in painful diabetic neuropathy. *Journal of the Neurological Sciences* 1986;74(1):1-9.
30. Oh SJ, Melo AC, Lee DK, Cichy SW, Kim DS, Demerci M, Seo JH, Claussen GC. Large-fiber neuropathy in distal sensory neuropathy with normal routine nerve conduction. *Neurology* 2001;56(11):1570-2.

31. Forouzandeh F, Aziz Ahari A, Abolhasani F, Larijani B. Comparison of different screening tests for detecting diabetic foot neuropathy. *Acta Neurologica Scandinavica* 2005;112(6):409-13.
32. Hurvitz EA, Richardson JK, Werner RA. Unipedal stance testing in the assessment of peripheral neuropathy. *Archives of Physical Medicine & Rehabilitation* 2001;82(2):198-204.
33. Kamei N, Yamane K, Nakanishi S, Yamashita Y, Tamura T, Ohshita K, Watanabe H, Fujikawa R, Okubo M, Kohno N. Effectiveness of Semmes-Weinstein monofilament examination for diabetic peripheral neuropathy screening. *Journal of Diabetes & its Complications* 2005;19(1):47-53.
34. Meijer JW, Smit AJ, Lefrandt JD, van der Hoeven JH, Hoogenberg K, Links TP. Back to basics in diagnosing diabetic polyneuropathy with the tuning fork! *Diabetes Care* 2005;28(9):2201-5.
35. Meijer JW, Links TP, Smit AJ, Groothoff JW, Eisma WH. Evaluation of a screening and prevention programme for diabetic foot complications. *Prosthetics and Orthotics International* 2001;25(2):132-8.
36. Oh SJ, Demirci M, Dajani B, Melo AC, Claussen GC. Distal sensory nerve conduction of the superficial peroneal nerve: new method and its clinical application. *Muscle & Nerve* 2001;24(5):689-94.
37. Onde ME, Ozge A, Senol MG, Togrol E, Ozdag F, Saracoglu M, Misirli H. The sensitivity of clinical diagnostic methods in the diagnosis of diabetic neuropathy. *Journal of International Medical Research* 2008;36(1):63-70.
38. Park TS, Baek HS, Park JH. Advanced diagnostic methods of small fiber diabetic peripheral neuropathy. *Diabetes Research & Clinical Practice* 2007;77:S190-3.
39. Ahmmed AU, Mackenzie IJ. Posture changes in diabetes mellitus. *Journal of Laryngology and Otology* 2003;117(5):358-64.
40. Boucher P, Teasdale N, Courtemanche R, Bard C, Fleury M. Postural Stability in Diabetic Polyneuropathy. *Diabetes Care* 1995;18(5):638-45.
41. Pollock AS, Durward BR, Rowe PJ, Paul JP. What is balance? *Clinical Rehabilitation* 2000;14(4):402-6.
42. Winter DA. Human balance and posture control during standing and walking. *Gait & Posture* 1995;3(4):193-214.
43. Collins JJ, De Luca CJ, Burrows A, Lipsitz LA. Age-related changes in open-loop and closed-loop postural control mechanisms. *Experimental Brain Research* 1995;104(3):480-92.
44. Winter DA, Patla AE, Frank JS. Assessment of balance control in humans. *Medical Progress through Technology* 1990;16(1-2):31-51.
45. Yasuda T, Nakagawa T, Inoue H, Iwamoto M, Inokuchi A. The role of the labyrinth, proprioception and plantar mechanosensors in the maintenance of an upright posture. *European Archives of Oto-Rhino-Laryngology* 1999;256:S27-32.

46. Fitzpatrick R, Rogers DK, McCloskey DI. Stable human standing with lower-limb muscle afferents providing the only sensory input. *Journal of Physiology* 1994;480(2):395-403.
47. Maurer C, Mergner T, Peterka RJ. Multisensory control of human upright stance. *Experimental Brain Research* 2006;171(2):231-50.
48. Vaugoyeau M, Viel S, Amblard B, Azulay JP, Assaiante C. Proprioceptive contribution of postural control as assessed from very slow oscillations of the support in healthy humans. *Gait & Posture* 2008;27(2):294-302.
49. Redfern MS, Yardley L, Bronstein AM. Visual influences on balance. *Journal of Anxiety Disorders* 2001;15(1-2):81-94.
50. Perry SD, Santos LC, Patla AE. Contribution of vision and cutaneous sensation to the control of centre of mass (COM) during gait termination. *Brain Research* 2001;913(1):27-34.
51. Ray CT, Horvat M, Croce R, Mason RC, Wolf SL. The impact of vision loss on postural stability and balance strategies in individuals with profound vision loss. *Gait & Posture* 2008;28(1):58-61.
52. Mergner T, Rosemeier T. Interaction of vestibular, somatosensory and visual signals for postural control and motion perception under terrestrial and microgravity conditions - a conceptual model. *Brain Research - Brain Research Reviews* 1998;28(1-2):118-35.
53. Creath R, Kiemel T, Horak F, Jeka JJ. The role of vestibular and somatosensory systems in intersegmental control of upright stance. *Journal of Vestibular Research* 2008;18(1):39-49.
54. Horak FB, Nashner LM, Diener HC. Postural strategies associated with somatosensory and vestibular loss. *Experimental Brain Research* 1990;82(1):167-77.
55. Parietti-Winkler C, Gauchard GC, Simon C, Perrin PP. Visual sensorial preference delays balance control compensation after vestibular schwannoma surgery. *Journal of Neurology, Neurosurgery & Psychiatry* 2008;79(11):1287-94.
56. Fitzpatrick R, McCloskey DI. Proprioceptive, visual and vestibular thresholds for the perception of sway during standing in humans. *Journal of Physiology* 1994;478(Pt 1):173-86.
57. Jeka J, Oie K, Schoner G, Dijkstra T, Henson E. Position and velocity coupling of postural sway to somatosensory drive. *Journal of Neurophysiology* 1998;79(4):1661-74.
58. Fukuoka Y, Nagata T, Ishida A, Minamitani H. Characteristics of somatosensory feedback in postural control during standing. *IEEE Transactions on Neural Systems and Rehabilitation Engineering* 2001;9(2):145-53.
59. Kavounoudias A, Roll R, Roll JP. Foot sole and ankle muscle inputs contribute jointly to human erect posture regulation. *Journal of Physiology* 2001;532(Pt 3):869-78.
60. Kavounoudias A, Roll R, Roll JP. The plantar sole is a 'dynamometric map' for human balance control. *Neuroreport* 1998;9(14):3247-52.

61. Maurer C, Mergner T, Bolha B, Hlavacka F. Vestibular, visual, and somatosensory contributions to human control of upright stance. *Neuroscience Letters* 2000;281(2-3):99-102.
62. Diener HC, Dichgans J, Guschlbauer B, Mau H. The significance of proprioception on postural stabilization as assessed by ischemia. *Brain Research*;296(1):103-9.
63. Do MC, Bussel B, Breniere Y. Influence of plantar cutaneous afferents on early compensatory reactions to forward fall. *Experimental Brain Research* 1990;79(2):319-24.
64. Hong SL, Manor B, Li L. Stance and sensory feedback influence on postural dynamics. *Neuroscience Letters* 2007;423(2):104-8.
65. Mauritz KH, Dietz V. Characteristics of postural instability induced by ischemic blocking of leg afferents. *Experimental Brain Research* 1980;38(1):117-9.
66. McKeon PO, Hertel J. Diminished plantar cutaneous sensation and postural control. *Perceptual & Motor Skills* 2007;104(1):56-66.
67. Meyer PE, Oddsson LI, De Luca CJ. Reduced plantar sensitivity alters postural responses to lateral perturbations of balance. *Experimental Brain Research* 2004;157(4):526-36.
68. Perry SD, McIlroy WE, Maki BE. The role of plantar cutaneous mechanoreceptors in the control of compensatory stepping reactions evoked by unpredictable, multi-directional perturbation. *Brain Research* 2000;877(2):401-6.
69. Stal F, Fransson PA, Magnusson M, Karlberg M. Effects of hypothermic anesthesia of the feet on vibration-induced body sway and adaptation. *Journal of Vestibular Research* 2003;13(1):39-52.
70. Thoumie P, Do MC. Changes in motor activity and biomechanics during balance recovery following cutaneous and muscular deafferentation. *Experimental Brain Research* 1996;110(2):289-97.
71. Wang TY, Lin SI. Sensitivity of plantar cutaneous sensation and postural stability. *Clinical Biomechanics* 2008;23(4):493-9.
72. Ducic I, Taylor NS, Dellon AL. Relationship between peripheral nerve decompression and gain of pedal sensibility and balance in patients with peripheral neuropathy. *Annals of Plastic Surgery* 2006;56(2):145-50.
73. Powell MW, Carnegie DH, Burke TJ. Reversal of diabetic peripheral neuropathy with phototherapy (MIRE) decreases falls and the fear of falling and improves activities of daily living in seniors. *Age & Ageing* 2006;35(1):11-6.
74. Bloem BR, Allum JH, Carpenter MG, Honegger F. Is lower leg proprioception essential for triggering human automatic postural responses? *Experimental Brain Research* 2000;130:375-91.
75. Feuerbach JW, Grabiner MD, Koh TJ, Weiker GG. Effect of an ankle orthosis and ankle ligament anesthesia on ankle joint proprioception. *American Journal of Sports Medicine* 1994;22(2):223-9.

76. You SH, Granata KP, Bunker LK. Effects of circumferential ankle pressure on ankle proprioception, stiffness, and postural stability: a preliminary investigation. *Journal of Orthopaedic & Sports Physical Therapy* 2004;34(8):449-60.
77. Vuillerme N, Pinsault N. Re-weighting of somatosensory inputs from the foot and the ankle for controlling posture during quiet standing following trunk extensor muscles fatigue. *Experimental Brain Research* 2007;183(3):323-7.
78. Allison LK, Kiemel T, Jeka JJ. Multisensory reweighting of vision and touch is intact in healthy and fall-prone older adults. *Experimental Brain Research* 2006;175(2):342-52.
79. Horak FB, Hlavacka F. Somatosensory loss increases vestibulospinal sensitivity. *Journal of Neurophysiology* 2001;86(2):575-85.
80. Mahboobin A, Loughlin PJ, Redfern MS, Sparto PJ. Sensory re-weighting in human postural control during moving-scene perturbations. *Experimental Brain Research* 2005;167(2):260-7.
81. Oie KS, Kiemel T, Jeka JJ. Multisensory fusion: simultaneous re-weighting of vision and touch for the control of human posture. *Cognitive Brain Research* 2002;14(1):164-76.
82. Vuillerme N, Chenu O, Pinsault N, Boisgontier M, Demongeot J, Payan Y. Inter-individual variability in sensory weighting of a plantar pressure-based, tongue-placed tactile biofeedback for controlling posture. *Neuroscience Letters* 2007 Jun 27;421(2):173-7.
83. Anand V, Buckley JG, Scally A, Elliott DB. Postural stability in the elderly during sensory perturbations and dual tasking: the influence of refractive blur. *Investigative Ophthalmology & Visual Science* 2003;44(7):2885-91.
84. Maki BE, McIlroy WE. Cognitive demands and cortical control of human balance-recovery reactions. *Journal of Neural Transmission* 2007;114(10):1279-96.
85. Woollacott M, Shumway-Cook A. Attention and the control of posture and gait: a review of an emerging area of research. *Gait & Posture* 2002;16(1):1-14.
86. Iles JF, Baderin R, Tanner R, Simon A. Human standing and walking: comparison of the effects of stimulation of the vestibular system. *Experimental Brain Research* 2007;178(2):151-66.
87. Fitzpatrick RC, Day BL. Probing the human vestibular system with galvanic stimulation. *Journal of Applied Physiology* 2004;96(6):2301-16.
88. Horak FB, Earhart GM, Dietz V. Postural responses to combinations of head and body displacements: vestibular-somatosensory interactions. *Experimental Brain Research* 2001;141(3):410-4.
89. Lord SR, Clark RD, Webster IW. Physiological Factors Associated with Falls in An Elderly Population. *Journal of the American Geriatrics Society* 1991;39(12):1194-200.
90. Courtine G, De Nunzio AM, Schmid M, Beretta MV, Schieppati M. Stance- and locomotion-dependent processing of vibration-induced proprioceptive inflow from multiple muscles in humans. *Journal of Neurophysiology* 2007;97(1):772-9.

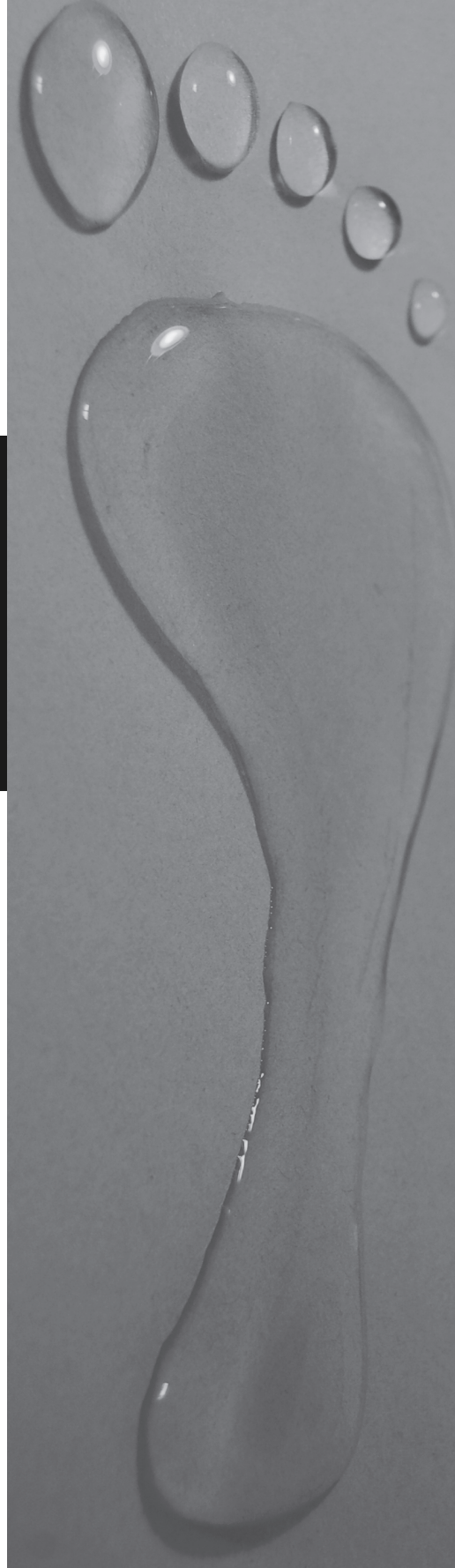
A systematic review of the
effects of shoes and other
ankle or foot appliances on
balance in older people and
people with peripheral
nervous system disorders

2

Juha M. Hijmans
Jan H.B. Geertzen
Pieter U. Dijkstra
Klaas Postema

Gait & Posture 25 (2007) 316–323

Reprinted with kind permission



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

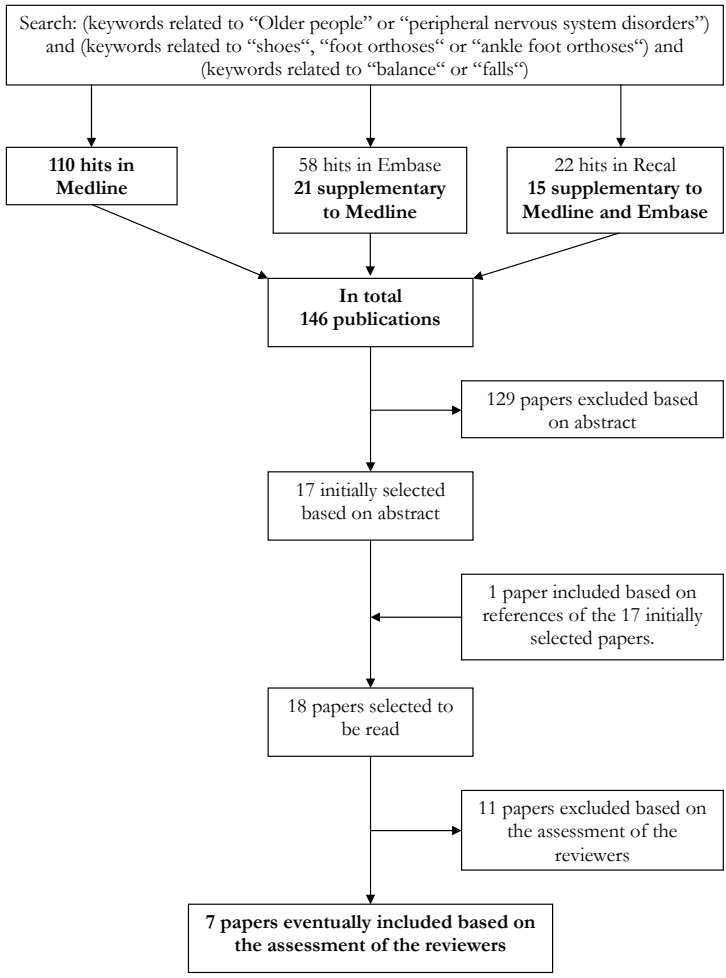


Figure 1. Flowchart of the review process.

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

REFERENCES

1. Simoneau GG, Ulbrecht JS, Derr JA, Becker MB, Cavanagh PR. Postural instability in patients with diabetic sensory neuropathy. *Diabetes Care* 1994;17:1411–21.
2. Richardson JK, Hurvitz EA. Peripheral neuropathy: a true risk factor for falls. *J Gerontol A Biol Sci Med Sci* 1995;50: M211–5.
3. Simmons RW, Richardson C, Pozos R. Postural stability of diabetic patients with and without cutaneous sensory deficit in the foot. *Diabetes Res Clin Pract* 1997;36:153–60.
4. Maki BE, McIlroy WE. Control of compensatory stepping reactions: age-related impairment and the potential for remedial intervention. *Physiother Theory Pract* 1999;15:69–90.
5. Konrad HR, Girardi M, Helfert R. Balance and aging. *Laryngoscope* 1999;109:1454–60.
6. Young MJ, Boulton AJM, Macleod AF, Williams DRR, Sonksen PH. A multicentre study of the prevalence of diabetic peripheral neuropathy in the United Kingdom hospital clinic population. *Diabetologia* 1993;36:150–4.
7. Stel VS, Smit JH, Pluijijm SMF, Lips P. Balance and mobility performance as treatable risk factors for recurrent falling in older persons. *J Clin Epidemiol* 2003;56:659–68.
8. Maurer C, Mergner T, Bolha B, Hlavacka F. Human balance control during cutaneous stimulation of the plantar soles. *Neurosci Lett* 2001; 302:45–8.
9. Bray JJ, Cragg PA, Macknight ADC, Mills RG. *Human physiology* Oxford: Blackwell Science; 1999.
10. Kavounoudias A, Roll R, Roll JP. The plantar sole is a ‘dynamometric map’ for human balance control. *Neuroreport* 1998;9:3247–52.
11. Maurer C, Mergner T, Bolha B, Hlavacka F. Vestibular, visual, and somatosensory contributions to human control of upright stance. *Neurosci Lett* 2000;281:99–102.
12. Meyer PF, Oddsson LI, De Luca CJ. The role of plantar cutaneous sensation in unperturbed stance. *Exp Brain Res* 2004;156:505–12.
13. Bloem BR, Allum JH, Carpenter MG, Verschuuren JJ, Honegger F. Triggering of balance corrections and compensatory strategies in a patient with total leg proprioceptive loss. *Exp Brain Res* 2002;142: 91–107.
14. Bloem BR, Allum JH, Carpenter MG, Honegger F. Is lower leg proprioception essential for triggering human automatic postural responses? *Exp Brain Res* 2000;130:375–91.
15. Chong RK, Ambrose A, Carzoli J, Hardison L, Jacobson B. Source of improvement in balance control after a training program for ankle proprioception. *Percept Mot Skills* 2001;92:265–72.
16. Baier M, Hopf T. Ankle orthoses effect on single-limb standing balance in athletes with functional ankle instability. *Arch Phys Med Rehabil* 1998;79:939–44.

17. Feuerbach JW, Grabiner MD, Koh TJ, Weiker GG. Effect of an ankle orthosis and ankle ligament anesthesia on ankle joint proprioception. *Am J Sports Med* 1994;22:223–9.
18. Pyykko I, Jantti P, Aalto H. Postural control in elderly subjects. *Age Ageing* 1990;19:215–21.
19. Camicioli R, Panzer VP, Kaye J. Balance in the healthy elderly: posturography and clinical assessment. *Arch Neurol* 1997;54:976–81.
20. Robbins S, Waked E, McClaran J. Proprioception and stability: foot position awareness as a function of age and footwear. *Age Ageing* 1995;24:67–72.
21. Shumway-Cook A, Woollacott M. Attentional demands and postural control: the effect of sensory context. *J Gerontol A Biol Sci Med Sci* 2000;55:M10–6.
22. Brecht JS, Chang MW, Price R, Lehmann J. Decreased balance performance in cowboy boots compared with tennis shoes. *Arch Phys Med Rehabil* 1995;76:940–6.
23. Menz HB, Lord SR. Footwear and postural stability in older people. *J Am Podiatr Med Assoc* 1999;89:346–57.
24. Maki BE, Perry SD, Norrie RG, McIlroy WE. Effect of facilitation of sensation from plantar foot-surface boundaries on postural stabilization in young and older adults. *J Gerontol A Biol Sci Med Sci* 1999; 54:M281–7.
25. Rome K, Brown CL. Randomized clinical trial into the impact of rigid foot orthoses on balance parameters in excessively pronated feet. *Clin Rehabil* 2004;18:624–30.
26. You SH, Granata KP, Bunker LK. Effects of circumferential ankle pressure on ankle proprioception, stiffness, and postural stability: a preliminary investigation. *J Orthop Sports Phys Ther* 2004;34:449–60.
27. Robbins S, Gouw GJ, McClaran J. Shoe sole thickness and hardness influence balance in older men. *J Am Geriatr Soc* 1992;40:1089–94.
28. Suomi R, Kocejka DM. Effect of magnetic insoles on postural sway measures in men and women during a static balance test. *Percept Mot Skills* 2001;92:469–76.
29. Priplata AA, Niemi JB, Harry JD, Lipsitz LA, Collins JJ. Vibrating insoles and balance control in elderly people. *Lancet* 2003;362: 1123–4.
30. Dijkstra PU, Kalk WWI, Roodenburg JLN. Trismus in head and neck oncology: a systematic review. *Oral Oncol* 2004;40:879–89.
31. Waked E, Robbins S, McClaran J. The effect of footwear midsole hardness and thickness on proprioception and stability in older men. *J Test Eval* 1997;25:143–8.
32. Geurts ACH, Mulder TW, Nienhuis B, Rijken RA. Influence of orthopedic footwear on postural control in patients with hereditary motor and sensory neuropathy. *J Rehabil Sci* 1992;5:3–9.
33. Lindemann U, Scheible S, Sturm E, Eichner B, Ring C, Najafi B, Aminian K, Nikolaus Th, Becker C. Elevated heels and adaptation to new shoes in frail elderly women. *Z Gerontol Geriatr* 2003;36:29–34.

34. Robbins S, Waked E, Allard P, McClaran J, Krouglicof N. Foot position awareness in younger and older men: the influence of footwear sole properties. *J Am Geriatr Soc* 1997;45:61–6.
35. Lord SR, Bashford GM, Howland A, Munroe BJ. Effects of shoe collar height and sole hardness on balance in older women. *J Am Geriatr Soc* 1999;47:681–4.
36. Lord SR, Bashford GM. Shoe characteristics and balance in older women. *J Am Geriatr Soc* 1996;44:429–33.
37. Robbins S, Waked E, Krouglicof N. Improving balance. *J Am Geriatr Soc* 1998;46:1363–70.
38. Richardson JK, Ashton-Miller JA. Peripheral neuropathy: an often-overlooked cause of falls in the elderly. *Postgrad Med* 1996;99: 161–72.
39. Priplata A, Niemi J, Salen M, Harry J, Lipsitz LA, Collins JJ. Noise-enhanced human balance control. *Phys Rev Lett* 2002;89(238101): 1–4.
40. Moss F, Milton JG. Medical technology: balancing the unbalanced. *Nature* 2003;425:911–2.
41. Masse M, Gaillardetz C, Cron C, Abribat T. A new symmetry-based scoring method for posture assessment: evaluation of the effect of insoles with mineral derivatives. *J Manipulative Physiol Ther* 2000; 23:596–600.
42. Cavanagh PR, Simoneau GG, Ulbrecht JS. Ulceration, unsteadiness, and uncertainty: the biomechanical consequences of diabetes mellitus. *J Biomech* 1993;26(Suppl 1):23–40.
43. Lavery LA, Fleishli JG, Laughlin TJ, Vela SA, Lavery DC, Armstrong DG. Is postural instability exacerbated by off-loading devices in high risk diabetics with foot ulcers? *Ostomy Wound Manage* 1998;44:26–32, 34.

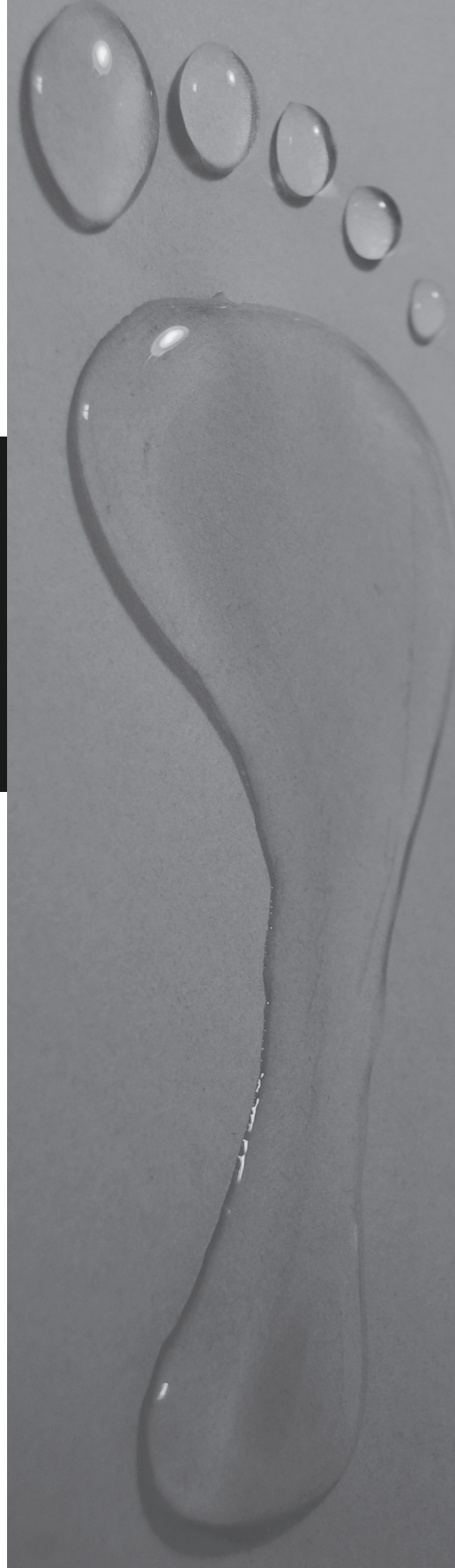
Foot and ankle compression
improves joint position sense
but not bipedal stance in
older people

3

Juha M. Hijmans
Wiebren Zijlstra
Jan H.B. Geertzen
At L. Hof
Klaas Postema

Gait & Posture 29 (2009) 322–325

Reprinted with kind permission



ABSTRACT

This study investigates the effects of foot and ankle compression on joint position sense (JPS) and balance in older people and young adults. Twelve independently living healthy older persons (77-93y) were recruited from a senior accommodation facility. Fifteen young adults (19-24y) also participated. Compression was applied at the ankles and feet using medical compression hosiery. The mean velocity of the centre of pressure (COP) displacements and the root mean square of the COP velocity, in both anteroposterior and mediolateral directions, were measured with a foot pressure plate. In older people, ankle compression was associated with an improvement of JPS towards normal values. However, a concurrent deterioration of their balance was found. In young adults compression had no effect on either JPS or balance.

INTRODUCTION

Balance disorders in older people are often associated with impaired somatosensory input from the lower limbs [1-5]. Somatosensory feedback is thought to provide the central nervous system (CNS) with joint position sense (JPS) and information concerning pressure distribution on the plantar surface of the feet [6;7]. It has been argued that postural control can be improved by enhancing the somatosensory input from the ankles and feet [8].

The application of ankle foot orthoses (AFOs) and compression of the ankle and foot have been shown to have an association with improvement of ankle JPS [9-15]. Due to compression, additional feedback from mechanoreceptors in the skin could contribute to the improvement in JPS. In healthy people ankle JPS plays little role in balance control [16]. Whereas in older people and those with disabilities JPS plays a greater role. Evidence is available about the immediate effects of an appliance providing compression at the ankle on JPS and balance [9-13]. However, these studies were on healthy young people or young athletes with ankle instability. No studies were found that described the effects of compression on balance or JPS in older people. In people with polyneuropathy, AFOs were associated with improved balance apparently due to additional somatosensory cues from the skin [14]. To some extent this population is comparable to older people who can experience problems in both JPS and balance [17]. To date there is no data showing whether compression improves JPS in older people or whether improvement of JPS is associated with improvements in balance in older people.

This study investigates whether JPS is enhanced by the application of compression by an elastic bandage (medical compression hosiery (MCH)) and whether enhanced JPS is related to enhanced standing balance in older people. In healthy young adults it is expected that MCH has no effect on either balance or JPS, given that they do not have sensory impairments.

METHODS

All residents of a senior accommodation facility in Groningen, the Netherlands, were invited to a lecture about balance and falls which took place in their common room. During the lecture they were invited to participate in research concerning the effects of compression on balance in older people. Residents were eligible to participate in this study if they were between 75 and 95 years of age and could stand and walk without assistive devices. People with diabetes, rheumatoid arthritis, foot wounds, an endoprosthesis, amputation of their lower limbs, deformities of ankles or feet, or history of stroke were excluded. They were also excluded if they used a lower limb orthosis, orthopaedic footwear, or MCH on a daily basis. A group of students (age 18-25y) were invited to participate as a control, matched on gender.

Participants

Nineteen older people who attended the lecture volunteered to participate (out of an approximate 50 attendees). One person was excluded because she was unable to stand without assistance. Two were excluded because they had obvious deformities of the foot and four were excluded because they used MCH on a daily basis. Twelve older people (10 female, 2 male), aged between 77 and 93 were included. Fifteen healthy students (11 female, 4 male) aged between 19 and 24 were included in the control group. All participants signed an informed consent and the study was approved by the medical ethics committee of the University Medical Center Groningen (UMCG) (METc2006/205). Participant details are summarised in Table 1.

Measurements

Tactile sensitivity was tested by pressing a 5.07/10g Semmes Weinstein Monofilament [18] three times at each test location (plantar side of: first toe, MTP1, MTP5 and heel of both feet). Vibrotactile sensitivity was tested with a 128Hz tuning fork pressed at both the medial and lateral malleolus (Table 1).

JPS was defined as the ability to indicate the steepness of a slope by standing on it with one foot. JPS was measured with a modified slope box [19-21], as a functional way of measuring JPS. In contrast with other JPS measures [11], the participant stood on a slope and estimated the angle. The slope box used in this study consisted of two parts: a flat surface; and an adjustable surface, in steps of 2.5° (Figure 1). The participant was asked to sense the steepness by stepping on the slope with their preferred foot. After the first step, the investigator made sure that every following step was with the same foot.

Each participant had to score the steepness of the slope on a -10 (plantar flexion) to 10 (dorsal flexion) scale for 10 times. A maximum score of 10 corresponded with the maximum angle of the slope box of 25°. Before the actual measurements, slopes with a score of 8 (20° dorsal flexion), 0 (horizontal) and -8 (20° plantar flexion) were presented to the participants as reference scores. During the actual measurements, ten different slopes were presented in a random order, varying 20° and -20°.

During the measurements the participants were asked to either close their eyes or to use special glasses that made it impossible to see the slope. All participants were allowed to hold on to the wall for stability. For safety, the investigator also supported the older participants by holding their arm. Only JPS in the plantar/dorsal flexion direction was measured. The perception error, expressed as the mean absolute error in degrees, was used as the primary outcome. JPS measurements were repeated two times, once with and once without MCH. Because compression was applied only once, the first measurement with compression (either the balance or the JPS measurement) was directly followed by the other measurement with

Table 1. Characteristics and sensitivity test results of the participants.

	Older participants (n = 12)		Younger participants (n = 15)	
	Left	Right	Left	Right
Mean age in years \pm SD	85.3 \pm 4.6		22.1 \pm 1.6	
% female (n)	83% (10)		73% (11)	
Mean mass in kg \pm SD	68.9 \pm 10.1		69 \pm 10.9	
% 5.07 / 10g SWM correctly located at first toe (n)	42% (5)	42% (5)	100% (15)	100% (15)
% 5.07 / 10g SWM correctly located at MTP1 (n)	33% (4)	50% (6)	100% (15)	100% (15)
% 5.07 / 10g SWM correctly located at MTP5 (n)	67% (8)	42% (5)	100% (15)	100% (15)
% 5.07 / 10g SWM correctly located at heel (n)	67% (8)	33% (4)	100% (15)	100% (15)
% correct response to 128Hz tuning fork (n)	25% (3)*	25% (3)*	100% (15)	100% (15)
Mean pressure under the MCH above medial malleolus in mm Hg \pm SD	22.0 \pm 3.5	22.0 \pm 4.3	26.1 \pm 3.7	26.3 \pm 4.0

SD= standard deviation; SWM = Semmes Weinstein Monofilaments; MTP = metatarsophalangeal joint; MCH = medical compression hosiery; * 2 older participants responded correctly to the tuning fork at both sides

compression. The remaining measurements (without compression) were presented in a random order.

Balance was defined as the displacements of the COP and was measured with a foot pressure plate (RSscan footscan® 2D Balance 0.5m system). Pressure plate data were sampled at 17 Hz and low-pass filtered (Butterworth) with a cut-off frequency of 6 Hz. The mean velocity of the COP displacement (vCOP) over a period of 40s was used as the primary outcome. Secondary outcomes were the root mean square of the COP velocity in anteroposterior (rmsAP) and mediolateral (rmsML) directions. The measurement protocol consisted of standing for 60s (first and last 10s were not taken into consideration) on the foot pressure plate in four different conditions. During the first condition, the participants were asked to stand with their arms relaxed at the side of their body, looking straight ahead at a dot on the wall (2.5m away), with the feet placed parallel and 7cm apart. The other three conditions were standing with the eyes closed, performing an attention demanding task (continuously

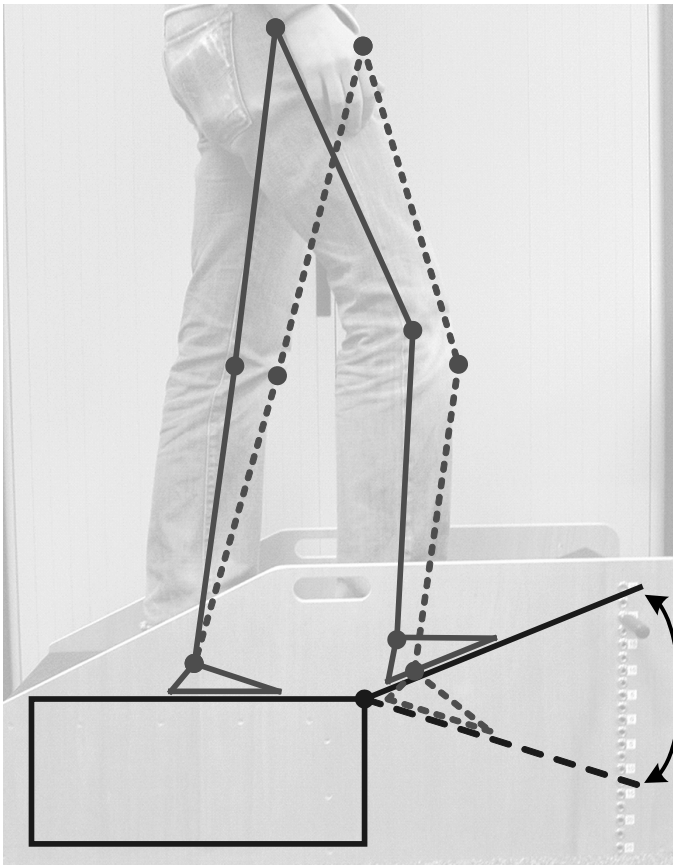


Figure 1. Modified slope box. The slope of the slope box on the right side of this figure can be altered between -25° and 25° in steps of 2.5° . The participant has to step on the slope with the preferred foot, is allowed to use the wall for stability, and is not allowed to see the slope.

subtracting six from a randomly chosen number) and standing in the Romberg position (feet placed against each other). These three conditions were presented in a random order.

JPS and balance of the older participants were measured in a room at their residence. The foot pressure plate was placed in a standardized position, 2.5m from a wall. The control group was measured with the same foot pressure plate at the Laboratory for Human Movement Analysis of the Center for Rehabilitation, UMCG.

Compression

Compression was applied with MCH type AB compression bandage class II (Varitex, Haarlem, the Netherlands). Type AB corresponds with an ordinary sock without toes.

According to the CEN European standard¹, compression class II corresponds with pressure under the MCH of 23-32mm Hg. Three different sizes of bandages were used. The applied size was chosen based on the circumferential of the thinnest part of the lower leg. Pressure under the MCH was measured with a pressure monitoring device (Kikuhime, Harada Company, Japan) [26] about 3cm proximal to the medial malleolus (Table 1).

Statistics

Differences in perception errors with and without compression were tested using the Wilcoxon signed rank test. Differences in perception errors between the two groups were tested with a Mann Whitney U test. The effects of compression on balance were tested with a multivariate analysis of variance (MANOVA) with repeated measures. SPSS software (version 14.0) was used for all statistical analyses.

RESULTS

In older participants a significant difference ($p = 0.025$) in perception error was found between conditions with ($3.2^\circ \pm 1.0$) and without ($4.8^\circ \pm 1.7$) compression. In younger participants no differences ($p = 0.93$) in perception errors were found ($3.0^\circ \pm 0.9$ and $3.1^\circ \pm 1.1$ with and without compression respectively). The difference in JPS between the older and younger participants when no compression was applied was significant ($p < 0.01$). When compression was applied, no differences in JPS between the two groups were found.

Table 2 shows the mean vCOP, rmsAP, and rmsML, with and without compression. A MANOVA, with repeated measures, showed a significant ($p = 0.03$) main effect of compression on balance in the older participants, with balance significantly disturbed. Univariate tests did not show significant main effects of compression on the vCOP ($p = 0.11$), rmsAP ($p = 0.09$), or rmsML ($p = 0.26$). In the younger participants no main effects of compression on balance were found.

In one case, the participant (older) was not able to stand in the Romberg position for 60 s. For this participant, calculations of the outcomes were based on the first 30s (which the participant completed both with and without compression).

DISCUSSION

This study demonstrated that JPS improved towards normal values as a result of the application of compression in older participants yet not in younger adults who had no impairment of JPS. The mean perception errors in this study while standing barefoot (younger: 3.1° ; older: 4.8°) are comparable to earlier research reporting errors of $2.9^\circ - 3.4^\circ$

1 CEN European Prestandard. ENV12718. Medical compression hosiery. European Committee for Standardization. Brussels,2001;1-43.

Table 2. Mean \pm standard error of the mean (SEM) of the mean velocity of the COP displacements, the RMS of the COP velocity in AP and ML direction, with and without compression, in older and younger participants, during four different conditions.

	Stance		Stance + Eyes closed		Stance + Attention demanding task		Stance in Romberg position		
	Comp	No-comp	Comp	No-comp	Comp	No-comp	Comp	No-comp	
Mean velocity of the COP displacements (mm/s)	Older n = 12	10.2 \pm 1.86	8.8 \pm 1.05	15.6 \pm 2.53	12.5 \pm 2.13	13.5 \pm 1.93	11.7 \pm 1.19	23.8 \pm 3.60	20.6 \pm 2.53
	Younger n = 15	6.2 \pm 0.47	6.7 \pm 0.41	7.7 \pm 0.46	7.1 \pm 0.56	8.5 \pm 0.73	9.5 \pm 1.34	12.2 \pm 0.59	11.9 \pm 0.77
RMS of the COP displacement velocity in AP direction (mm/s)	Older n = 12	9.9 \pm 1.85	7.7 \pm 0.97	15.4 \pm 2.38	12.2 \pm 2.28	12.7 \pm 2.02	10.9 \pm 1.10	15.2 \pm 1.96	14.6 \pm 1.62
	Younger n = 15	4.9 \pm 0.49	5.6 \pm 0.43	6.8 \pm 0.52	5.8 \pm 0.40	7.4 \pm 0.71	8.8 \pm 1.93	8.7 \pm 0.66	8.9 \pm 0.76
RMS of the COP displacement velocity in ML direction (mm/s)	Older n = 12	7.7 \pm 1.79	7.1 \pm 1.09	10.7 \pm 2.33	9.0 \pm 1.46	9.4 \pm 1.49	9.4 \pm 1.45	25.0 \pm 4.30	21.3 \pm 2.67
	Younger n = 15	5.1 \pm 0.37	5.1 \pm 0.28	5.8 \pm 0.37	5.6 \pm 0.55	6.4 \pm 0.66	6.7 \pm 0.65	12.1 \pm 0.59	11.2 \pm 0.75

Comp = with compression; No-comp = without compression; COP = centre of pressure; RMS = root mean square; AP = anteroposterior; ML = mediolateral

in young adults; 3.9° in older people (mean age 73y); and $3.9^\circ - 4.2^\circ$ in young adults with unstable ankles [19-21]. Interestingly, although JPS improved, balance deteriorated in older participants with the application of compression. Compared to barefoot standing, with the application of compression, all balance parameters deteriorated in all four balance conditions.

Several possible explanations can be given for this deterioration of balance in older participants. First, the role of JPS on balance during bipedal stance may be limited, because the angular rotations at the ankle were minimal ($<0.5^\circ$). Many studies have shown that with the application of compression, balance during unipedal stance improved in young athletes with ankle instability [8-15]. As few older people can [23] stand on one foot, unipedal stance was not an option in our study. More angular rotations at the ankle are present during unipedal stance. Improving the detection of these rotations (in other words improved JPS) may enhance unipedal balance control [12]. Compared to bipedal stance, the role of JPS in balance control during unipedal stance seems to be more important.

A possible explanation for the deterioration of balance in older people shown in this study, may be that the MCH on the plantar side of the foot reduced tactile feedback from plantar mechanoreceptors. Plantar mechanoreceptors play an important role in the detection of changes in plantar pressure distribution. These changes are directly related to changes in upright stance [6;7]. Possibly, compression of the dorsal part of the foot and the lower leg, provides the CNS with additional information, whereas compression of the plantar foot impairs the detection of plantar pressure changes. This deterioration may complicate balance control. Continuous pressure applied to plantar mechanoreceptors may result in an adaptation of these receptors [24]. This may cause a reduced ability to detect changes in pressure distribution, which in turn affects the control of upright stance. This explanation supports the idea that plantar pressure distribution, when compared to ankle JPS, is a more important source of information for balance control in upright stance [8].

Previous research provides an alternative explanation, suggesting that older people have problems in rapidly resolving the conflicting sensory information required for balance control [25]. A change in this sensory feedback may occur when compression is applied. Re-weighting of the gains for sensory feedback systems in the CNS must then take place in order to optimally control balance [26]. As this re-weighting takes place, balance may temporarily deteriorate. However, after the re-weighting process, balance may be restored or even improved. Whether this occurs after long-term use of compression cannot be analysed based on our data.

Some weaknesses of this study need to be acknowledged. Firstly, participants were chosen selectively. The older participants in our study may not represent the average population between 75 and 95 years of age. People with a better physical condition are likely to live more

independently, and people with a poorer physical and mental condition need more help in daily living and therefore, may live in a facility where more care is provided. Secondly, it may be possible that the MCH does not affect balance due to additional somatosensation alone; rather, it also may have a limited mechanical effect on stance. If a mechanical effect would have been present, however, effects in both populations would have been expected. Thirdly, the slope box and the related protocol were modified in our study compared to earlier work [23-25]. The older age of the participants was the main reason to apply the modifications. Finally, in this study we only used static balance measures. Although the inclusion of measures for dynamic balance would have provided a more comprehensive assessment of balance function, we decided to focus on a static balance task because the role of JPS in quiet standing tasks is thought to be relatively important.

In conclusion, in older people, ankle compression applied by MCH, was associated with an improvement of JPS towards normal values. However, a concurrent deterioration of their balance was evident. In young adults compression had no effect on either JPS or balance.

REFERENCES

1. Diener HC, Horak FB, Nashner LM. Influence of stimulus parameters on human postural responses. *J Neurophysiol* 1988;59:1888-1905.
2. Manchester D, Woollacott MH, Zederbauer-Hylton N, Marin O. Visual, vestibular and somatosensory contributions to balance control in older adult. *J Gerontol* 1989;44:M118-M127.
3. Jeka JJ, Ribeiro P, Oie KS, Lackner JR. The structure of somatosensory information for human postural control. *Motor Control* 1998;2:13-33.
4. Fukuoka Y, Nagata T, Ishida A, Minamitani H. Characteristics of somatosensory feedback in postural control during standing. *IEEE Trans Neural Syst Rehabil Eng* 2001;9:145-53.
5. Meyer PF, Oddsson LI, De Luca CJ. The role of plantar cutaneous sensation in unperturbed stance. *Exp Brain Res* 2004;156:505-12.
6. Bloem BR, Allum JH, Carpenter MG, Honegger F. Is lower leg proprioception essential for triggering human automatic postural responses? *Exp Brain Res* 2000;130:375-91.
7. Kavounoudias A, Roll R, Roll JP. The plantar sole is a 'dynamometric map' for human balance control. *Neuroreport* 1998;9:3247-52.
8. Hijmans JM, Geertzen JHB, Dijkstra PU, Postema K. 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. *Gait Posture* 2007;25:316-23.
9. Calmels P, Escafit M, Domenach M, Minaire P. Posturographic evaluation of the proprioceptive effect of ankle orthoses in healthy volunteers. *Int Disabil Stud* 1991;13:42-5.

10. Feuerbach JW, Grabiner MD. Effect of the aircast on unilateral postural control: amplitude and frequency variables. *J Orthop Sports Phys Ther* 1993;17:149-54.
11. Jerosch J, Hoffstetter I, Bork H, Bischoff M. The influence of orthoses on the proprioception of the ankle joint. *Knee Surg Sports Traumatol Arthrosc* 1995;1:39-46.
12. Baier M, Hopf T. Ankle orthoses effect on single-limb standing balance in athletes with functional ankle instability. *Arch Phys Med Rehabil* 1998;79:939-44.
13. You SH, Granata KP, Bunker LK. Effects of circumferential ankle pressure on ankle proprioception, stiffness, and postural stability: a preliminary investigation. *J Orthop Sports Phys Ther* 2004;34:449-60.
14. Rao N, Aruin A. Automatic postural responses in individuals with peripheral neuropathy and ankle-foot orthoses. *Diabetes Res Clin Pract* 2006;74:48-56.
15. Kaminski TW, Gerlach TM. The effect of tape and neoprene ankle supports on ankle joint position sense. *Phys Ther Sports* 2001;2:132-40.
16. Feuerbach JW, Grabiner MD, Koh TJ, Weiker GG. Effect of an ankle orthosis and ankle ligament anesthesia on ankle joint proprioception. *Am J Sports Med* 1994;22:223-9.
17. Robbins S, Waked E, Allard P, McClaran J, Krouglicof N. Foot position awareness in younger and older men: the influence of footwear sole properties. *J Am Geriatr Soc* 1997;45:61-6.
18. International Working Group on the Diabetic Foot. International consensus on the diabetic foot and practical guidelines on the management and the prevention of the diabetic foot. Amsterdam; 2007.
19. Robbins S, Waked E, McClaran J. Proprioception and stability: foot position awareness as a function of age and footwear. *Age Ageing* 1995;24:67-72.
20. Halasi T, Kynsburg A, Tallay A, Berkes I. Changes in joint position sense after surgically treated chronic lateral ankle instability. *Br J Sports Med* 2005;39:818-24.
21. Kynsburg A, Halasi T, Tallay A, Berkes I. Changes in joint position sense after conservatively treated chronic lateral ankle instability. *Knee Surg Sports Traumatol Arthrosc* 2006;14:1299-306.
22. Van den Kerckhove E, Fieuws S, Massagé P, Hierner R, Boeckx W, Deleuze JP, Laperre J, Anthonissen M. Reproducibility of repeated measurements with the Kikuhime pressure sensor under pressure garments in burn scar treatment. *Burns* 2007;33:572-8.
23. Bohannon RW, Larkin PA, Cook AC, Gear J, Singer J. Decrease in timed balance test scores with aging. *Phys Ther* 1984;64:1067-70.
24. Vedel JP, Roll JP. Response to pressure and vibration of slowly adapting cutaneous mechanoreceptors in the human foot. *Neurosci Lett* 1982;34:289-94.
25. Bugnariu N, Fung J. Aging and selective sensorimotor strategies in the regulation of upright balance. *J Neuroeng Rehabil* 2007;4:19.

26. Horak FB, Shupert CL, Mirka A. Components of postural dyscontrol in the elderly: A review. *Neurobiol Aging* 1989;10:727-38.

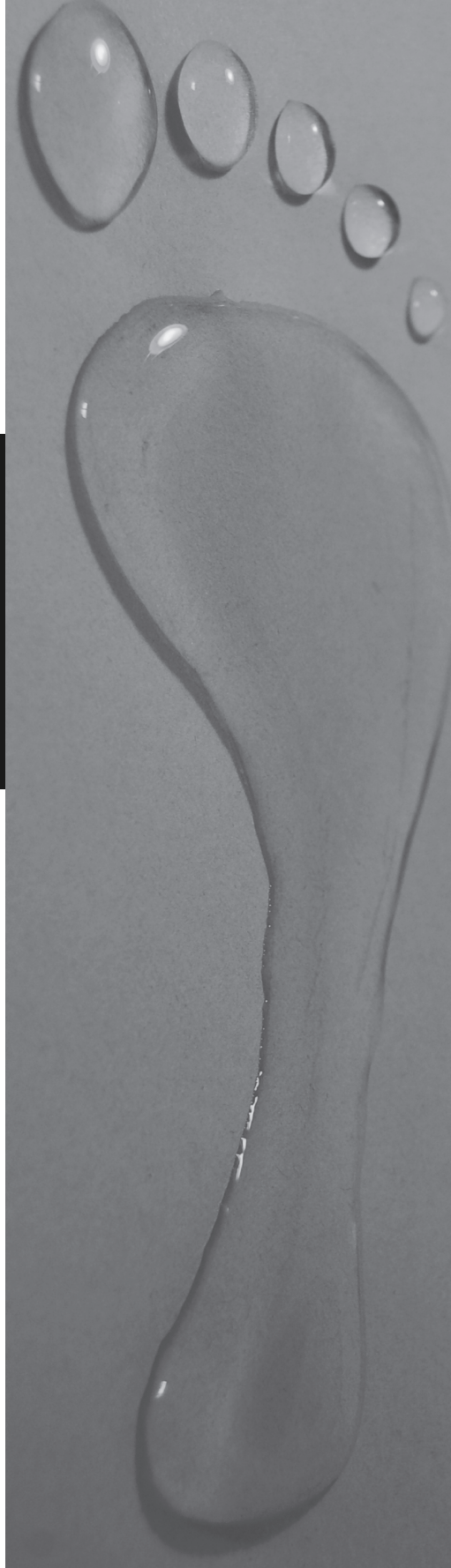
Effects of vibrating insoles on
standing balance
in diabetic neuropathy

4

Juha M. Hijmans
Wiebren Zijlstra
Jan H.B. Geertzen
At L. Hof
Klaas Postema

Journal of Rehabilitation Research &
Development 45 (2008) 1442–1450

Reprinted with kind permission



ABSTRACT

This study investigated the effects on standing balance in subjects with neuropathy and nondisabled subjects of random vibrations applied to the plantar side of the feet by vibrating insoles. In four different conditions (eyes open or closed and with or without an attention-demanding task (ADT)), subjects with neuropathy secondary to diabetes mellitus ($n = 17$) and nondisabled subjects ($n = 15$) stood for 60 s on vibrating insoles placed on a force plate. During each condition, the insoles were turned on for 30 s and off for 30 s (random order). The calculated balance measures were mean velocity of the centre of pressure displacements and root-mean-square of the velocity of these displacements in the anteroposterior and mediolateral directions. In subjects with neuropathy, an interaction effect between vibration and an ADT was found for balance. No effects of vibration on balance were found in nondisabled subjects. Vibrating insoles improved standing balance in subjects with neuropathy only when attention was distracted. Improvement of the insoles and their activation is needed to make their implementation in daily living possible and effective.

INTRODUCTION

In nondisabled humans, balance is under constant control. Several sensory mechanisms play a role in the control of balance. Information from the somatosensory, visual, and vestibular systems is used for the detection of postural changes [1–3], and attention plays a crucial part as well [4]. The somatosensory system can be subdivided into the tactile and the proprioceptive systems. Feedback from both these systems plays a part in the control of balance [3;5–6].

The tactile system provides the central nervous system (CNS) with information concerning the sense of touch. Mechanoreceptors such as Meissner's corpuscles, Pacinian corpuscles, Merkel's disks, and Ruffini endings are responsible for the detection of tactile input. Mechanoreceptors situated on the plantar side of the feet provide the CNS with information concerning the pressure distribution under the feet [3]. During stance, shear stresses and changes in pressure are related to changes in the centre of mass position, which are mediated by the plantar mechanoreceptors. Feedback concerning these changes is important for the maintenance of balance during standing.

The proprioceptive system can be seen as the system that provides the CNS with information concerning angles and angular changes of the joints. Muscle spindles, Golgi tendon organs, and joint afferents play a part in the detection of joint angles and angular velocities during both the stance and swing phases of walking [6]. In nondisabled people, the proprioceptive system seems to play only a minor role in balance control [7].

When problems arise in the conduction of somatosensory information to the CNS, problems in balance control are likely to occur, especially when the availability of compensatory mechanisms is limited. In persons with neuropathy, neither tactile nor proprioceptive information is conducted to the CNS with as much intensity as in persons without neuropathy. This reduction in somatosensory perception has detrimental effects on postural stability, resulting in an increased risk for falling [8–10]. Appliances for the foot (which do or do not encompass the ankle) may compensate for these detrimental effects [7].

Peripheral neuropathy is a common problem in persons with diabetes mellitus (DM). About one-third of persons with DM have peripheral neuropathy. Longer disease duration is one of the factors associated with a higher incidence of neuropathy [11]. In diabetic neuropathy, both large fibres and small fibres may be affected. In people with impaired tactile sensation, the large fibres are affected [12]. Therefore, in this study, we focus on large-fibre neuropathy only.

A new technique that may improve tactile, and possibly proprioceptive, feedback is the application of noise to the plantar surface of the feet [13–16]. By adding subthreshold electrical [13] or mechanical noise (vibration with a randomly varying frequency) [14–16] to a subthreshold sensory input, the sensory threshold may be crossed. In this way, a signal that

is not detected during normal circumstances can be detected. The subthreshold noise signal can enhance the tactile sensation of changes in pressure under the foot, resulting in more sensitive detection of these pressure changes. More sensitive detection may result in an earlier reaction to the change in pressure, which may result in better balance performance. The mechanism by which signal detection is improved by noise is called stochastic resonance (SR) [17]. A few studies have shown that the application of noise can improve tactile sensitivity [18] and balance in nondisabled adolescents, elderly adults, people with diabetic neuropathy, and those with stroke [13–16]. In Figure 1, the mechanism of SR is explained.

In the present study, we assessed the effects of vibrating insoles on balance in persons with peripheral neuropathy secondary to DM and in nondisabled subjects. Vibrating insoles were designed in which random vibrations are applied to the plantar surface of the feet by piezoelectric elements [19]. Piezoelectric elements are thin and relatively cheap and therefore ideal for application in an insole without appreciably increasing its thickness.

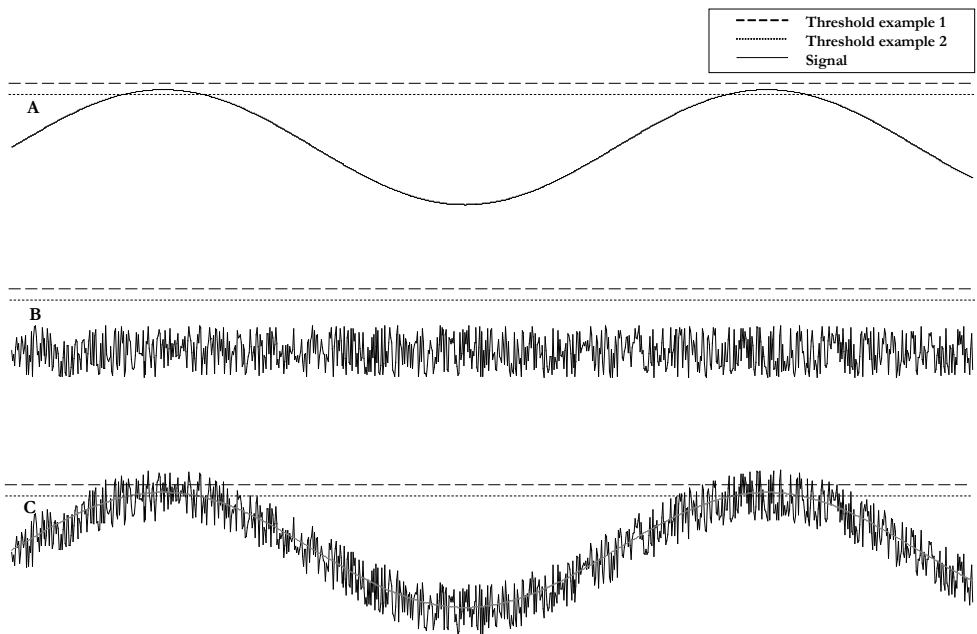


Figure 1. Stochastic resonance. (a) Sinusoid signal (solid line) with two examples of threshold (dashed line which is not reached and dotted line which is reached). (b) Noise signal below both examples of thresholds. (c) Mechanism of stochastic resonance. When the noise signal is added to the sinusoid signal, two important phenomena are noticed: (1) signal reaches threshold example 1 (dashed line), which is not reached under normal circumstances, and (2) signal reaches threshold example 2 (dotted line), which is reached under normal circumstances.

METHODS

Subjects

We screened the medical records of all persons with DM (type 1 and 2) between 40 and 60 years of age who visited the outpatient clinics of the Diabetes Center of the University Medical Center Groningen (UMCG) between June 2006 and April 2007. This age range was chosen because persons with DM usually do not develop neuropathy before 40 years of age. Older people without DM may develop plantar surface insensitivity [20]. We expected that in a control group with a maximum age of 60 years, sensory problems would be uncommon and the sensory problems in the study group would be secondary to DM. When the presence of neuropathy was mentioned in the medical record, the individual was invited to participate if he or she met the other inclusion criteria. All participants signed an informed consent. The procedures were approved and registered by the medical ethics committee of the UMCG.

To include or exclude a patient, we tested for the presence of neuropathy by pressing a 10 g Semmes-Weinstein monofilament (SWM) (North Coast Medical, Inc; Morgan Hill, California) [21] three times at each test location (first toe, first metatarsophalangeal (MTP) joint, MTP5, and heel) [20]. Neuropathy was defined as inability to feel the SWM (for all three test trials) at four or more of the eight test locations [21]. Exclusion criteria for both groups were (1) ulcerations and/or infections on the plantar surface of the feet, (2) (partial) foot or toe amputation, (3) inability to stand without aid, (4) inability to understand the instructions of the examiner, (5) disorder of the musculoskeletal system (unrelated to DM, e.g., rheumatoid arthritis), and severe visual impairment. Exclusion criteria for the nondisabled subjects were (1) DM, (2) inability to feel the 10 g SWM on more than two test locations [21], and (3) inability to report correctly whether a tuning fork positioned at the medial side of MTP1 of both feet was vibrating [21]. Vibrotactile sensitivity was part of the inclusion criteria for nondisabled people in order to be sure that the control group had no sensory problems.

A total of 45 persons with DM was selected based on their medical record. Of these, 18 did not participate for various reasons (e.g., physician reported an exclusion criterion, patient did not want to participate). The other 27 persons with DM were tested. We excluded 10 for various reasons (no neuropathy $n = 6$, inability to stand without aid with the eyes closed $n = 2$, toe amputation $n = 1$, severe visual impairment $n = 1$). In addition to the included subjects with neuropathy ($n = 17$), we included 15 nondisabled subjects, matched by age and sex.

Procedures

After inclusion, all subjects' vibrotactile sensitivity was tested. To test the tactile sensitivity

of the plantar surface of the feet in both nondisabled subjects and subjects with neuropathy, we used a set of 20 SWMs that varied between 0.008 g and 300 g [22]. The SWM was pressed to the skin three times at each location (first toe, MTP1, and MTP5). The SWM with the smallest buckling force that could be located correctly at least two of the three times was noted. To test vibrotactile sensitivity of the subjects, we used a 128 Hz tuning fork positioned at MTP1 [23]. The subjects had to report whether the tuning fork was vibrating or not. Vibrotactile sensitivity was tested so we could describe additional characteristics of the subjects with neuropathy.

After the sensitivity tests, subjects were asked to stand on a pair of vibrating insoles that were attached to a force plate (Bertec 4060, Bertec Corporation; Columbus, Ohio) with double-sided tape. The insoles were made in five sizes, and the best fitting pair of insoles for each subject was chosen. The distance between the heels was 5 cm, and the insoles were positioned in 15° external rotation. This is the foot position used in platform stabilometry [24]. While the subject was standing on the insoles, we separately determined the perception thresholds for the noise signal for both feet. The amplitude of the noise was gradually increased by the examiner, and the subject had to report when the noise signal was perceived. Then, the amplitude was set at 90 percent of the tactile threshold for each individual subject (therefore, the vibrations were not perceptible). Previous research reported on a 90 percent threshold [15–16]. In this way, subjects were blinded to the intervention. When the threshold could not be reached, the maximum amplitude that could be applied to the piezoelectric elements (120 V) was chosen. Subject characteristics, including vibrotactile sensitivity and amplitude of the insole vibrations, are reported in Table 1.

The measurement protocol consisted of five trials in which the subjects were asked to stand on the vibrating insoles for 60 s. During the first and fifth trial, the subjects stood with their eyes open looking straight ahead. The other three trials consisted of subjects standing with their eyes closed, performing an attention-demanding task (ADT), and completing a combination of both. These three trials were presented in random order. The ADT was a calculation task, consisting of continuously subtracting six from a random number. Throughout each 60 s trial, the vibrating insoles were turned on during either the first or second 30 s (randomly chosen). During the other 30 s, the insoles were turned off. Because the vibrations of the insoles were audible to the subjects, we applied a sound to both ears using earphones to ensure the subjects were unaware of whether the vibrations were turned on or off. The subjects were allowed to rest after every trial for a maximum of 2 minutes.

Vibrating Insoles

The vibrating insoles consisted of a cork sole with three built-in piezoelectric elements (piezo element EPZ35MS29, 35 mm diameter, Karl/Heinz Mauz GMBH; Ostfildern, Germany) at MTP1, MTP5, and the heel; the sole was covered with a thin leather layer. We chose the

Table 1. Characteristics and test results of subjects.

	Neuropathy (n = 17)		Healthy (n = 15)	
Mean (SD) age (y),	52.1 (6.0)		51.8 (5.6)	
% (n) female	53% (9)		53% (8)	
Mean (SD) weight (kg)	92.6 (23.1)		78.0 (12.1)	
% DM type I diabetes	65% (11 type I; 6 type II)			
	Left	Right	Left	Right
% (n) 5.07/10g SWM correctly located at first toe	12% (2)	6% (1)	100% (15)	100% (15)
% (n) 5.07/10g SWM correctly located at MTP1	0% (0)	6% (1)	100% (15)	100% (15)
% (n) 5.07/10g SWM correctly located at MTP5	18% (3)	6% (1)	100% (15)	100% (15)
% (n) 5.07/10g SWM correctly located at heel	12% (2)	22% (4)	93% (14)	93% (14)
Median (range) thinnest detected SWM at first toe (g)	60 (6-xx)	60 (6-xx)	1.4 (0.16-4)	1.4 (0.16-4)
Median (range) thinnest detected SWM at MTP1 (g)	100 (15-xx)	60 (10-xx)	2 (0.6-8)	1.4 (0.16-6)
Median (range) thinnest detected SWM at MTP5 (g)	60 (6-300)	26 (10-xx)	2 (0.6-8)	2 (0.6-4)
Median (range) thinnest detected SWM at heel (g)	60 (8-xx)	26 (2-xx)	4 (1.4-15)	4 (1-15)
% (n) 128Hz tuning fork at MTP1 correctly reported	24% (4)	12% (2)	100% (15)	87% (13)
Median (range) vibration amplitude (V)	120 (42-120)	120 (42-120)	47 (22-120)	48 (24-120)

SD= standard deviation; DM= diabetes mellitus; SWM = Semmes Weinstein Monofilaments; MTP = metatarsophalangeal joint; xx= Thickest (6.67/300g) SWM could not be detected

position of the actuators in order to apply the noise to the anterior and posterior supporting areas. The total thickness of the insole was 6 mm. The piezoelectric elements were driven by a custom-built amplifier. Input to the amplifier was an on/off signal, changing between 0 and 5 V at random intervals between 2 and 40 ms. This signal was generated on a personal computer and output to the amplifier via the digital output of a USB-DAQ AD/DA card

(USB-6008, National Instruments, Corp; Austin, Texas). The amplitude of the amplifier output signal could be manually adjusted from 0 to 120 V for each insole individually, but the input for the three actuators in a single insole was identical. Taking into account the limited frequency response of the actuators (not specified by the manufacturer), we found that this resulted in a random noise signal with a nominal bandwidth from 25 to 500 Hz and adjustable amplitude. The vibrating insole configuration is described in Figure 2.

The analog signals from the force plate (Bertec 4060) were acquired by the AD/DA

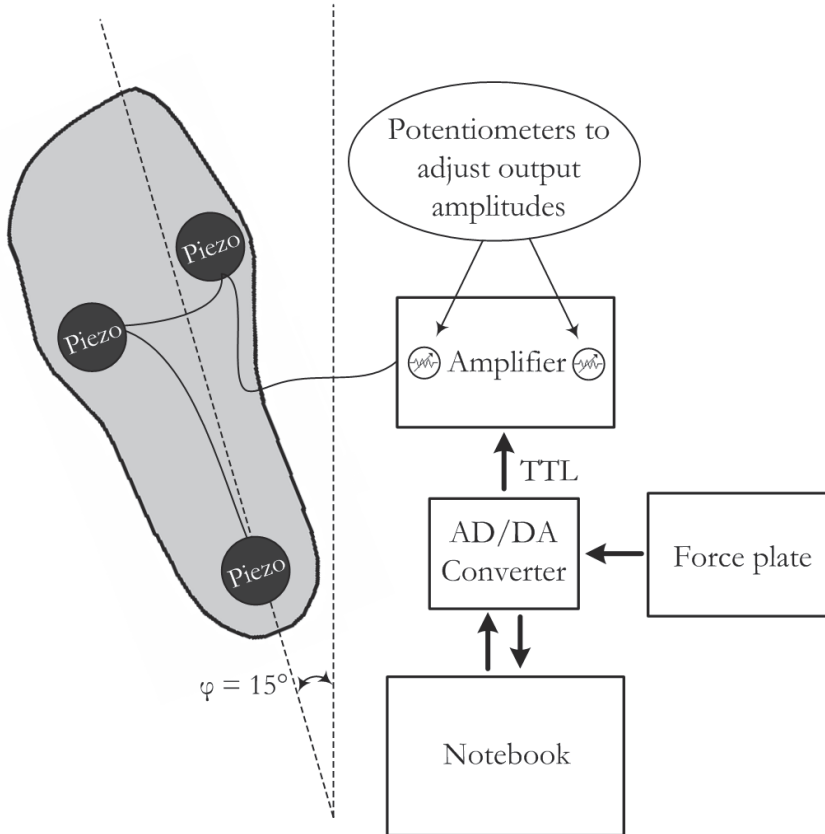


Figure 2. Schematic representation of vibrating insoles and their activation. Via portable USB-DAQ AD/DA card a transistor-to-transistor logic (TTL) input signal of varying frequency was provided to the amplifier by a personal computer. The amplifier provided the piezoelectric elements in the insoles with input with a manually adjustable amplitude. The amplitude of the output signal to both insoles could be adjusted separately. Same personal computer and USB-DAQ AD/DA card were used to record force plate data.

channels of the USB-DAQ card. Signal generation and data acquisition were done with custom LabVIEW software (version 8.0, National Instruments, Corp). Force plate data were sampled at 100 Hz and low-pass filtered (Butterworth) with a cut off frequency of 6 Hz. Data processing was done in MATLAB (version 7.1, The MathWorks, Inc; Natick, Massachusetts).

Outcome Measures and Statistics

The primary outcome measure was the mean velocity of the center of pressure (COP) displacements in millimeters per second. The total path length of the COP displacements was measured over a period of 25 s, and the mean velocity was calculated. During each measurement (60 s), two intervals of 25 s were used to collect outcome data (vibration-on and vibration-off condition). Data from the first 5 s of both conditions were left out of consideration. Secondary outcomes were the root-mean-square (RMS) of the anteroposterior (AP) and mediolateral (ML) COP velocity.

In a repeated measures analysis of variance (ANOVA) model, the effects of vibrating insoles on balance, defined by previously described outcome measures, were tested. Main effects of vibration (on or off), vision (eyes open or closed), and ADT (calculation task or not) and interaction effects of vibration \times vision and vibration \times ADT were tested. Differences between the neuropathy group and the nondisabled group were tested with a two-way ANOVA. A t-test was used to test the differences between the first and the fifth measurement. We used SPSS (version 14.0, SPSS, Inc; Chicago, Illinois) for all statistical analyses.

RESULTS

Mean Velocity of COP Displacements

Both the nondisabled and the neuropathy groups showed significant main effects of vision and ADT (eyes closed and an ADT increased mean velocity of COP displacements) on mean velocity of COP displacements (main effect of vision: $p = 0.01$, main effect of ADT: $p < 0.01$ in neuropathy group, main effects of both vision and ADT: $p < 0.01$ in nondisabled group) (Figure 3). Compared with the nondisabled controls, subjects with neuropathy showed a significant increase in the mean velocity of COP displacements ($p < 0.01$). No main effect of vibration was found for either the neuropathy group (Figure 3(a)) or the nondisabled group (Figure 3(b)) ($p = 0.07$ neuropathy group, $p = 0.37$ nondisabled group). The neuropathy group showed a significant favourable interaction effect of vibration \times ADT ($p = 0.05$). No interaction between vision and vibration was found in the neuropathy group ($p = 0.17$). In the nondisabled group, no interaction effects were found between vibration and either vision or ADT ($p = 0.79$ and $p = 0.28$, respectively).

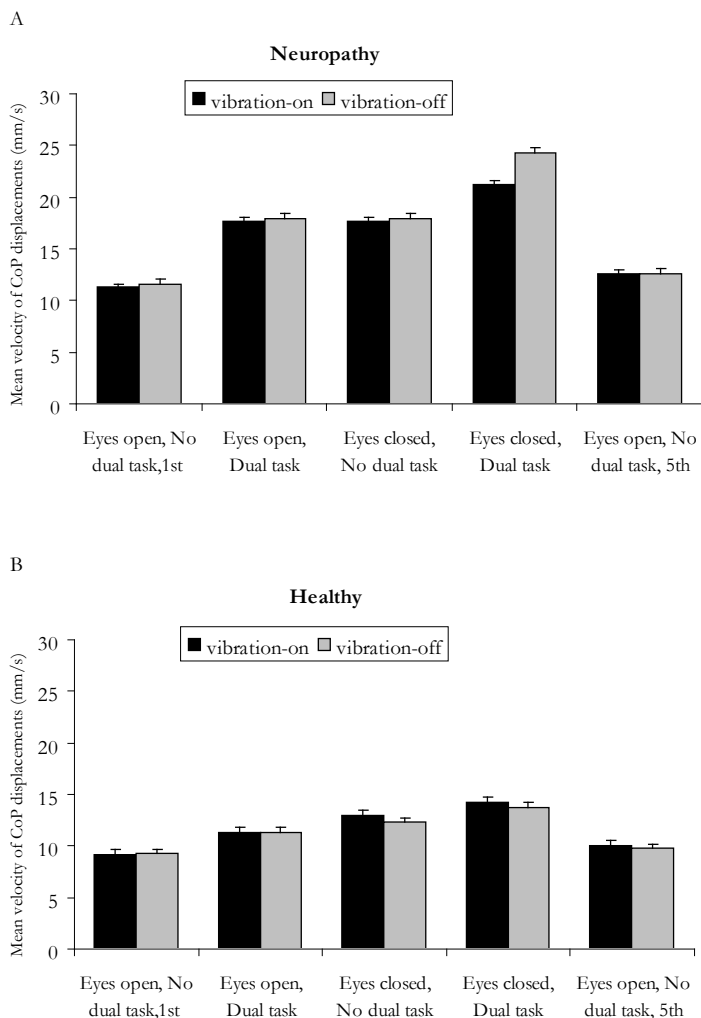


Figure 3. Mean velocity of center of pressure (COP) displacements with vibrating insoles turned on (black bars) and off (gray bars) in (a) subjects with neuropathy and (b) nondisabled subjects during five different trials. ADT = attention-demanding task. Error bars = standard error of the mean.

No significant differences between the identical first and fifth condition (both conditions consisted of eyes open without an ADT) on mean velocity of COP displacements were found ($p = 0.11$ and $p = 0.29$ in the neuropathy group and $p = 0.24$ and $p = 0.52$ in the nondisabled group for the vibration-on and vibration-off condition, respectively). Therefore, the fifth measurement was omitted. Data from both the first and the fifth measurements are shown in Figure 3 and Tables 2 and 3 in order to show the absence of fatigue.

RMS of COP Velocity in AP and ML Direction

As the data presented in Tables 2 and 3 show, no main effects of vibration on RMS of the COP velocity in the AP or ML direction were found for either group (neuropathy group: $p = 0.12$ in AP direction and $p = 0.35$ in ML direction, nondisabled group: $p = 0.30$ in AP direction and $p = 0.43$ in ML direction). Significant main effects of vision and ADT (eyes closed and an ADT increased RMS in the AP direction) on RMS of the COP velocity in

Table 2. Mean \pm standard error of mean of root-mean-square of center of pressure velocity in anteroposterior direction with vibrating insoles turned on and off in subjects with neuropathy and nondisabled control subjects during five different trials.

	Neuropathy		Nondisabled	
	vibration on	vibration off	vibration on	vibration off
Eyes open; No ADT; 1st measurement	9.6 (0.5)	10.0 (0.6)	7.5 (0.5)	7.5 (0.5)
Eyes open; ADT	17.1 (2.5)	17.1 (1.7)	12.0 (1.5)	10.7 (0.7)
Eyes closed; No ADT	17.5 (2.5)	16.9 (2.7)	9.7 (0.8)	9.6 (0.9)
Eyes closed; ADT	20.4 (2.5)	24.3 (3.3)	14.2 (1.5)	12.6 (1.1)
Eyes open; No ADT; 5th measurement	11.3 (0.9)	11.2 (1.1)	8.7 (0.8)	8.0 (0.6)

ADT = attention demanding task

Table 3. Mean \pm standard error of mean of root-mean-square of center of pressure velocity in mediolateral direction with vibrating insoles turned on and off in subjects with neuropathy and nondisabled control subjects during five different trials.

	Neuropathy		Nondisabled	
	vibration on	vibration off	vibration on	vibration off
Eyes open; No ADT; 1st measurement	8.6 (0.4)	8.7 (0.4)	7.4 (0.5)	7.5 (0.4)
Eyes open; ADT	12.1 (1.0)	12.4 (0.8)	9.6 (0.8)	9.2 (0.7)
Eyes closed; No ADT	11.3 (0.8)	12.1 (1.0)	8.8 (0.6)	8.6 (0.6)
Eyes closed; ADT	14.5 (1.4)	14.9 (1.2)	10.2 (0.9)	9.9 (0.8)
Eyes open; No ADT; 5th measurement	9.0 (0.5)	9.2 (0.5)	7.6 (0.3)	7.6 (0.5)

ADT = attention demanding task

the AP direction were found in both groups (main effect of vision $p = 0.01$ and $p = 0.01$; main effect of ADT $p = 0.01$ and $p < 0.01$ in the neuropathy group and nondisabled group, respectively). Significant main effects of vision and ADT (eyes closed and an ADT increased RMS in the ML direction) on RMS of the COP velocity in the ML direction were found in both groups as well (main effect of vision $p = 0.01$ and $p < 0.01$; main effect of ADT $p < 0.01$ and $p < 0.01$ in the neuropathy group and nondisabled group, respectively).

The neuropathy group showed a significant favourable interaction effect of vibration \times ADT on RMS of the COP velocity in the AP direction ($p = 0.05$), whereas this interaction effect was not present in the ML direction ($p = 0.76$). In the nondisabled group, no interaction effects of vibration and either vision or ADT on the RMS of the COP velocity were found in either the AP or ML direction.

DISCUSSION

In line with other research [9–10;25], we found that in subjects with neuropathy, balance was impaired and that balance problems worsen when the balance task becomes more difficult. Moreover, when an ADT was presented, vibrating insoles improved balance in subjects with neuropathy, suggesting that when attention is distracted from the standing task, random vibrations applied to the feet improve balance. In contrast to earlier research [15–16], we found no effects of vibrating insoles in nondisabled subjects. The interaction effect in persons with neuropathy can mainly be explained by the improvement in balance as a result of vibrating insoles during the most difficult balance task: standing with the eyes closed and performing an ADT (Figure 3). The results from our study show that when vision is occluded and attention is distracted, the destabilizing effect of these interventions seems to diminish when random vibrations are applied to the plantar surface of the feet. During the condition with the eyes closed and an ADT, subjects have fewer compensatory options for balance control. Therefore, subjects have to rely more on the remaining information sources, of which mechanoreceptors on the plantar side of the feet are the most important, to control their standing balance. Improvement of the sensation of plantar surface pressure by vibrating insoles may lead to improved balance when subjects cannot use compensatory strategies.

The interaction between vibration and attention in subjects with neuropathy can mainly be explained by a decrease in COP velocity in the AP direction and not the ML direction. One possible explanation is that COP velocity in the AP direction was relatively more affected by the additional ADT (without vibration) than the COP velocity in the ML direction and, therefore, more improvement was possible in the AP direction. A second and more important explanation could be that plantar cutaneous mechanoreceptors play a more important role in the control of COP in the AP direction than in the ML direction [26]. This study showed deteriorated COP control in the AP direction after plantar hypoesthesia. Improving plantar

sensation of people with reduced plantar sensation (neuropathy) by vibrating insoles may therefore lead to improvement in balance control in the AP rather than the ML direction.

The findings of this study seem to be less pronounced compared with earlier research on vibrating insoles and application of noise to the feet [13–16]. The effects in persons with neuropathy seemed smaller, and in contrast with previous research, no effects in nondisabled people were found. Several explanations may account for these less pronounced effects. In our study, different measures and a different measuring device for balance were used. The first studies concerning vibrating insoles used excursions of a single shoulder marker to determine balance [15–16]. These shoulder-marker excursions are not commonly used as outcome measures for balance [27]. For example, rotation about the longitudinal axis will result in excursions of a single shoulder marker but is not a balance mechanism. However, according to Priplata *et al.* (2003, 2006), excursions of a shoulder marker used in their studies on vibrating insoles [15–16] correlated with COP displacements measured by a force plate [28]. This can only be the case when the human body acts completely as an inverted pendulum and no bending at the hip takes place. A possible explanation, although not very plausible, for the less pronounced findings in our study may be that vibrating insoles have a larger effect on hip strategy and less on ankle strategy, which may explain larger shoulder excursions measured by cameras and smaller effects on COP measured by a force plate.

The physical properties of the insoles differed from those used in the work of Priplata *et al.* (2003, 2006) as well [15–16]. In our study, we used insoles of 5 mm-thick cork with three built-in piezoelectric elements that were covered with a thin leather layer, whereas the first vibrating insole studies used gel-based insoles that were 16 mm thick and had electromagnetic actuators. We chose to use this insole configuration for several reasons. First, in this study, piezoelectric activators were used because these are much thinner than electromagnetic actuators. Therefore, it was possible to develop 6 mm-thick insoles that could be more easily implemented in clinical practice. Second, we decided to use rather hard insoles, because soft insoles may deteriorate balance due to deteriorated feedback concerning plantar pressure distribution. Differences in effects between the current study and previous work could be a result of these differences in insole configuration.

A weakness of our study is the applied amplitude of the vibrations. In the majority of the included subjects with neuropathy (71%), the maximum amplitude that could be applied by our vibrating insole system (120 V) was not sufficient to reach the sensory detection threshold. Therefore, in 71 percent of the included subjects with neuropathy, the amplitude of the vibrations was probably below 90 percent of the sensory detection threshold. On the other hand, in 93 percent of the nondisabled subjects, the threshold was reached. However, in the nondisabled group, no effects of vibration were found. This result suggests that the ability to detect the maximum amplitude of the vibrations, as was found in 93 percent of the nondisabled subjects, does not imply improvement of balance by vibrating insoles.

The weight of the people with neuropathy in our study was almost 15 kg more than the nondisabled subjects. This difference might influence the differences in balance between the two groups. However, because in this study the effects of mechanical noise were tested in a crossover design in which the subjects served as their own controls, we did not expect that the weight of the subjects would influence the results.

The noise type used in this study was a transistor-transistor logic signal with a randomly varying frequency band of 25 to 500 Hz. In previous research, digitized white noise, low-pass filtered to 100 Hz, with uniformly distributed amplitude was used. Research is needed to optimise the input signal to the insoles. Application of a fourth piezoelectric element under the big toe, where many mechanoreceptors are located, and an individually controllable amplitude of each piezoelectric element may contribute to improvement of the effects of the vibrating insoles [19].

CONCLUSION

The findings from this study are encouraging. The use of vibrating insoles in which the vibration is applied by piezoelectric elements seems to be an option for increasing stability in persons with neuropathy when compensatory strategies to control balance are limited. These insoles are thin (6 mm) and can therefore easily be worn in regular shoes. The absence of effects of vibrating insoles in nondisabled subjects and in persons with neuropathy when attention is not distracted requires extension of current research and development. The next step is to optimise the properties of the random vibrations applied to the feet, followed by research concerning the effects of these insoles on balance during walking and ultimately on fall frequency. To make the latter research possible, researchers must develop a wearable device that provides input to the plantar surface of the feet.

Finally, random vibrations applied to the plantar surface of the feet improved balance of persons with neuropathy only when attention was distracted and vision was occluded. The balance improvement can mainly be explained by improvement of the COP displacement velocity in the AP and not the ML direction. Assessment of the effects of vibrating insoles on a more functional level, such as research on the effects on balance during walking, is essential before implementation in daily living is recommended. Moreover, improvement of the insoles and their activation is necessary to make the use of these medical aids in daily living possible and effective.

ACKNOWLEDGEMENTS

We would like to thank OIM Holding BV, the Netherlands; K. Vaartjes, W.A. Kaan, W. Hollander, and K.S. Veldman for their technical support; and the Diabetes Center at UMCG for its help in patient recruitment. This material is the result of work supported with

resources of Stichting Beatrixoord Noord-Nederland, the Netherlands, and the Annafonds, the Netherlands.

The authors have declared that no competing interests exist.

REFERENCES

1. Maurer C, Mergner T, Bolha B, Hlavacka F. Vestibular, visual, and somatosensory contributions to human control of upright stance. *Neurosci Lett.* 2000;281(2–3):99–102.
2. Roll R, Kavounoudias A, Roll JP. Cutaneous afferents from human plantar sole contribute to body posture awareness. *Neuroreport.* 2002;13(15):1957–61.
3. Kavounoudias A, Roll R, Roll JP. Foot sole and ankle muscle inputs contribute jointly to human erect posture regulation. *J Physiol.* 2001;532(Pt 3):869–78.
4. Shumway-Cook A, Woollacott M. Attentional demands and postural control: The effect of sensory context. *J Gerontol A Biol Sci Med Sci.* 2000;55(1):M10–6.
5. Maurer C, Mergner T, Peterka RJ. Multisensory control of human upright stance. *Exp Brain Res.* 2006;171(2):231–50.
6. Bloem BR, Allum JH, Carpenter MG, Honegger F. Is lower leg proprioception essential for triggering human automatic postural responses? *Exp Brain Res.* 2000;130(3):375–91.
7. Hijmans JM, Geertzen JHB, Dijkstra PU, Postema K. 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. *Gait Posture.* 2007; 25(2):316–23.
8. Horak FB, Dickstein R, Peterka RJ. Diabetic neuropathy and surface sway-referencing disrupt somatosensory information for postural stability in stance. *Somatosens Mot Res.* 2002;19(4):316–26.
9. Simoneau GG, Ulbrecht JS, Derr JA, Becker MB, Cavanagh PR. Postural instability in patients with diabetic sensory neuropathy. *Diabetes Care.* 1994;17(12):1411–21.
10. Uccioli L, Giacomini PG, Monticone G, Magrini A, Durola L, Bruno E, Parisi L, Di Girolamo S, Menzinger G. Body sway in diabetic neuropathy. *Diabetes Care.* 1995; 18(3):339–44.
11. Young MJ, Boulton AJ, MacLeod AF, Williams DR, Sonksen PH. A multicentre study of the prevalence of diabetic peripheral neuropathy in the United Kingdom hospital clinic population. *Diabetologia.* 1993;36(2):150–54.
12. Brown MJ, Asbury AK. Diabetic neuropathy. *Ann Neurol.* 1984;15(1):2–12.
13. Priplata A, Niemi J, Salen M, Harry J, Lipsitz LA, Collins JJ. Noise-enhanced human balance control. *Phys Rev Lett.* 2002;89(23):238101.
14. Gravelle DC, Laughton CA, Dhruv NT, Katdare KD, Niemi JB, Lipsitz LA, Collins JJ. Noise-enhanced balance control in older adults. *Neuroreport.* 2002;13(15):1853–56.

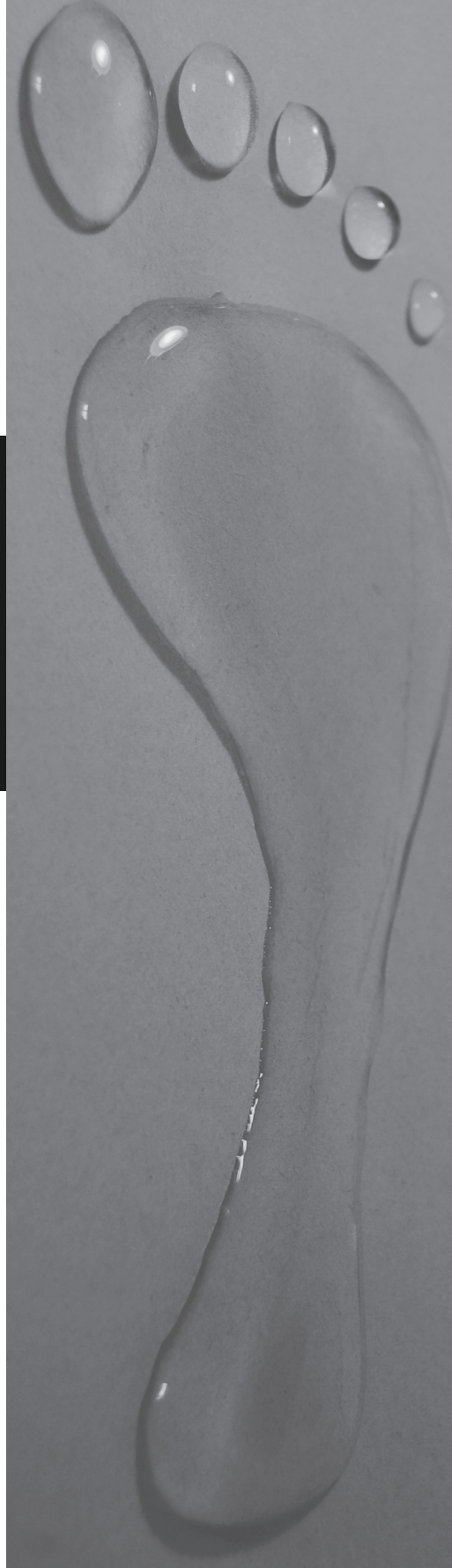
15. Priplata AA, Niemi JB, Harry JD, Lipsitz LA, Collins JJ. Vibrating insoles and balance control in elderly people. *Lancet*. 2003;362(9390):1123–24. [
16. Priplata AA, Pattriti BL, Niemi JB, Hughes R, Gravelle DC, Lipsitz LA, Verves A, Stein J, Bonato P, Collins JJ. Noise-enhanced balance control in patients with diabetes and patients with stroke. *Ann Neurol*. 2006;59(1):4–12.
17. Collins JJ, Priplata AA, Gravelle DC, Niemi J, Harry J, Lipsitz LA. Noise-enhanced human sensorimotor function. *IEEE Eng Med Biol Mag*. 2003;22(2):76–83.
18. Liu W, Lipsitz LA, Montero-Odasso M, Bean J, Kerrigan DC, Collins JJ. Noise-enhanced vibrotactile sensitivity in older adults, patients with stroke, and patients with diabetic neuropathy. *Arch Phys Med Rehabil*. 2002;83(2):171–76.
19. Hijmans JM, Geertzen JH, Schokker B, Postema K. Development of vibrating insoles. *Int J Rehabil Res*. 2007;30(4): 343–45.
20. Perry SD. Evaluation of age-related plantar-surface insensitivity and onset age of advanced insensitivity in older adults using vibratory and touch sensation tests. *Neurosci Lett*. 2006;392(1–2):62–67.
21. International Working Group on the Diabetic Foot. International consensus on the diabetic foot and practical guidelines on the management and the prevention of the diabetic foot. Amsterdam: International Working Group on the Diabetic Foot; 2003.
22. Sosenko JM, Kato M, Soto R, Bild DE. Comparison of quantitative sensory-threshold measures for their association with foot ulceration in diabetic patients. *Diabetes Care*. 1990;13(10):1057–61.
23. Meijer JW, Smit AJ, Lefrandt JD, Van der Hoeven JH, Hoogenberg K, Links TP. Back to basics in diagnosing diabetic polyneuropathy with the tuning fork! *Diabetes Care*. 2005;28(9):2201–5.
24. Kapteyn TS, Bles W, Njikiktjien CJ, Kodde L, Massen CH, Mol JM. Standardization in platform stabilometry being a part of posturography. *Agressologie*. 1983;24(7): 321–26.
25. Corriveau H, Prince F, Hébert R, Raïche M, Tessier D, Maheux P, Ardilouze JL. Evaluation of postural stability in elderly with diabetic neuropathy. *Diabetes Care*. 2000; 23(8):1187–91.
26. McKeon PO, Hertel J. Plantar hypoesthesia alters time-to-boundary measures of postural control. *Somatosens Mot Res*. 2007;24(4):171–77.
27. Lafond D, Mouchnino L, Prince F. Tactile stimulation of insoles and balance control in elderly people. *Lancet*. 2004; 363(9402):84.
28. Priplata AA, Niemi JB, Harry JD, Lipsitz LA, Collins JJ. Tactile stimulation of insoles and balance control in elderly people. *Lancet* 2004;363(9402):85–6.

Development of vibrating insoles

5

Juha M. Hijmans
Jan H.B. Geertzen
Bart Schokker
Klaas Postema

International Journal of Rehabilitation
Research 30 (2007) 343–345
Reprinted with kind permission



ABSTRACT

The objective of this study was to describe the development of vibrating insoles. Insoles, providing a subsensory mechanical noise signal to the plantar side of the feet, may improve balance in healthy young and older people and in patients with stroke or diabetic neuropathy. This study describes the requirements for the tactors (tactile actuators), insole material, and noise generator. A search for the components of vibrating insoles providing mechanical noise to the plantar side of the feet was performed. The mechanical noise signal should be provided by tactors built in an insole or shoe and should obtain an input signal from a noise generator and an amplifier. Possible tactors are electromechanical tactors, a piezo actuator or the VBW32 skin transducer. The Minirator MR1 of NTI, a portable MP3 player or a custom-made noise generator can provide these tactors with input. The tactors can be built in foam, silicone or cork insoles. In conclusion, a C2 electromechanical tactor, a piezo actuator or the VBW32 skin transducer, activated by a custom-made noise generator, built in a cork insole covered with a leather layer seems the ideal solution.

INTRODUCTION

Stochastic resonance (SR) can be described as a counter-intuitive mechanism whereby the addition of noise to a nonlinear system can enhance the detection of weak stimuli or enhance the information content of a signal [1]. SR is associated with biological systems and even with human somatosensation [2]. The somatosensory system provides the central nervous system with information concerning joint position sense and the sense of touch. Mechanoreceptors, muscle spindles, Golgi tendon organs and joint afferents are responsible for somatosensation. Mechanoreceptors situated in the soles of the feet provide the central nervous system with information concerning pressure distribution under the feet. Muscle spindles, Golgi tendon organs and joint afferents situated in the lower leg are responsible for the detection of changes in the ankle joint angle. During standing, changes in pressure and changes in ankle joint angle are often related to changes in upright position. In older people and people with peripheral sensory deficits the detection of changes in upright position is often impaired, resulting in impaired balance and an increased risk for falling.

Application of mechanical noise to the feet may improve somatosensation due to SR. Vibrating insoles may be used for the application of a subsensory mechanical noise signal to the soles of the feet [3;4]. The subsensory noise signal may amplify tactile input like change in pressure distribution under the sole of the foot, resulting in earlier detection of the pressure change. It has been shown that the sway amplitude, measured by motion capture of a shoulder marker, decreased when vibrating insoles were applied to healthy adolescents, elderly, stroke patients, and patients with diabetic neuropathy [3;4]. Our research group is engaged in studies concerning the effects of ankle and foot appliances on balance. To be able to compare the effects of vibrating insoles with the effects of other appliances we developed vibrating insoles. In this study we will describe the development and the requirements for vibrating insoles.

METHODS

The main reason for developing vibrating insoles is to improve balance in people with a deterioration of the somatosensory feedback from mechanoreceptors that play a role in balance control. Most crucial mechanoreceptors are located at the metatarsal phalangeal joint (MTP) region, the heel and the plantar side of the first toe [5]. Therefore, it seems reasonable to position vibrating tactile actuators, called tactors, at these positions (Fig. 1). To apply a vibration to the soles of the feet, these tactors should be built in an inlay or in the shoe. As the mechanical noise should be applied with a certain adaptable amplitude, some requirements for the actuator should be taken into account.

Requirements for tactors

To make it possible to build in tactors in an insole or shoe without increasing the thickness of

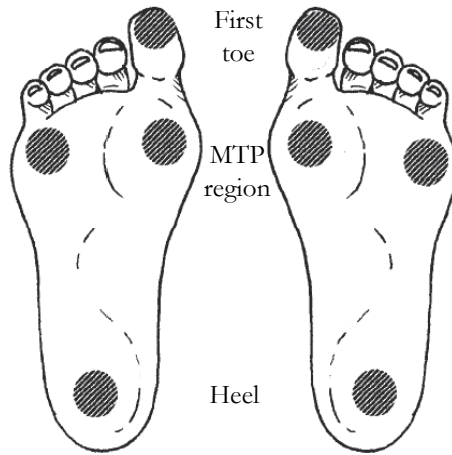


Figure 1. Tactor locations; one at the first toe, two at the metatarsal phalangeal joint (MTP) region and one at the heel.

the sole too much, the tactors should be as thin as possible. A large sole thickness (between 16 and 27 mm) is associated with deterioration of balance [6]. Therefore, the thickness of the tactor should not exceed 15 mm. As two actuators should be positioned next to each other at the MTP region (as seen in Fig. 1), the width of the tactor should not exceed half of the width of the foot at this location. Moreover, one of the tactors should fit under the first toe. Consequently, the width or diameter of the tactors should not exceed 35 mm. The vibration frequency should be adjustable within limits of about 1–1000 Hz (noise signal with varying frequency) and the tactors should instantly react to the input frequency changes. In the only studies concerning the effects of vibrating insoles on balance, the amplitude of the vibration was set at 90% of the sensory threshold [3;4]. Therefore, the amplitude of the vibration applied by the tactor should be adjustable, to make tuning of the amplitude towards individual differences in tactile perception threshold possible. As the appliance may benefit people with impairment of the somatosensory system, the maximum amplitude when loaded should reach the tactile perception threshold in these people. The average threshold amplitude (vibration perception threshold) in a neuropathic population is about 400 mm, in a healthy population this threshold is about 20 mm, both at a vibration frequency of 60 Hz [7].

Requirements for noise generator/amplifier

The tactors should be activated by a noise generator and possibly by an amplifier. To make utilization in daily living (e.g. during walking) possible, both the noise generator and the amplifier should be portable. It is not known what the ideal frequency range of the noise signal should be and whether white noise or coloured noise has the best effects on

balance. Therefore, the noise generator should be able to produce different types of noise within a wide range of frequencies. Moreover, it would be best to set the amplitude of all tactors individually, because of differences in tactile perception thresholds at the different locations.

Requirements for material

It would be best to replace a standard insole by a vibrating insole without making any modifications to the shoe, instead of building in tactors in a shoe. The material of which this insole is made plays an important role. The material should be comfortable, should not absorb the vibration and should be adaptable to make fitting of the actuators possible. Moreover, the material should be relatively hard (Shore A50), because soft insoles (Shore A15 or A33) are associated with negative effects on balance [6]. In a diabetic population, however, too hard material will increase the risk for wounds owing to incorrect pressure distribution.

RESULTS

A profound search resulted in a wide range of brands and types of actuators that can produce a vibration. In Table 1 the actuators found and their properties are shown. All actuators described in Table 1 should be provided with an input signal. Noise generators may be responsible for the input signal.

A lot of different noise generators exist. Most of them are, however, not portable, or have to be built in a personal computer. Only one suitable portable noise generator was found. The Minirator MR1 of NTI is an analogue noise generator that can produce a noise signal with a frequency range of 20 Hz–20 kHz. This noise generator has only one output channel. Another possibility is to use a portable audio player, such as a MP3 player; these have only one output channel as well.

Materials most used for insoles are synthetic foam (as polyurethane and ethylene vinyl acetate; Shore A10A80), rubber (Shore A10-A95), silicone (rubber) (Shore A5-A90) and cork, combined with thermoplastic material to make adaptations possible when the material is heated (Shore A55-A65). All these materials are often covered with a thin leather or fabric layer, to make the insole more comfortable.

DISCUSSION

A combination of a tactor, a noise generator and sole material should make the ideal product to apply a random vibration to the soles of the feet. For prototyping and individually moulded insoles, cork covered with a thin leather layer seems an ideal product. The hardness of the cork material ranges between Shore A55 and A65. In our opinion, Shore A55 is soft enough,

Table 1. Tactile actuators and their properties.

Actuator	Dimensions	Suitable	Frequency	Suitable	Amplitude	Suitable
C2 Tactor	D = 30.5 mm H = 7.9 mm	Yes	Not known	Possibly	0.635 mm	Yes
C1026B200F Vibration motor	D = 10 mm H = 5 mm	Yes	Max. 55 Hz	No	Not known	Possibly
B5A-11W Vibration motor	L = 11 mm W = 11 mm H = 2 mm	Yes	10 – 150 Hz	No	Not known	Possibly
P-289 Piezo actuator	D = 50 mm H = 12 mm	No	1 st resonance freq. = 1.1 kHz	Yes	0.2 mm	Possibly
APA400M Actuator	L = 48.4 mm W = 11.5 mm H = 13.0 mm	Yes	1 st resonance freq. = 4.6 kHz	Yes	0.4 mm	Yes
VBW32 Skin Transducer	L = 25.4 mm W = 18.5 mm H = 10.7 mm	Yes	100 – 800 Hz	Possibly	Till 50 dB above threshold	Possibly

D= Diameter (of round actuators); H= Height (in actuation direction); L= Length; W= Width

especially when a leather layer on top of the cork is used.

Different tactors can be used in vibrating insoles. Vibration motors are not usable because only a small frequency range can be applied and the amplitude of the vibration depends on the design of the vibration motor only, and is therefore not individually adaptable. Possible tactors are the C2 electromechanical tactor, used by Priplata *et al.* (2003, 2006) in vibrating insoles [3;4]; piezo actuators, for example the APA400M actuator; or the VBW32 skin transducer. The dimensions, frequency range and amplitude of the vibration applied by these tactors seem to be suitable for vibrating insoles.

The different tactors should be provided with different input. Piezo actuators require a high voltage and low amperage, whereas the C2 tactor and the VBW32 skin transducer require a lower voltage and a higher amperage. Moreover, the tactors applying a subthreshold vibration to the soles of the feet should be individually controlled, to be set on 90% of the tactile threshold on a specific portion of the foot sole. For both reasons, portable noise generators on the market and standard portable audio players are not usable in vibrating insoles. The power supply for vibrating insoles should be custom-made. A custom-made noise generator can be constructed in a small and light version, and can be constructed in such a way that the amplitude of the vibration can be set for every insole individually.

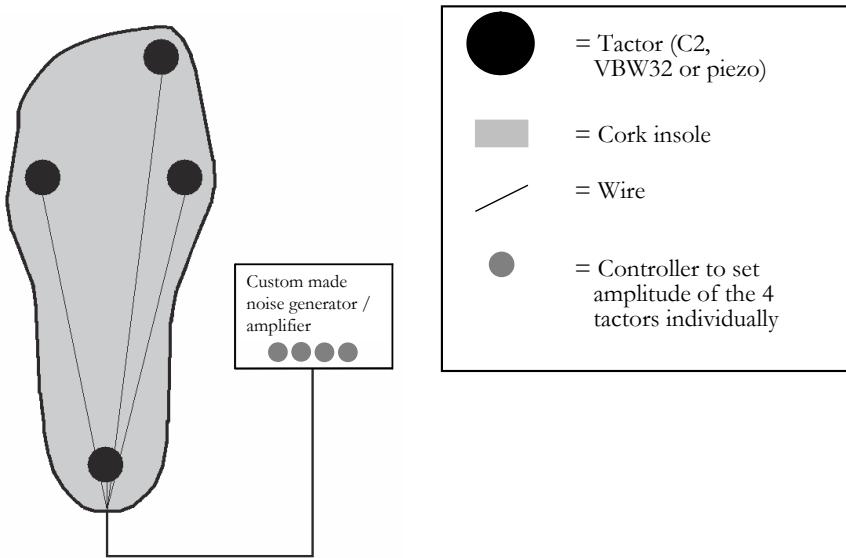


Figure 2. The design of vibrating insoles. The cork insole and the tactors will be covered with a leather layer.

CONCLUSION

Figure 2 shows the final design of the vibrating insoles.

REFERENCES

1. Collins JJ, Priplata AA, Gravelle DC, Niemi J, Harry J, Lipsitz LA (2003). Noise-enhanced human sensorimotor function. *IEEE Eng Med Biol Mag* 22:76–83.
2. Moss F, Ward LM, Sannita WG (2004). Stochastic resonance and sensory information processing: a tutorial and review of application. *Clin Neurophysiol* 115:267–281.
3. Priplata AA, Niemi JB, Harry JD, Lipsitz LA, Collins JJ (2003). Vibrating insoles and balance control in elderly people. *Lancet* 362:1123–1124.
4. Priplata AA, Patrilli BL, Niemi JB, Hughes R, Gravelle DC, Lipsitz LA, Veves A, Stein J, Bonato P, Collins JJ. (2006). Noise-enhanced balance control in patients with diabetes and patients with stroke. *Ann Neurol* 59:4–12.
5. Kennedy PM, Inglis JT. (2002) Distribution and behaviour of glabrous cutaneous receptors in the human foot sole. *J Physiol* 538:995–1002.
6. Van Deursen RW, Sanchez MM, Derr JA, Becker MB, Ulbrecht JS, Cavanagh PR (2001). Vibration perception threshold testing in patients with diabetic neuropathy: ceiling effects and reliability. *Diabet Med* 18:469–475.

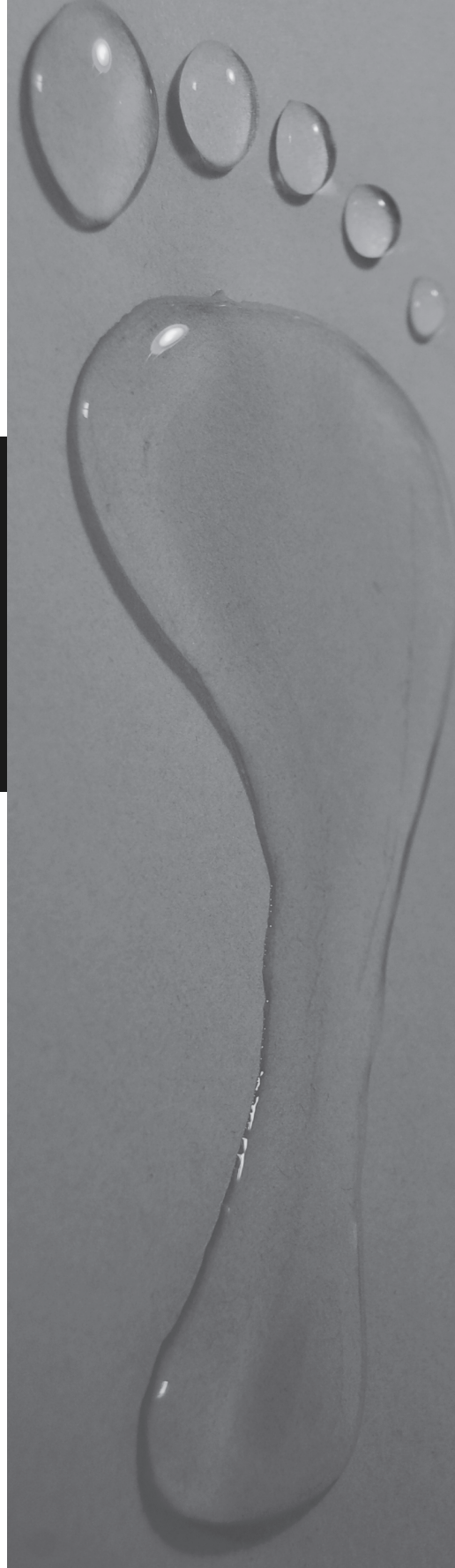
7. Robbins S, Gouw GJ, McClaran J (1992). Shoe sole thickness and hardness influence balance in older men. *J Am Geriatr Soc* 40:1089–1094.

Properties of noise to improve
standing balance in people
with diabetic neuropathy.
A single case design.

6

Juha M. Hijmans
Wiebren Zijlstra
Jan H.B. Geertzen
At L. Hof
Klaas Postema

Submitted



ABSTRACT

This study aims to determine the most effective properties of a mechanical noise signal, applied by vibrating insoles to the plantar surface of the feet, in order to improve standing balance in people with diabetic neuropathy. In a single case experimental approach (n=5) the effects on balance of mechanical noise with different properties were studied. Three different amplitudes and three different frequency bands (nine different interventions) were studied. Force plate measurements were used to calculate the mean velocity of the centre of pressure displacement, which was used as the measure for balance. The effects on standing balance of the nine different noise signals were compared to both the baseline interval before and after the intervention. Both the intervention and the baseline condition lasted for 30 s. This study confirmed that mechanical noise applied to the feet by vibrating insoles can improve balance in people with minor to moderate diabetic neuropathy. Noise, low pass filtered with an upper cut-off frequency of 200 Hz seems the most effective in improving balance; the applied amplitude with this cut-off frequency seems arbitrary.

INTRODUCTION

Diabetes Mellitus (DM) leads to the development of diabetic neuropathy (DN) in about 30% of the cases [1-3]. Prolonged disease duration, older age and poor glycemic control all increase the probability of developing DN [1-3]. The main cause of DN is axonal degeneration and demyelination due to a reduced nerve blood flow and therefore a reduced oxygenation [4]. Symptoms of DN include higher thresholds for tactile and vibrotactile sensation [5]. Impaired tactile sensation from the plantar surface of the feet may lead to deteriorated balance, because changes in pressure distribution are detected less accurately [5].

In normal stance, the body is not stationary. Rather, during quiet stance the body is constantly moving with the direction of the movement constantly changing. Postural control refers to maintaining the centre of gravity (CoG) within the base of support (BoS) [6]. Tactile sensation from the plantar surface of the foot is an important source of information for the control of balance [7;8]. When this tactile sensation is reduced balance is often impaired, which is the case in DN [5;9-11]. Improvement of this reduced tactile sensation of the plantar surface of the feet is thought to lead to improvement of balance [12].

Previously, it was shown that insoles providing mechanical noise to the plantar surface of the feet can improve tactile sensation and therefore improve standing balance in people with a deteriorated tactile sensation [13-15]. The rationale for improved balance from the application of mechanical noise to the plantar surface of the feet can be found in a mechanism called stochastic resonance (SR) [16]. SR can be described as a counterintuitive mechanism whereby the addition of noise to a non-linear system can enhance the detection of weak stimuli or enhance the information content of a signal [16]. In this study, the changing pressure under a certain part of the foot can be seen as the non-linear system. Based on the mechanism described earlier (SR) the noise, applied by vibrating insoles, is thought to have immediate effects on balance, which are thought to disappear immediately when the noise is turned off.

The positive effects on balance from insoles which apply mechanical noise to the plantar surface of the feet varied in magnitude [13-15]. In order to achieve clinically relevant effects and to use the insoles in daily life, improvement of the insoles leading to larger effects on balance is needed. One explanation for the limited effects may be that the optimal properties have not yet been applied. Therefore, the goal of this study was to determine the properties of the mechanical noise signal applied to the feet that lead to larger improvements in standing balance for those with reduced tactile sensation in the feet.

The effects of mechanical noise with different properties are studied in a single case experimental approach. This design is an experiment in which one entity is observed repeatedly during a certain period under different levels (treatments) of at least one independent variable [17]. Visual inspection of the graphs is used to explore the effects

of the intervention. It should not be confused with a case study in which there is often no experimental approach or manipulation of an independent variable [17]. Although this type of research is not often used in evaluating balance [18] the intervention in this study is well suited to a single case design. The intervention is thought to have an immediate effect on balance and the effects are thought to disappear instantaneously when the intervention is ended.

METHODS

In this study, five patients with DN aged between 42 and 52 years with various degrees of sensory loss of the plantar surface of the feet were included. Participants were selected where DN was mentioned in their medical records. The degree of sensory loss was assessed by a 10g Semmes Weinstein Monofilament (SWM) and a 128 Hz tuning fork [19]. Tactile sensation was tested at four locations on the plantar surface of each foot (heel, first metatarsophalangeal joint (MTP1), fifth metatarsophalangeal joint (MTP5) and first toe). Vibrotactile sensation was tested at the medial malleolus and the medial side of MTP1 of both feet. (Vibro)tactile sensitivity and other characteristics are presented in table 1. All participants signed informed consent. The procedures were approved and registered by the medical ethics committee of the University Medical Center Groningen (UMCG).

Balance was tested on a force plate. During each measurement, participants stood with their feet parallel (7 cm apart) and eyes closed. An AMTI force plate (BP 400600-1000) was used to measure ground reaction forces. Data were sampled at 1000 Hz and were low pass filtered (Butterworth) with a cut-off frequency of 6 Hz. The path length of the Center of

Table 1. Characteristics of the participants.

Subject number	1	2	3	4	5
Age in years	49	49	42	52	52
Gender	female	female	male	male	female
Mass in kg	82	59	94	98	102
Diabetes Mellitus type	I	I	I	I	II
Number of locations at which 10g SWM was perceived (max. 8)	0	8	0	2	8
Number of locations at which the tuning fork was perceived correctly (max. 4)	0	0	0	0	4
History of ulceration	no	yes	yes	no	no

SWM: Semmes Weinstein Monofilament

Pressure (COP) displacement was first calculated. Following the main outcome measure for balance, mean velocity of the COP displacement was calculated by dividing the path length by the sample duration. Data processing was completed with MatLab 7.1 (The MathWorks, Inc). In total, nine different trials were recorded. In some participants, the nine different trials were presented twice (both with eyes closed), once with and once without performing an attention demanding task (ADT). Because of fatigue and technical problems not all participants were able to complete the second set of measurements with an ADT. In previous research we showed an effect of vibrating insoles on balance only when an ADT had to be preformed [15]. The ADT consisted of a calculation task in which the participant had to continuously subtract 6 or 7 from a randomly chosen number between 300 and 500.

The participant stood on a pair of vibrating insoles, placed on the force plate during all measurements. The vibrating insoles were constructed as designed in a previous study [20], although rubber (Realux) was used instead of cork. Two rubber insoles with four piezoelectric actuators each, placed under the first toe (Noliac CMBR1; $\text{Ø}=20\text{mm}$), MTP1, MTP5, and the heel (Noliac CMBR7; $\text{Ø}=40\text{mm}$) covered with a fabric layer (Alantara) were used. The total thickness of the insoles (including actuators) was 4 mm.

The signal applied by the piezoelectric actuators consisted of white noise with a bandwidth from 10 Hz to 20 kHz which was low-pass filtered with a fifth order filter. The output was band limited white noise with an upper cut-off frequency of 50 Hz, 200 Hz or 1000 Hz. The amplitude of the output was adjustable between 0 V and 200 V (peak-to-peak) in 255 steps. The output of 200 V was the theoretical maximum (not reached because of the noisy character of the output signal). The amplitudes, were set on 150, 200 and 255 on a linear scale from 0 – 255, corresponding with a theoretically maximum output voltage of 118 V, 157 V and 200 V respectively. An output of 200 V matches a free stroke of 185 μm of the CMBR7 piezoelectric actuator (placed under the heel, MTP1, and MTP5) in both upward and downward direction, with a blocking force of 13 N. The maximum stroke of the CMBR1 actuator (placed under the first toe) was 47 μm , with a blocking force of 9 N. To define the most effective amplitude and bandwidth of the noise signal, nine different spectra of mechanical noise were tested; three different bandwidths (upper cut-off frequencies of 50 Hz, 200 Hz, and 1000 Hz), each with three different amplitudes (150, 200 and 255). The insoles were activated by a custom-made portable amplifier. The amplifier had a wireless connection to a notebook computer. Using LabView (version 8.0 National Instruments) based customised software, the upper cut-off frequency and amplitude of the noise signal were set.

During each trial of 60 s the vibrating insoles were turned on during the last 30 s. The outcomes were based on the interval between 2.5 s and 27.5 s (baseline) and the interval between 32.5 s and 57.5 s (intervention). This procedure was used because the exact point in time when the insoles were turned on was not recorded.

For each subject the effects of the nine interventions were compared to their baseline measure using a single case experimental design. Preceding each intervention, a baseline (control) condition was presented. Following this intervention a second interval of 25 s baseline was used to compare the intervention to. The study can be seen as an A_1 - B - A_2 - C - A_3 - D - A_4 - E - A_5 - F - A_6 - G - A_7 - H - A_8 - I - A_9 - J design in which A is the baseline condition (no vibration) and B to J are the nine different interventions. B was compared to both A_1 and A_2 , C was compared to both A_2 and A_3 and so forth. After three measurements of 60 s (intervention and preceding baseline measurement), the participants were allowed to rest for two minutes. This possibility was not used by any of the participants. The total duration of the measurements was almost one hour (when the nine different trials were presented twice). Interventions B to J were presented in a random order.

Since the order in each participant was different, it was chosen not to present the data of the five participants in one graph showing the outcomes (mean velocity of the COP displacement) of each participant chronologically, because in this way it is hard to interpret the different effects of the nine interventions, which were presented in random order. It was also chosen not to present the data clustered by intervention type, because in this way information about the changes in baseline over time was lost. Because in this study a single subject design was used, only descriptive statistics were presented.

RESULTS

As an example, XY plots of the COP of one participant (subject 5 ADT) during all nine interventions, combined with the preceding baseline measurements are presented in figure 1. This figure shows the behaviour of the COP during each trial.

Figure 2 presents the baseline conditions (A_1 - A_9) of the five participants chronologically, in order to explore the effects of time (e.g. learning or fatigue). Subject 1 completed only four of the nine trials. This participant was physically unable to stand for a longer duration. Two participants (subject 4 and 5) were measured twice, once with and once without ADT. The change in time of the two ADT measurements (subject 4 and 5) are in opposite direction. The largest change in baseline is present between A_1 and A_2 in most cases.

The difference between each intervention and both the preceding (figure 3) and the subsequent baseline measurement (figure 4) are presented as outcomes of this study. Differences in mean velocity of the COP displacement in terms of percentages are shown. By visual inspection of the scatter plots the most effective noise condition (amplitude and bandwidth) applied to the plantar surface of the feet was determined. Figure 3 demonstrates that most interventions resulted in a positive score. A positive difference in terms of percentages indicates a favourable effect of the intervention (increased stability) in mean velocity of the COP displacement (smaller velocity) compared to the preceding baseline measurement.

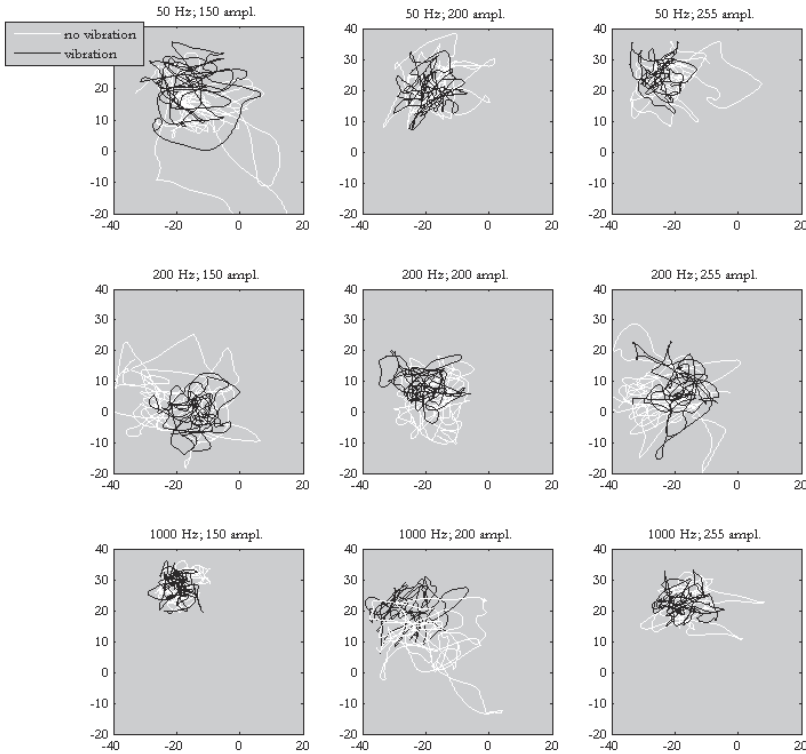


Figure 1. XY plots of the COP position (mm) during 55 s of subject 5 (with ADT); the first and last 2.5 s of the measurements are left out of consideration in this figure. The white lines represent the preceding baseline conditions. The black lines represent the COP during the nine different interventions.

The difference between the nine interventions and the subsequent baseline scores are presented in figure 4. Again, a positive score is indicative of a favourable effect of the application of mechanical noise on balance. The ninth intervention had no subsequent baseline measurements, therefore only eight differences are presented for the four participants that completed nine trials. This figure also demonstrates a favourable effect of the interventions compared to baseline. Both figure 3 and 4 display that largest improvements in terms of percentages compared to baseline can be found when noise with an upper cut-off frequency of 200 Hz is presented. When other upper cut-off frequencies are applied, larger amplitudes seem to be more effective than smaller.

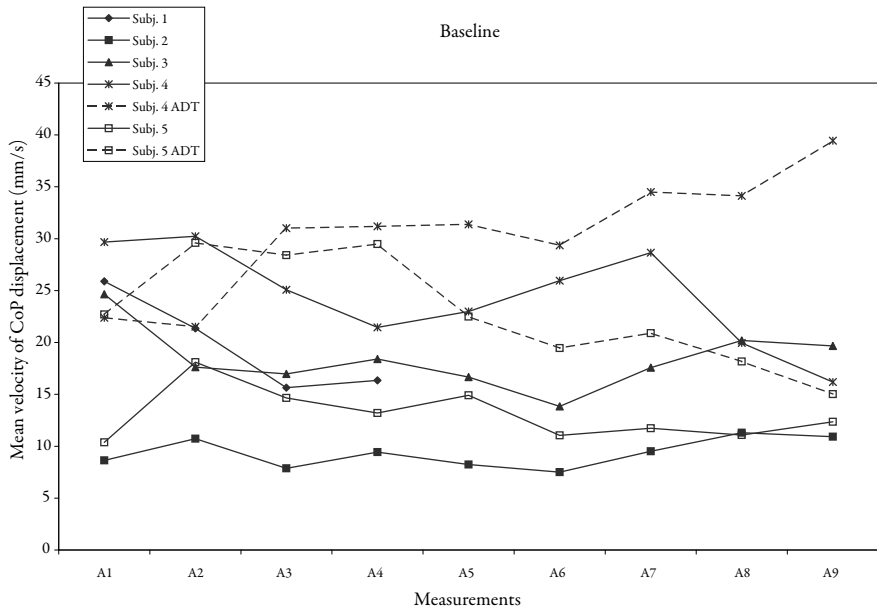


Figure 2. Repeated baseline measurements of the mean velocity of the COP displacement of the 5 participants in chronological order. The dashed lines represent the measurements when performing an attention demanding task (ADT).

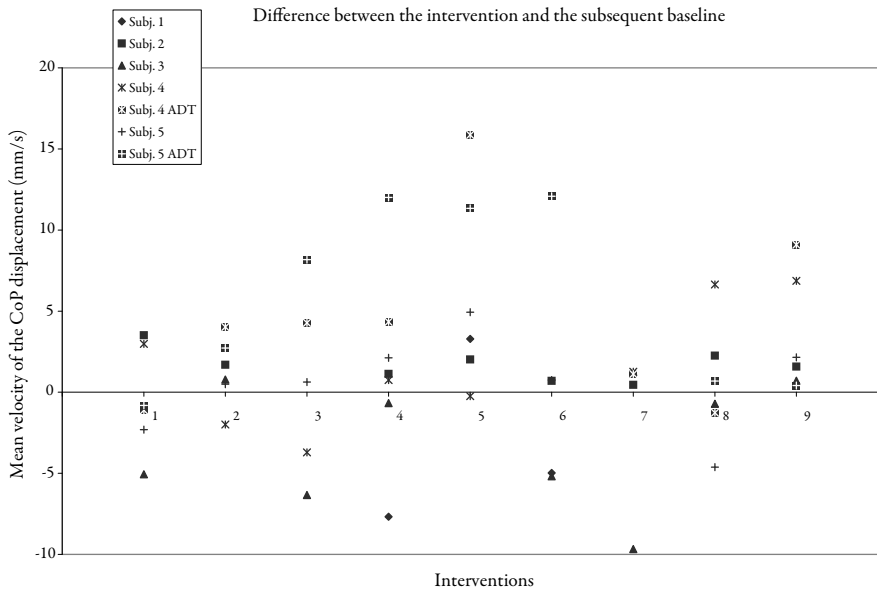


Figure 3. Difference between the preceding baseline measurement and the nine interventions in terms of percentages compared to baseline. A positive score indicates a favourable effect of the intervention. On the X-axis the upper cut-off frequency and amplitude of the nine different noise signals are presented. The dotted lines separate the different upper cut-off frequencies.

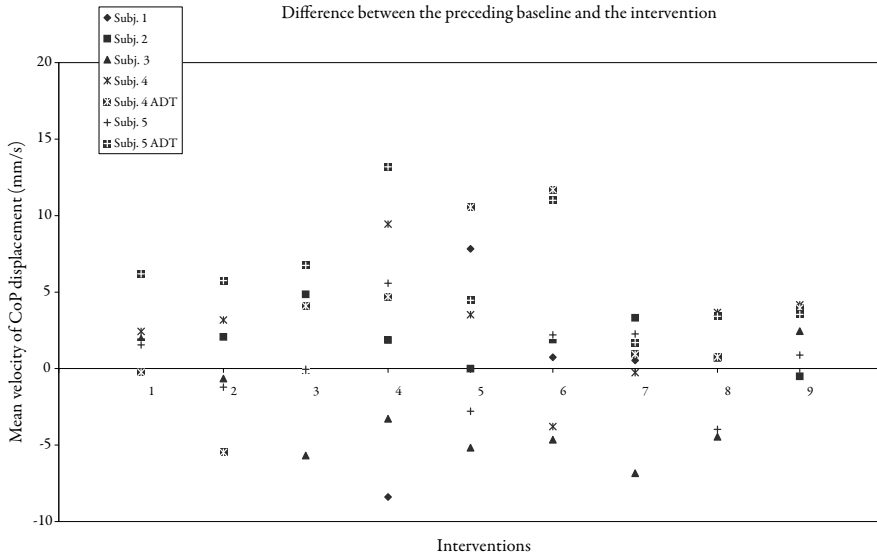


Figure 4. Difference between the nine interventions and the subsequent baseline measurement in percentage compared to baseline. A positive score indicates a favourable effect of the intervention. On the X-axis the upper cut-off frequency and amplitude of the noise signal are presented. The dotted lines separate the different upper cut-off frequencies.

DISCUSSION

In this study it was shown that the baseline of the participants was not steady (figure 2). However, the group of participants did not show a consistent in- or decrease over time in baseline mean velocity of COP displacement. Some of the participants did show a gradual in- or decrease, suggesting an effect of repeated measurements (fatigue or learning) and possibly an unexpected effect of the intervention on subsequent baseline outcomes. Because this effect was not shown in all participants and the direction of the change over time varied between participants, the vibrations applied are not thought to have either a positive or a negative effect on balance once the vibration is turned off. This is in line with theories about SR. In order to tackle the problem of the changing baseline over time, the interventions were compared to both the preceding and the subsequent measurement.

The figures showing the differences between the intervention and the preceding (figure 3) and the subsequent (figure 4) baseline measurement, generally demonstrate a favourable effect of the different interventions. Forty of the 58 (69%) interventions, resulted in a smaller mean velocity of the COP displacement compared to the preceding baseline, suggesting improved balance; two participants received 18 interventions, two participants received nine interventions and one participant received four interventions. Of all 51 interventions

with a subsequent baseline measurement, 32 (63%) showed a favourable effect of noise compared to this baseline. One participant (subject 3; triangles) seemed not to benefit from the mechanical noise. This participant had severe neuropathy with a long history of ulcerations. When his results are left out of consideration, the percentages increase to 78% and 74% respectively. Moreover, the percentages of improvement (score above 0) are larger than the deterioration percentages (score below 0), emphasising the favourable effects of the insoles. These results indicate that vibrating insoles seem to improve balance.

Not all interventions were thought to improve balance, rather the optimal noise properties were sought. Figures 3 and 4 demonstrate that noise when low pass filtered with an upper cut-off frequency of 200 Hz, seems more effective in decreasing the mean velocity of the COP displacement compared to an upper cut-off frequency of either 50 Hz or 1000 Hz. These graphs also display that when noise low-pass filtered with an upper cut-off frequency of 50 Hz or 1000 Hz is presented, larger amplitudes are more effective than smaller. With the application of an upper cut-off frequency of 200 Hz, an amplitude of 200, and compared to the subsequent baseline measurement, the largest average improvement was found (approximately 35%). Because of the design of this study (single case experimental approach), this study should be seen as a first step in the exploration of the most effective noise signal. In future the effects of the most suitable frequency bands and amplitude should be examined in a larger group.

In line with our previous research it was demonstrated that during the ADT condition, the favourable effects of the vibrating insoles were the largest (both in percentages as well as in absolute numbers) [15], in particular when an upper cut-off frequency of 200 Hz was applied. This suggests that when less processing capacity to control balance is available, the vibrating insoles are the most effective.

It was not possible to reach the threshold for sensing the vibration of the insoles in all participants (only subject 2 and 5 were able to feel the maximum vibration). Of the 9 presented interventions, maximally one intervention was consciously sensed by these two participants (upper cut-off frequency of 1000 Hz with an amplitude of 255). All other interventions were below the tactile threshold, therefore the participants can be considered as blinded for these interventions.

We suggested earlier that the amplitude for each of the eight actuators should be individually adjustable [20]. This feature was embedded in the system but not used. The reason was that in three participants the maximum amplitude was not sufficient to reach the threshold and in the two participants in whom the threshold could be reached it was near the maximum amplitude of the system. In the future a system which enables larger amplitudes might prove the value of this feature. The Noliac CMBR piezoelectric actuators used, have the ability to reach larger amplitudes, however the custom made portable insole system could not deliver

the required high voltages.

The piezoelectric actuators are quite fragile; it is important to build the actuators into a solid base, preventing any bending forces on actuators. The piezoelectric actuators require large voltages (up to 200 V peak-to-peak, in people with moderate DN) to reach the tactile threshold. This requires a large power and a heavy power source (battery). This raises the question of the potential of piezoelectric actuator based vibrating insoles in daily activity. Possibly in future, other actuators should be considered. However the possibilities are limited. Electromagnetic actuators heat up when activated, which is an undesirable side effect. All other actuators are rather thick and therefore difficult to build in an insole. Other actuators, however, seem to be more durable than piezoelectric ones.

The single case design is ideal in customizing treatments [17]. This study was designed to assess the optimal type of noise in order to improve balance in DN. This design was able to increase the knowledge about the most suitable noise signal. It should be mentioned that in this study the variation within one baseline measurement could not be studied. In order to report reliable COP based outcomes, the interval of 25 s cannot be subdivided. Usually, the within baseline variation is presented in a single case design in order to demonstrate that effects of the interventions are not based on chance, but are consistent. Because nine subsequent baselines were presented, and the idea that the intervention does not affect the subsequent baseline, this problem was handled.

In conclusion, mechanical noise applied to the feet by vibrating insoles may improve standing balance in people with minor to moderate DN. Where severe neuropathy is present, balance may be better addressed using other methods. Noise, low pass filtered with an upper cut-off frequency of 200 Hz, seems most effective. Using this upper cut-off frequency, the applied amplitude seems arbitrary; regardless of the amplitude, balance seems to improve. Where other upper cut-off frequencies are used, larger amplitudes seem to be more effective than smaller. This study provides further support to the potential role of vibrating insoles in improving standing balance where DN is present.

ACKNOWLEDGEMENTS

This work was supported by the Annafonds, the Netherlands and Stichting Beatrixoord Noord-Nederland, the Netherlands. The authors thank Ben Vorenkamp (University of Groningen, Faculty of Mathematics and Natural Sciences, Technical Support Unit) for the design, development, and production of the noise generator, amplifier, and software, OIM Holding BV for providing the insole material, and the Diabetes Center, UMCG for their assistance in patient recruitment.

REFERENCES

1. Boru UT, Alp R, Sargin H, Kocer A, Sargin M, Luleci A, Yayla, A. Prevalence of peripheral neuropathy in type 2 diabetic patients attending a diabetes center in Turkey. *Endocr J* 2004 Dec;51(6):563-7.
2. Valensi P, Giroux C, Seeboth-Ghalayini B, Attali JR. Diabetic peripheral neuropathy: effects of age, duration of diabetes, glycemic control, and vascular factors. *J Diabetes Complications* 1997 Jan;11(1):27-34.
3. Young MJ, Boulton AJ, MacLeod AF, Williams DR, Sonksen PH. A multicentre study of the prevalence of diabetic peripheral neuropathy in the United Kingdom hospital clinic population. *Diabetologia* 1993 Feb;36(2):150-4.
4. Tesfaye S, Malik R, Ward JD. Vascular factors in diabetic neuropathy. *Diabetologia* 1994 Sep;37(9):847-54.
5. Ahmed AM, Hussein A, Ahmed NH. Diabetic autonomic neuropathy. *Saudi Med J* 2000 Nov;21(11):1034-7.
6. Pollock AS, Durward BR, Rowe PJ, Paul JP. What is balance? *Clin Rehabil* 2000 Aug;14(4):402-6.
7. Kavounoudias A, Roll R, Roll JP. Foot sole and ankle muscle inputs contribute jointly to human erect posture regulation. *J Physiol* 2001 May 1;532(3):869-78.
8. Maurer C, Mergner T, Bolha B, Hlavacka F. Human balance control during cutaneous stimulation of the plantar soles. *Neurosci Lett* 2001;302(1):45-8.
9. Horak FB, Dickstein R, Peterka RJ. Diabetic neuropathy and surface sway-referencing disrupt somatosensory information for postural stability in stance. *Somatosens Mot Res* 2002;19(4):316-26.
10. Simoneau GG, Ulbrecht JS, Derr JA, Becker MB, Cavanagh PR. Postural instability in patients with diabetic sensory neuropathy. *Diabetes Care* 1994 Dec;17(12):1411-21.
11. Uccioli L, Giacomini PG, Monticone G, Magrini A, Durola L, Bruno E, Parisi L, Di Girolamo S, Menzinger G. Body sway in diabetic neuropathy. *Diabetes Care* 1995;18(3):339-44.
12. Hijmans JM, Geertzen JH, Dijkstra PU, Postema K. 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. *Gait Posture* 2007 Feb;25(2):316-23.
13. Priplata AA, Niemi JB, Harry JD, Lipsitz LA, Collins JJ. Vibrating insoles and balance control in elderly people. *Lancet* 2003;362(9390):1123-4.
14. Priplata AA, Prittelli BL, Niemi JB, Hughes R, Gravelle DC, Lipsitz LA, Veves A, Stein J, Bonato P, Collins JJ. Noise-enhanced balance control in patients with diabetes and patients with stroke. *Ann Neurol* 2006 Jan;59(1):4-12.

15. Hijmans JM, Zijlstra W, Geertzen JHB, Hof AL, Postema K. Effects of vibrating insoles on standing balance in diabetic neuropathy. *J Rehabil Res Dev* 2008;45(9):1441-50.
16. Collins JJ, Priplata AA, Gravelle DC, Niemi J, Harry J, Lipsitz LA. Noise-enhanced human sensorimotor function. *IEEE Eng Med Biol Mag* 2003 Mar;22(2):76-83.
17. Onghena P, Edgington ES. Customization of pain treatments: single-case design and analysis. *Clin J Pain* 2005 Jan;21(1):56-68.
18. Mattacola CG, Lloyd JW. Effects of a 6-Week Strength and Proprioception Training Program on Measures of Dynamic Balance: A Single-Case Design. *J Athl Train* 1997 Apr;32(2):127-35.
19. Meijer JW, Smit AJ, Lefrandt JD, van der Hoeven JH, Hoogenberg K, Links TP. Back to basics in diagnosing diabetic polyneuropathy with the tuning fork! *Diabetes Care* 2005 Sep;28(9):2201-5.
20. Hijmans JM, Geertzen JHB, Schokker B, Postema K. Development of vibrating insoles. *Int J Rehabil Res* 2007 Dec;30(4):343-5.

General Discussion

7



In this thesis ankle and foot appliances to improve standing balance of people with somatosensory loss at their lower limbs were studied. The medical devices which this thesis focused on, were chosen or developed for their tactile or proprioceptive feedback enhancing properties. Enhancing somatosensory feedback from the lower limbs is thought to improve balance concurrently. The main research question addressed was: Which orthotic devices applied to the lower limb can improve standing balance in people with somatosensory loss?

In the systematic review presented in *Chapter 2* it was concluded that both the quality and the quantity of the current research were insufficient to draw conclusions about the effectiveness of lower limb orthotics in improving balance in people with somatosensory loss. However, the reviewed literature provided some interesting developments with several orthotic devices described, which may improve balance in people with somatosensory loss. People with decreased tactile sensitivity of the plantar surface of the foot often show impaired balance. In *Chapter 2* it was shown that tactile feedback from the plantar surface of the feet can be enhanced, with subsequent beneficial effects on balance. Insoles with tubing at the plantar surface boundaries, or vibrating insoles providing mechanical noise to the plantar surface of the feet, have both demonstrated to have these tactile sensation enhancing properties. On the other hand, soft insoles seem to impair balance.

In the literature also ideas about other possible orthotic solutions to improve somatosensation were presented. A possible intervention that, in theory, might improve balance is the enhancement of proprioception of the ankle. In the literature it was shown that enhancement of joint position sense (JPS) can be achieved with compression applied to the ankle and foot. Additional feedback, about joint angles and changes in these angles, gained from the application of ankle and foot compression has shown to improve balance in athletes with ankle instability. Additional proprioceptive feedback might then also improve balance in people with somatosensory loss. The rationale for this assumption is that, similar to athletes with ankle instability, both JPS and balance are often affected in people with somatosensory loss. Only when balance is impaired, improvement is thought to be possible with additional proprioceptive feedback. The review presented in *Chapter 2* has guided the development of research presented in *Chapters 3 to 6* of this thesis; the effects on standing balance of compression applied to the ankles and feet and vibrating insoles was further investigated.

CHAPTER 2 RECONSIDERED

Review reconsidered based on this thesis

The studies presented in *Chapter 3 to 6* are based on the preceding review (*Chapter 2*). It is therefore of interest to reconsider the results from the review incorporating the new findings in this thesis. In *Chapter 3* it was shown that the impaired JPS in the older participants

improved towards normal values with the application of ankle compression. Despite the expected improvement of JPS, no concurrent improvement of standing balance was found. In fact, standing balance even deteriorated when compression was applied. The proposed theory, that standing balance can be improved by improving ankle JPS with ankle and foot compression, must be revised in the light of the conclusions and recommendations, demonstrated in *Chapter 3* of this thesis. The theoretically promising option, to apply compression to the ankle, was proven to be ineffective in improving standing balance in older people with somatosensory loss. Focus should not be on improving JPS as a method to improve balance in people with somatosensory loss.

Vibrating insoles apply mechanical noise to the plantar surface of the feet. Although noise is usually associated with signal distortion, it can also improve the performance of a sensory system. The mechanism behind this improvement is called stochastic resonance [1;2]. It has previously been shown that tactile sensation of different body parts improves with the application of noise [3-9]. In *Chapter 4* it was demonstrated that in patients with diabetic neuropathy (DN), with eyes closed and performing an attention demanding task, so when compensatory strategies are limited, standing balance can be improved by enhancing tactile sensation of the plantar surface of the foot with the addition of sub threshold mechanical noise. However, this improvement was limited. A reduction in mean velocity of centre of pressure (COP) displacements of about 13% was shown in our study, only during a condition with the eyes closed and in combination with an attention demanding task. Previous research showed a favourable change in sway parameters, between 2.9% and 53.8% (different outcome measures were used), even during a less challenging condition of standing with the eyes closed without an attention demanding task [4;10].

The design of the insoles used in *Chapter 4* and the properties of the noise signal applied may be the cause of the limited effects. Therefore, a new prototype of a vibrating insole system was developed. This development was described in *Chapter 5*. The material, mechanical properties, and configuration of the insoles, as well as the selection of components which in theory are thought to be the most effective in improving balance were presented. Relatively hard insoles with, four tactors (tactile actuator) applied under the heel, first metatarsophalangeal joint (MTP1), fifth metatarsophalangeal joint (MTP5) and the first toe, seemed most effective. The amplitude of the tactors should be individually controlled and both electromagnetic and piezoelectric actuators can be applied.

In *Chapter 6*, different properties of the applied mechanical noise signal (amplitude and frequency band) were studied in a single case design. The insoles used in this chapter were based on the requirements described in *Chapter 5*. It was shown that white noise, low pass filtered with an upper cut-off frequency of 200 Hz seemed the most effective in improving standing balance in DN. When this upper cut-off frequency was applied, the amplitude seemed arbitrary within the tested range. When other cut-off frequencies were applied,

larger amplitudes seemed to be the most effective in improving standing balance in DN. The methodology used in *Chapter 6*, a single subject experimental approach, does not allow for generalisation of the results, and therefore does not contribute to the level of evidence. However, it should be mentioned that the improvements found reach clinically relevant values when an upper cut-off frequency of 200 Hz was applied; the average improvement in mean velocity of the COP displacement was 35%. Thus the main conclusion from the review, based on studies till the end of 2004 (*Chapter 2*), should be changed based on this thesis. However, only *Chapter 3 and 4* should be taken into account when changing these conclusions.

The evidence base of the balance improvement due to the application of mechanical noise to the plantar surface of the feet was enhanced with the research presented in *Chapter 4*. However, the clinical relevance of these devices is yet not proven. It was shown that insoles providing mechanical noise to the plantar surface of the feet improve standing balance in people with impaired tactile sensation. This improvement is thought to be caused by improved and increased feedback from the plantar surface of the feet, providing information about pressure distribution. The view that vibrating insoles have favourable effects on standing balance was further supported by the results from *Chapter 6*, in which even larger effects were demonstrated in a single case design. Improving tactile sensation of the plantar surface of the feet seems a more effective way of improving standing balance in people with somatosensory loss than the improvement of JPS.

Review reconsidered based on recent literature

Between 2005 and 2008 new studies on the effects of ankle and foot orthotics on balance in people with somatosensory loss were presented in the literature. Simultaneously with the research presented in this thesis, recent literature may enhance the evidence base of ankle and foot devices with balance improving possibilities.

In contrast with our study on compression (*Chapter 3*), Rao *et al.* (2006) demonstrated that an ankle foot orthosis (AFO) can improve balance due to additional somatosensory cues [11]. Their study was performed in people with neuropathy, whereas our study was performed in older people. Possibly when more severe somatosensory problems are present, and plantar sensation cannot be used for the control of balance, enhancing JPS can contribute to improving balance. Also because of the younger age of the participants, less problems in re-weighting of sensory feedback are thought to be present in their study population [12]. Therefore, these people may be able to use the auxiliary information more effectively. Most importantly, perturbed balance was measured in this study whereas our study tested unperturbed standing balance. Possibly due to larger ankle rotations resulting from the platform perturbation, balance improved in their study, whereas in our study, rotations at the ankle were too small to provide sufficient auxiliary cues. Moreover, a flexible custom fitted polypropylene AFO was used, providing an increasing pressure on the skin with

increasing angular change at the ankle. It is questionable whether such a device should be recommended in people with DN at risk for ulcers.

Recently, research focused more on the effects of insoles with tactile sensitivity enhancing properties on balance than on the improvement of JPS or joint motion sense. Priplata *et al.* (2006) demonstrated that vibrating insoles improve balance in people with somatosensory loss, as well as in other pathologies [10]. With this research earlier findings were confirmed. However, it should be mentioned that also in this second study on vibrating insoles, only single shoulder marker movement was measured, which is not common in balance research.

Several studies focused recently on the effects of textured insoles on balance. Perry *et al.* (2008) reported improved lateral stability during walking with an insole with tubing at the plantar surface boundaries (SoleSensor) [13]. With this research they came a step closer towards reducing falls in older people [13]. Whether these insoles can be used in people with DN at risk for ulcerations remains questionable, because the tubing might cause pressure spots. Custom fitted semi-rigid foot orthoses seem to improve balance as well, even in healthy subjects, probably due to improved tactile sensation [14]. However, the effects of textured insoles on balance are contradictory. Several studies demonstrated no effects of textured insoles [15;16]. In contrast, Corbin *et al.* (2007) showed improved standing balance with the application of textured insoles [17] and Nurse *et al.* (2005) reported effects of insole texture on lower leg muscle activation patterns during walking, probably due to additional sensory feedback [18]. All of these studies were in people without either sensory or balance deficits. Moreover, the texture was applied to the whole plantar foot surface, whereas the insoles with tubing only provide additional feedback when pressure is shifting towards the plantar surface boundaries.

Perry *et al.* (2007) demonstrated that variations of midsole material and even the presence of it may lead to impaired dynamic balance control [19]. Offloading or cushioning seems to lead to decreased balance control, because of the offloading properties of midsole cushioning. In contrast, Van Geffen *et al.* (2007) did not find any effect of insole hardness on balance in DN [20]. Possibly, this difference is caused by differences in type of insoles they used. In the latter study, flat insoles were used with less offloading properties. Menant *et al.* (2008) reported in two studies on the effects of shoe characteristics, that besides soft soles, elevated heels should not be recommended because these heels impair balance control [21;22]. Above standard sole hardness, a thread sole, or raised collar height did neither improve nor deteriorate balance control [21;22].

High heels and midsole cushioning should be avoided in people with somatosensory loss because they impair balance [21;22]. Regarding this topic it should be mentioned that midsole cushioning is an offloading intervention. Offloading is often used in people with

DN to prevent or cure ulcers at the feet, a common problem in this population. Offloading devices like therapeutic footwear are often prescribed in order to decrease the chance of developing ulcerations. Offloading however, may result in decreased information transfer concerning plantar pressure distribution and therefore may have an adverse effect on balance [23;24]. The above presented research shows that sensation of plantar pressure distribution and changes in this distribution, detected by mechanoreceptors, situated in the plantar surface of the feet, is a relatively important source of information for balance control.

Some of the previously mentioned studies enhance the evidence base of the possibilities to improve balance with orthotic interventions in people with somatosensory loss. The conclusions from the review (*Chapter 2*) should be changed based on both this thesis and recent publications. Currently the evidence base is sufficient to conclude that standing balance can be improved by enhancing the tactile sensitivity of the plantar surface of the foot. This can be achieved by either vibrating insoles (*Chapter 4 & 6*) [4;10] or by insoles with tubing [13;25]. A first step towards fall prevention is made by Perry *et al.* (2008), showing that improved sensation from the plantar surface boundaries improved perturbed walking (walking over uneven terrain consisting of six platforms with an inclination of 10° in different directions) [13]. Future research should study whether insoles with tubing can safely be used in people with DN at risk for ulcerations. Whether JPS improving devices should be used to improve balance in people with somatosensory loss remains questionable.

OTHER INTERVENTIONS TO ENHANCE SOMATOSENSORY FEEDBACK

It was shown in this thesis that the relative role of feedback concerning plantar pressure distribution in the control of balance is high. The importance of plantar sensation warrants for research on this topic. When possible, enhancement of decreased plantar sensation seems an important solution to improve balance in these people. However, when this enhancement is not possible or sufficient for any reason, other compensatory solutions to improve balance should be investigated.

Sense of touch from other body parts

In the literature it has been shown that tactile sensation from the finger and other body parts, when touching a stationary object, can help to restore or improve balance, apart from the mechanical effects [26-32]. When the finger is touching a stationary object, sway decreases. It has also been demonstrated that finger tip touch can improve the quality of reactions on slips and trips [33]. Therefore, it is important to teach people with balance difficulties the importance of the use of their fingers or hands in order to receive additional balance related sensory feedback. Apart from their mechanical effects, walking aids like canes, crutches, and rollators (wheeled walker) can provide the central nervous system with information related to their postural stability.

Biofeedback

Besides the direct use of somatosensory information by touching a cane or wall for additional sway related feedback, sensations from any part of the body can be used as a form of biofeedback [34]. Biofeedback has proven to be an important balance improving solution. Several forms of biofeedback providing additional sway related information are described in the literature. The first discussed is vibrotactile feedback. Vibrotactile biofeedback of body tilt, applied to the trunk, has shown to improve balance [35;36]. Similarly, a stimulus that rubs the skin of the leg or shoulder as the body sways, has also shown to improve balance control [37]. Vibrotactile feedback applied to the head, based on the rotation of the thigh measured by gyroscopes, seems to have a limited effect on stepping reactions on a balance perturbation [38]. Haptic feedback provided by a pneumatically controlled cuff, providing information about the plantar pressure distribution, measured with insoles with force sensors, developed for lower limb amputees [39] might be usable for people with intact lower limbs who lack plantar sensation. Another possibility is the use of a vest with vibrators providing information about the orientation of the trunk with respect to the ground, which is used by astronauts for their orientation [40]. Possibly, such a tool can also improve balance due to additional feedback about orientation of the body on earth.

A second way of providing balance related biofeedback is electrotactile stimulation of the tongue. This type of biofeedback when concerning ankle angles improves JPS [41], although it remains unclear whether this information can be used to improve balance and reduce falling in people with somatosensory loss. This same type of biofeedback when based on plantar pressure distribution has shown to improve balance, with the largest improvement in the most instable subjects [42].

Visual feedback is a third way in which balance related biofeedback can be presented. Visual display of the position of, and change in COP position, improves balance [43]. A fourth type of biofeedback is auditory feedback. This type of feedback providing sway related information has demonstrated to improve balance [44]. It should however be mentioned that the way auditory feedback is used depends on the proportion of use of the remaining sensory information [44].

In future, body fixed sensors that measure foot pressure, segmental angles, or accelerations might be used to provide information which can be used for balance related biofeedback [45]. Many forms of balance related biofeedback seem promising in improving balance, which might decrease the chance of falling. In order to develop a system that could be used in daily living, the feedback should not intervene with normal sensation.

Improvement of somatosensation

As mentioned in the introduction, glycemic control plays a role in the development of DN [46]. Therefore, advice on this topic is an important step to prevent or delay the

development of DN. Not only to prevent loss of balance, but more importantly also to prevent ulceration and amputation. When DN develops, some options are described to reduce the somatosensory loss in these people.

Surgical nerve decompression for example can improve plantar sensation with concurrent balance improvement [47]. Another technique described, is near infra-red therapy applied by Anodyne Therapy System [48]. This is a system that improves circulation by dilation of the blood vessels. In patients with moderate sensory loss due to DN, it was demonstrated that tactile sensitivity can be improved with the use of this non-invasive device [48]. Powell *et al.* (2006) confirmed retrospectively that this therapy even reduced fear of falling as well as the risk of falling [49].

OTHER SOLUTIONS TO IMPROVE BALANCE AND REDUCE FALLING

In this thesis focus was on possibilities to improve standing balance by enhancing somatosensation. However, there are other ways to improve balance as well. Three sensory systems play a role in balance control and people can compensate from loss of one of the systems. In this thesis, as well as in many other balance studies, the participants were asked to close their eyes. When visual input is absent, the relative role of the somatosensory system increases because less compensatory mechanisms to control balance are present. In patients with DN as well as in the older subjects, it was shown that the effects of vision were larger than in healthy people. Visual correction (mono-focal glasses or surgical intervention), as well as sufficient illumination are therefore useful interventions to improve balance control and prevent falling [50].

The motor capabilities of an individual are important in balance control as well [51]. In an older group it is important to specifically intervene when balance is to be improved [51]. In order to effectively intervene in people at risk for falling, it is important to identify fallers in an older population. Causes of falls can be subdivided in intrinsic and environmental [52]. The main intrinsic factors are (in order of importance): balance and gait disorders, dizziness (including orthostatic hypotension), drop attack (sudden muscle weakness without loss of consciousness), visual disorders, and syncope (sudden loss of consciousness) [52;53]. Older people who have fallen previously are at a high risk of falling [54]. Most falls, however, are related to environmental factors (e.g. poor lighting, slippery floors, no handrails, medication). Several simple clinical assessments (posturography and other) can identify older people at risk for falling [55-59]. Detection and amelioration of the risk factors can reduce the rate of future falls [53]. A study reviewing the literature till the beginning of 2003 showed that a number of interventions are likely to be beneficial: a muscle strengthening and balance retraining program, a 15-week Tai Chi intervention program, a home hazard assessment and modification program, withdrawal of psychotropic medication, and multidisciplinary and multifactorial health/environmental risk factor screening/intervention

programs [52]. Agreement seems to exist in the literature that multifactorial interventions (including balance and walking exercises) are the most effective in fall reduction in older people [52;60-63]. It is even suggested that only multifactorial approaches to prevent falls in older people are effective, whereas unifactorial are not [64]. However, recently the effectiveness of these multifactorial approaches is argued [65]. In this review it was shown that the effects of multifactorial approaches on fall reduction are limited. More intensive interventions, addressing specific risk factors might be more effective [65].

Another factor playing a role in falling in older people is the increased reaction time, caused by changes in both the peripheral as well as the central nervous system [66]. It was even shown that increased reaction time was the best predictor for falling [66]. A possible way of improving reaction time is physical exercise [67]. When falling is aimed to be reduced, reaction time should be considered as a modifiable factor.

LIMITATIONS OF THIS THESIS

Some of the weaknesses of the research presented in this thesis should be acknowledged. First, only standing balance has been analysed. Possibly a more functional way of measuring balance could have provided more insight in clinically relevant changes resulting from the application of ankle and foot appliances. However, many of these measures are not suitable to evaluate the immediate effects of an intervention. Evaluation of these immediate effects is a clear first step in this field of research. One of the next steps to be taken is studying the effects of orthotics with somatosensation enhancing properties during perturbed standing balance, normal walking, perturbed walking and other dynamic balance measurements (e.g. tandem walking).

In this thesis it was chosen to use COP based outcomes for measuring standing balance. Although these measures are often used, there is a discussion in the literature about the relevance of the COP signal as a measure for balance, as it basically measures only ankle moment [68;69]. However, it is suggested that quiet stance is mainly controlled by ankle mechanisms [70]. Therefore, COP based measures do provide important information about the control of balance. This view is supported by Raymakers *et al.* (2005) who concluded that the mean displacement velocity of the COP, also used as main outcome variable in this thesis, is the most informative sway related parameter in most situations [59]. Horak *et al.* (1990 & 2002) support this view when research concerns the populations studied in this thesis, suggesting that people with somatosensory loss lack more COP related information than centre of mass or ankle angle related information [71;72].

Balance research is often performed with the ultimate goal to decrease the chance of falling. The exact link between COP related measures during quiet standing and the chance of falling remains unclear. COP displacements in mediolateral direction, however, have shown

to be a major factor in fall frequency [63;73]. Prospective studies on the effects of ankle and foot appliances on falling are difficult to perform because either self report or continuous motion capture should be used. Self report is an unreliable measure [74] and continuous motion capture for several months or even years is still difficult to perform because of technical problems [45].

The research presented in this thesis may possibly be a relevant first step towards development of an intervention with fall reducing and mobility improving possibilities. It should be mentioned that the focus in this thesis was on somatosensation of people with balance problems. In DN, reduced somatosensation is the main cause of their instability. In older people, however, instability and falls are caused by a range of intrinsic and extrinsic factors [52]. Balance control is a complex motor skill, based on a number of sensorymotor processes. Impaired balance in older people is not only caused by sensory deficits, but also by motor impairments, increased reaction time, and movement strategies used [51;75]. On the other hand, the sensory neurons are the first to decline with age compared to the motor neurons [76].

IMPLICATIONS OF THIS THESIS

The research presented in this thesis can be seen from two perspectives. First, it can be seen as an approach to study the effects of medical devices. The goal in this approach would be to give insight in the efficiency of the device in improving balance in older people and people with DN. If a device proves to be effective in improving balance, the research should be broadened in order to investigate the effects of the device on dynamic balance and fall frequency in this group.

On the other hand, the patients with neuropathy and the older participants with somatosensory loss can be used to study the relative role of somatosensation on balance. The gradual decrease and long term adaptive mechanisms can however mask the relative role of somatosensation. By improving either JPS or tactile sensitivity experimentally, using a medical device in a group known to use compensatory strategies, the immediate effects of ameliorating impaired somatosensation can be demonstrated. The immediate effects may explain the relative role of the systems intervened, the used compensatory strategies and the possibilities to use a sudden increase in somatosensory feedback for balance control.

Implications for future research

It was shown that insoles providing mechanical noise to the plantar surface of the feet, improve standing balance in DN when attention was distracted. This was a first step in research, ultimately focussing on improving mobility and reducing fall frequency in people with somatosensory loss. The findings in this thesis warrant future research on this topic. The next step should be to study the effects of these insoles on dynamic balance. The

research should focus on outcomes that can measure the immediate effects of improved somatosensation, for example by balance perturbation studies (during standing and walking) and balance during challenged walking (e.g. tandem walking). When these types of studies confirm the effectiveness, insoles should be developed that can be used in daily living. Subsequently, the effects of long term use of vibrating insoles on static and dynamic balance as well as frequency of falling should be studied.

When research is to be performed on the possibilities to implement vibrating insoles in daily living, the possibilities to use piezoelectric actuators as their own power supply is interesting. The piezoelectric effect, defined as the possibility of material to apply a certain stress when an electric potential is presented, is reversible. So when stress is presented (stepping on the actuator) the piezoelectric element will generate an electric potential. Possibly this electric potential can be used as power supply for the insoles. Currently the actuators require a heavy battery (630 g) which runs out of power within an hour. Therefore implementation in daily practice of a vibrating insole system, similar to the one used in *Chapter 6* seems to be difficult.

Besides the application of mechanical noise, an electrical noise signal has shown to be effective in improving balance [6;7]. An electrical noise system requires less power. Therefore research is warranted on noisy electro stimulation, applied in daily living of people with somatosensory loss. This thesis supports the view that sensation can be improved by application of a sub threshold noise signal. There are numerous situations in which improved sensation is beneficial. Broadening of research by exploring these possibilities is of great interest.

Based on findings in this thesis it is suggested that future research concerning ankle and foot appliances should focus on improvement of plantar sensation rather than on ankle JPS. Whether vibrating insoles are the best way of improving tactile sensation at the plantar surface of the feet is questionable. Other appliances like insoles with tubing or intervention providing biofeedback might be as useful or even more, with in some cases, less costs involved. Moreover, it would be interesting to combine vibrating insoles with insoles with tubing. Increased sensation due to the application of mechanical noise to the plantar surface of the foot and the increased feedback when pressure is shifting towards the plantar surface boundaries might have accumulative effects on balance.

Also the role of compression on JPS warrants for future research. Although it did not improve balance, the improved JPS might be useful in other situations in which improved proprioceptive feedback of a joint is needed. In sports compression is often used mainly for its proprioceptive effect [77;78]. Although it can be argued whether or not compression applying devices have these proprioception improving possibilities, this thesis adds important information to this topic.

Implications for clinical practice

The direct implications for clinical practice of the appliances studied in this thesis are limited. At this point, the vibrating insoles cannot be used in clinical practice. Developments aimed to improve tactile sensitivity with the addition of noise are warranted, because it seems a valuable intervention to improve mobility and decrease falling in future.

Compression applied to the ankles and feet deteriorates balance. Because of the small deterioration, use of compression for other purposes (e.g. oedema) should not be discouraged, based on this thesis. At this time, the use of available interventions that improve tactile sensation of the plantar surface of the foot, as well as other interventions that improve balance and decrease the chance for falling, should be encouraged.

CONCLUSIONS

In this thesis it was demonstrated that to improve standing balance in people with somatosensory loss, enhancing somatosensation is a relevant intervention. Enhancing JPS, which can be achieved by compression of the ankle and foot, does not improve standing balance. When balance of people with somatosensory loss is intended to be improved with orthotic devices, focus should be on enhancing tactile sensation of the plantar surface of the foot. One of the possibilities to achieve this enhanced tactile sensation, with concurrent improvement of standing balance, is the application of mechanical noise to the plantar surface of the feet by vibrating insoles.

REFERENCES

1. Collins JJ, Priplata AA, Gravelle DC, Niemi J, Harry J, Lipsitz LA. Noise-enhanced human sensorimotor function. *IEEE Engineering in Medicine & Biology Magazine* 2003;22(2):76-83.
2. Moss F, Milton JG. Medical technology: balancing the unbalanced. *Nature* 2003 Oct 30; 425(6961):911-2.
3. Priplata A, Niemi J, Salen M, Harry J, Lipsitz LA, Collins JJ. Noise-enhanced human balance control. *Physical Review Letters* 2002;89(23):238101.
4. Priplata AA, Niemi JB, Harry JD, Lipsitz LA, Collins JJ. Vibrating insoles and balance control in elderly people. *Lancet* 2003;362(9390):1123-4.
5. Collins JJ, Imhoff TT, Grigg P. Noise-enhanced tactile sensation. *Nature* 1996;383(6603):770.
6. Dhruv NT, Niemi JB, Harry JD, Lipsitz LA, Collins JJ. Enhancing tactile sensation in older adults with electrical noise stimulation. *Neuroreport* 2002;13(5):597-600.
7. Gravelle DC, Laughton CA, Dhruv NT, Katdare KD, Niemi JB, Lipsitz LA, Collins JJ. Noise-enhanced balance control in older adults. *Neuroreport* 2002;13(15):1853-6.

8. Liu W, Lipsitz LA, Montero-Odasso M, Bean J, Kerrigan DC, Collins JJ. Noise-enhanced vibrotactile sensitivity in older adults, patients with stroke, and patients with diabetic neuropathy. *Archives of Physical Medicine & Rehabilitation* 2002;83(2):171-6.
9. Richardson KA, Imhoff TT, Grigg P, Collins JJ. Using electrical noise to enhance the ability of humans to detect subthreshold mechanical cutaneous stimuli. *Chaos* 1998;8(3):599-603.
10. Priplata AA, Patritti BL, Niemi JB, Hughes R, Gravelle DC, Lipsitz LA, Veves A, Stein J, Bonato P, Collins JJ. Noise-enhanced balance control in patients with diabetes and patients with stroke. *Annals of Neurology* 2006;59(1):4-12.
11. Rao N, Aruin AS. Automatic postural responses in individuals with peripheral neuropathy and ankle-foot orthoses. *Diabetes Research & Clinical Practice* 2006;74(1):48-56.
12. Horak FB, Shupert CL, Mirka A. Components of postural dyscontrol in the elderly: a review. *Neurobiology of Aging* 1989;10(6):727-38.
13. Perry SD, Radtke A, McIlroy WE, Fernie GR, Maki BE. Efficacy and effectiveness of a balance-enhancing insole. *Journals of Gerontology Series A-Biological Sciences & Medical Sciences* 2008;63(6):595-602.
14. Mattacola CG, Dwyer MK, Miller AK, Uhl TL, McCrory JL, Malone TR. Effect of orthoses on postural stability in asymptomatic subjects with rearfoot malalignment during a 6-week acclimation period. *Archives of Physical Medicine & Rehabilitation* 2007;88(5):653-60.
15. Wilson ML, Rome K, Hodgson D, Ball P. Effect of textured foot orthotics on static and dynamic postural stability in middle-aged females. *Gait & Posture* 2008;27(1):36-42.
16. Hatton AL, Dixon J, Martin D, Rome K. The effect of textured surfaces on postural stability and lower limb muscle activity. *Journal of Electromyography & Kinesiology* 2008. *in press*
17. Corbin DM, Hart JM, McKeon PO, Ingersoll CD, Hertel J. The effect of textured insoles on postural control in double and single limb stance. *Journal of Sport Rehabilitation* 2007;16(4):363-72.
18. Nurse MA, Hulliger M, Wakeling JM, Nigg BM, Stefanyshyn DJ. Changing the texture of footwear can alter gait patterns. *Journal of Electromyography & Kinesiology* 2005;15(5):496-506.
19. Perry SD, Radtke A, Goodwin CR. Influence of footwear midsole material hardness on dynamic balance control during unexpected gait termination. *Gait & Posture* 2007;25(1):94-8.
20. Van Geffen JA, Dijkstra PU, Hof AL, Halbertsma JP, Postema K. Effect of flat insoles with different Shore A values on posture stability in diabetic neuropathy. *Prosthetics & Orthotics International* 2007;31(3):228-35.
21. Menant JC, Steele JR, Menz HB, Munro BJ, Lord SR. Effects of footwear features on balance and stepping in older people. *Gerontology* 2008;54(1):18-23.

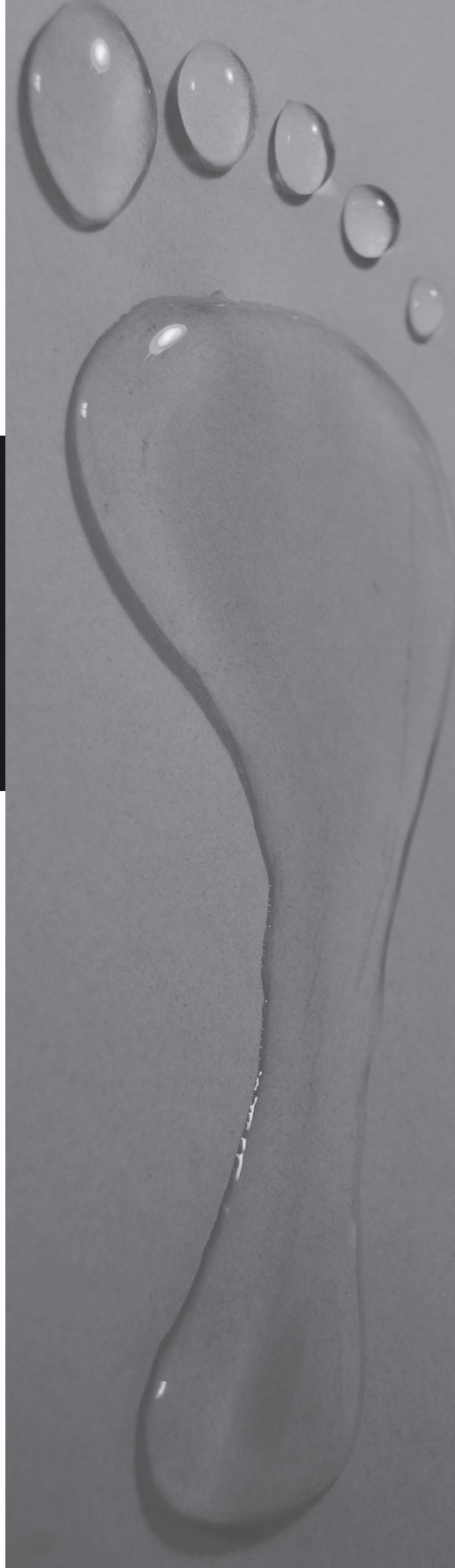
22. Menant JC, Perry SD, Steele JR, Menz HB, Munro BJ, Lord SR. Effects of shoe characteristics on dynamic stability when walking on even and uneven surfaces in young and older people. *Archives of Physical Medicine & Rehabilitation* 2008;89(10):1970-6.
23. van Deursen R. Footwear for the neuropathic patient: offloading and stability. *Diabetes/ Metabolism Research Reviews* 2008;24:S96-S100.
24. van Deursen RW, Simoneau GG. Foot and ankle sensory neuropathy, proprioception, and postural stability. *Journal Orthopaedic Sports Physical Therapy* 1999;29(12):718-26.
25. Maki BE, Perry SD, Norrie RG, McIlroy WE. Effect of facilitation of sensation from plantar foot-surface boundaries on postural stabilization in young and older adults. *Journals of Gerontology Series A-Biological Sciences & Medical Sciences* 1999;54(6):M281-M287.
26. Baccini M, Rinaldi LA, Federighi G, Vannucchi L, Paci M, Masotti G. Effectiveness of fingertip light contact in reducing postural sway in older people. *Age & Ageing* 2007;36(1):30-5.
27. Jeka JJ, Schoner G, Dijkstra T, Ribeiro P, Lackner JR. Coupling of fingertip somatosensory information to head and body sway. *Experimental Brain Research* 1997;113(3):475-83.
28. Jeka JJ, Lackner JR. Fingertip contact influences human postural control. *Experimental Brain Research* 1994;100(3):495-502.
29. Jeka JJ, Lackner JR. The role of haptic cues from rough and slippery surfaces in human postural control. *Experimental Brain Research* 1995;103(2):267-76.
30. Norrsell U, Backlund H, Gothner K. Directional sensibility of hairy skin and postural control. *Experimental Brain Research* 2001;141(1):101-9.
31. Tremblay F, Mireault AC, Dessureault L, Manning H, Sveistrup H. Postural stabilization from fingertip contact: I. Variations in sway attenuation, perceived stability and contact forces with aging. *Experimental Brain Research* 2004;157(3):275-85.
32. Lackner JR, Rabin E, DiZio P. Stabilization of posture by precision touch of the index finger with rigid and flexible filaments. *Experimental Brain Research* 2001;139(4):454-64.
33. Dickstein R, Peterka RJ, Horak FB. Effects of light fingertip touch on postural responses in subjects with diabetic neuropathy. *Journal of Neurology, Neurosurgery & Psychiatry* 2003;74(5):620-6.
34. Wasling HB, Norrsell U, Gothner K, Olausson H. Tactile directional sensitivity and postural control. *Experimental Brain Research* 2005;166(2):147-56.
35. Wall C, III, Weinberg MS. Balance prostheses for postural control. *IEEE Engineering in Medicine & Biology Magazine* 2003;22(2):84-90.
36. Wall C, III, Kentala E. Control of sway using vibrotactile feedback of body tilt in patients with moderate and severe postural control deficits. *Journal of Vestibular Research* 2005;15(5-6):313-25.

37. Rogers MW, Wardman DL, Lord SR, Fitzpatrick RC. Passive tactile sensory input improves stability during standing. *Experimental Brain Research* 2001;136(4):514-22.
38. Asseman F, Bronstein AM, Gresty MA. Using vibrotactile feedback of instability to trigger a forward compensatory stepping response. *Journal of Neurology* 2007;254(11):1555-61.
39. Fan RE, Culjat MO, King CH, Franco ML, Boryk R, Bisley JW, Dutton E, Grundfest WS. A haptic feedback system for lower-limb prostheses. *IEEE Transactions on Neural Systems & Rehabilitation Engineering* 2008;16(3):270-7.
40. van Erp J, van Veen HAHC, Ruijsendaal M. More than a feeling: bringing touch into astronauts' spatial orientation. *Microgravity – Science and Technology* 2007;19(4-5):108-12.
41. Vuillerme N, Chenu O, Demongeot J, Payan Y. Improving human ankle joint position sense using an artificial tongue-placed tactile biofeedback. *Neuroscience Letters* 2006;405(1-2):19-23.
42. Vuillerme N, Chenu O, Pinsault N, Boisgontier M, Demongeot J, Payan Y. Inter-individual variability in sensory weighting of a plantar pressure-based, tongue-placed tactile biofeedback for controlling posture. *Neuroscience Letters* 2007;421(2):173-7.
43. Vuillerme N, Bertrand R, Pinsault N. Postural effects of the scaled display of visual foot center of pressure feedback under different somatosensory conditions at the foot and the ankle. *Archives of Physical Medicine & Rehabilitation* 2008;89(10):2034-6.
44. Dozza M, Horak FB, Chiari L. Auditory biofeedback substitutes for loss of sensory information in maintaining stance. *Experimental Brain Research* 2007;178(1):37-48.
45. Zijlstra W, Aminian K. Mobility assessment in older people: new possibilities and challenges. *European Journal of Ageing* 2007;4(1):3-12.
46. Cameron NE, Eaton SE, Cotter MA, Tesfaye S. Vascular factors and metabolic interactions in the pathogenesis of diabetic neuropathy. *Diabetologia* 2001;44(11):1973-88.
47. Ducic I, Taylor NS, Dellon AL. Relationship between peripheral nerve decompression and gain of pedal sensibility and balance in patients with peripheral neuropathy. *Annals of Plastic Surgery* 2006;56(2):145-50.
48. Leonard DR, Farooqi MH, Myers S. Restoration of sensation, reduced pain, and improved balance in subjects with diabetic peripheral neuropathy: a double-blind, randomized, placebo-controlled study with monochromatic near-infrared treatment. *Diabetes Care* 2004;27(1):168-72.
49. Powell MW, Carnegie DH, Burke TJ. Reversal of diabetic peripheral neuropathy with phototherapy (MIRE) decreases falls and the fear of falling and improves activities of daily living in seniors. *Age & Ageing* 2006;35(1):11-6.
50. Anand V, Buckley JG, Scally A, Elliott DB. Postural stability in the elderly during sensory perturbations and dual tasking: the influence of refractive blur. *Investigative Ophthalmology & Visual Science* 2003;44(7):2885-91.

51. Horak FB. Postural orientation and equilibrium: what do we need to know about neural control of balance to prevent falls? *Age & Ageing* 2006;35:ii7-ii11.
52. Gillespie LD, Gillespie WJ, Robertson MC, Lamb SE, Cumming RG, Rowe BH. Interventions for preventing falls in elderly people. *Cochrane Database of Systematic Reviews* 2003;(4): CD000340.
53. Rubenstein LZ. Falls in older people: epidemiology, risk factors and strategies for prevention. *Age & Ageing* 2006;35:ii37-ii41.
54. Ganz DA, Bao Y, Shekelle PG, Rubenstein LZ. Will my patient fall? *Journal of the American Medical Association* 2007;297(1):77-86.
55. Buatois S, Gueguen R, Gauchard GC, Benetos A, Perrin PP. Posturography and risk of recurrent falls in healthy non-institutionalized persons aged over 65. *Gerontology* 2006;52(6):345-52.
56. Lajoie Y, Gallagher SP. Predicting falls within the elderly community: comparison of postural sway, reaction time, the Berg balance scale and the Activities-specific Balance Confidence (ABC) scale for comparing fallers and non-fallers. *Archives of Gerontology & Geriatrics* 2004;38(1): 11-26.
57. Lord SR, Sturnieks DL. The physiology of falling: assessment and prevention strategies for older people. *Journal of Science & Medicine in Sport* 2005;8(1):35-42.
58. Melzer I, Benjuya N, Kaplanski J. Postural stability in the elderly: a comparison between fallers and non-fallers. *Age & Ageing* 2004;33(6):602-7.
59. Raymakers JA, Samson MM, Verhaar HJ. The assessment of body sway and the choice of the stability parameter(s). *Gait & Posture* 2005;21(1):48-58.
60. American Geriatrics Society, British Geriatrics Society, and American Academy of Orthopaedic Surgeons Panel on Falls Prevention. Guideline for the prevention of falls in older persons. *Journal of the American Geriatrics Society* 2001;49(5):664-72.
61. Campbell AJ, Robertson MC. Implementation of multifactorial interventions for fall and fracture prevention. *Age & Ageing* 2006;35:ii60-ii64.
62. Rao SS. Prevention of falls in older patients. *American Family Physician* 2005;72(1):81-8.
63. Stel VS, Smit JH, Pluijm SM, Lips P. Balance and mobility performance as treatable risk factors for recurrent falling in older persons. *Journal of Clinical Epidemiology* 2003;56(7):659-68.
64. Coussement J, De Paepe L, Schwendimann R, Denhaerynck K, Dejaeger E, Milisen K. Interventions for preventing falls in acute- and chronic-care hospitals: a systematic review and meta-analysis. *Journal of the American Geriatrics Society* 2008;56(1):29-36.
65. Gates S, Fisher JD, Cooke MW, Carter YH, Lamb SE. Multifactorial assessment and targeted intervention for preventing falls and injuries among older people in community and emergency care settings: systematic review and meta-analysis. *British Medical Journal* 2008;336(7636):130-3.

66. Lajoie Y, Girard A, Guay M. Comparison of the reaction time, the Berg Scale and the ABC in non-fallers and fallers. *Archives of Gerontology & Geriatrics* 2002;35(3):215-25.
67. Lord SR, Castell S. Physical activity program for older persons: effect on balance, strength, neuromuscular control, and reaction time. *Archives of Physical Medicine & Rehabilitation* 1994;75(6):648-52.
68. van der Kooij H, van Asseldonk E, van der Helm FC. Comparison of different methods to identify and quantify balance control. *Journal of Neuroscience Methods* 2005;145(1-2):175-203.
69. Winter DA, Patla AE, Frank JS. Assessment of balance control in humans. *Medical Progress through Technology* 1990;16(1-2):31-51.
70. Gatev P, Thomas S, Kepple T, Hallett M. Feedforward ankle strategy of balance during quiet stance in adults. *Journal of Physiology* 1999;514(3):915-28.
71. Horak FB, Dickstein R, Peterka RJ. Diabetic neuropathy and surface sway-referencing disrupt somatosensory information for postural stability in stance. *Somatosensory & Motor Research* 2002;19(4):316-26.
72. Horak FB, Nashner LM, Diener HC. Postural strategies associated with somatosensory and vestibular loss. *Experimental Brain Research* 1990;82(1):167-77.
73. Pajala S, Era P, Koskenvuo M, Kaprio J, Tormakangas T, Rantanen T. Force platform balance measures as predictors of indoor and outdoor falls in community-dwelling women aged 63-76 years. *Journals of Gerontology Series A-Biological Sciences & Medical Sciences* 2008;63(2):171-8.
74. Mackenzie L, Byles J, D'Este C. Validation of self-reported fall events in intervention studies. *Clinical Rehabilitation* 2006;20(4):331-9.
75. Sturme DL, St George R, Lord SR. Balance disorders in the elderly. *Clinical Neurophysiology* 2008;38:467-78.
76. Shaffer SW, Harrison AL. Aging of the somatosensory system: A translational perspective. *Physical Therapy* 2007;87(2):193-207.
77. Jerosch J, Hoffstetter I, Bork H, Bischoff M. The influence of orthoses on the proprioception of the ankle joint. *Knee Surgery, Sports Traumatology, Arthroscopy* 1995;1:39-46.
78. You SH, Granata KP, Bunker LK. Effects of circumferential ankle pressure on ankle proprioception, stiffness, and postural stability: a preliminary investigation. *Journal of Orthopaedic & Sports Physical Therapy* 2004;34:449-60.

Summary



Balance in people with somatosensory loss is impaired because of decreased tactile and proprioceptive feedback from the lower limbs. The two largest groups of people with sensory loss because of peripheral nervous system disorders are older people and people with diabetic neuropathy (DN). In this thesis, focus was on balance in people with somatosensory loss and on possibilities to improve balance by enhancing somatosensory feedback from the lower limbs with ankle and foot appliances.

In *Chapter 2*, all publications investigating the effects of ankle and/or foot appliances (AFA) on balance in older people (≥ 60 years) and patients with peripheral nervous system disorders (PNSD) were identified and reviewed. The 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 published to date, current theories on the role of somatosensory mechanisms in control of balance and how balance can be affected by AFA were briefly summarized. A systematic literature review was presented in which publications were searched in Medline, Embase and ReCal. In total 146 papers were identified from which 18 were selected based on title and abstract for qualitative assessment by two independent reviewers. Seven of these 18 papers fulfilled predetermined qualitative criteria and were selected for detailed review. No definitive conclusions could 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 indicated 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.

The results from the review presented in *Chapter 2* guided the research in the chapters following. In *Chapter 3* the effects of foot and ankle compression on joint position sense (JPS) and balance in older people and young adults was studied. Twelve independently living healthy older persons (77-93y) were recruited from a senior accommodation facility. Fifteen young adults (19-24y) also participated. Compression was applied at the ankles and feet using medical compression hosiery. The mean velocity of the centre of pressure (COP) displacements and the root mean square of the COP velocity, in both anteroposterior and mediolateral directions, were measured with a foot pressure plate. In older people, ankle compression was associated with an improvement of JPS towards normal values. However, a concurrent deterioration of their balance was found. In young adults compression had no effect on either JPS or balance.

The objective of *Chapter 4* was to investigate the effects of sub threshold mechanical noise, applied to the plantar surface of the feet, on standing balance in subjects with neuropathy

and healthy subjects. The noise was applied by vibrating insoles. The mechanism in which somatosensation is improved by the addition of noise is based on a phenomenon called stochastic resonance. When mechanical noise is applied together with other forces (changing pressure on the plantar surface of the foot during stance) information processing to the central nervous system is thought to be driven by the combination of the two forces. These forces cooperate in order to cross a certain threshold which under normal circumstances would not have been crossed. In four different conditions (eyes open or closed and with or without an attention demanding task) subjects with DN ($n=17$) and healthy subjects ($n=15$) stood for 60s on vibrating insoles placed on a force plate. During each condition the insoles were turned on for 30s and off for 30s (random order). The calculated balance measures were mean velocity of the centre of pressure displacements and root mean square of the velocity of these displacements in anteroposterior direction and mediolateral direction. In subjects with neuropathy, an interaction effect on balance was found between vibration and an attention demanding task. No effects of vibration on balance were found in healthy subjects. Vibrating insoles improved standing balance only in subjects with neuropathy and only when attention was distracted. Improvement of the insoles and their activation is needed to make implementation in daily living possible and effective.

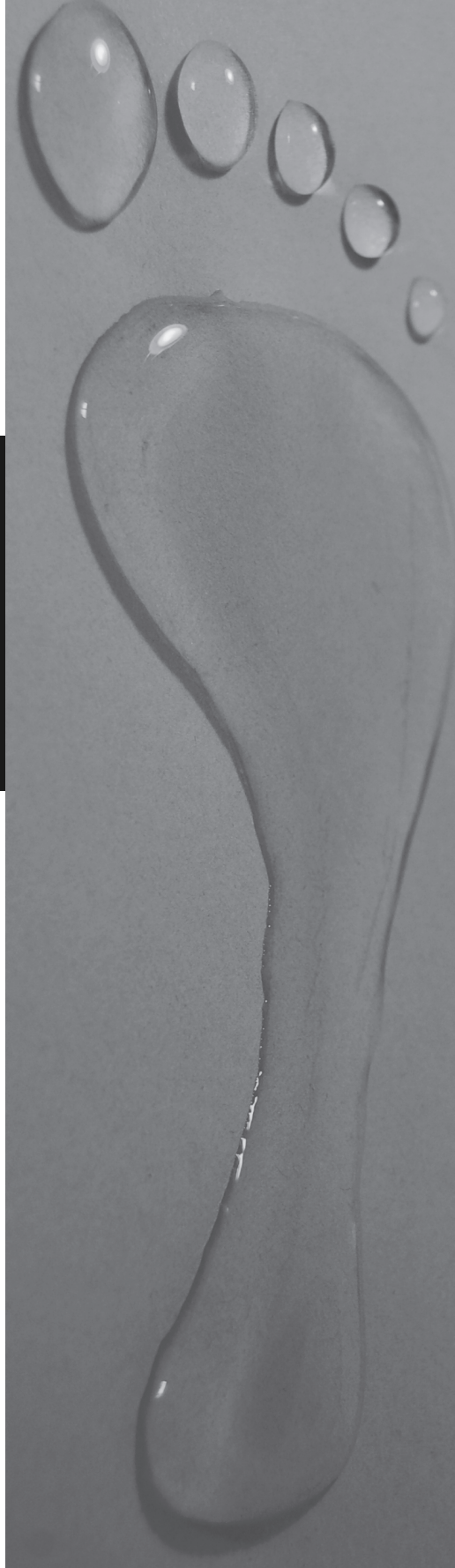
In order to improve the effectiveness of the vibrating insoles used in *Chapter 4*, the development of vibrating insoles that are thought to have an increased ability to improve balance, was presented in the following chapter. This study described the requirements for the tactors (tactile actuators), insole material and noise generator. A search for the components of vibrating insoles providing mechanical noise to the plantar surface of the feet was performed. The mechanical noise signal should be provided by tactors built in an insole or shoe and should obtain an input signal from a noise generator and an amplifier. Possible tactors are electromechanical tactors, a piezoelectric actuator, or the VBW32 Skin Transducer. The Minirator MR1 of NTI, a portable MP3 player, or a custom made noise generator can provide these tactors with input, amplified by a custom made amplifier. The tactors can be built in foam, silicone, or cork insoles. A C2 electromechanical tactor, a piezoelectric actuator, or the VBW32 Skin Transducer, activated by a custom made noise generator, built in a cork insole with a leather cover layer seems the ideal solution.

In *Chapter 6* the most effective properties of a mechanical noise signal applied to the plantar surface of the feet were determined. As in the previous chapters, the noise was applied by vibrating insoles, in order to improve standing balance in people with DN. In a single case experimental approach ($n=5$) the effects on balance of mechanical noise were studied. Noise was applied at three different amplitudes and was low pass filtered with three different cut-off frequencies (nine different interventions). Mean velocity of centre of pressure displacement, measured using a force plate, was used as the measure of balance. The effects of the nine different noise levels were compared with both the interval before and the interval after. The

results showed that mechanical noise applied to the feet by vibrating insoles can improve balance in people with minor to moderate neuropathy. Noise, low pass filtered with a cut-off frequency of 200Hz seemed to be the most effective in improving balance; the applied amplitude with this cut-off frequency seemed arbitrary.

In *Chapter 7* the impact of the research presented in this thesis is discussed. Recent literature provided information about more orthotic possibilities to improve balance in people with somatosensory loss. Moreover, other options to improve balance in people with somatosensory loss were presented. From this thesis, it can be concluded that although ankle compression improves JPS, it caused balance to deteriorate concurrently. Insoles providing mechanical noise to the plantar surface of the feet improve balance. However, these insoles can not yet be applied in daily practice. In future, research should focus on the development of a vibrating insole system that can be used in daily practice and on other interventions to improve plantar sensation.

Samenvatting



Mensen met somatosensorische problemen vertonen vaak balansproblemen ten gevolge van een achteruitgang in tactiele en proprioceptieve feedback. De twee grootste groepen mensen met somatosensorische problemen ten gevolge van een aandoening van het perifere zenuwstelsel betreffen ouderen en mensen met een diabetische neuropathie. Dit proefschrift richt zich op balans van mensen met somatosensorische problemen en op de mogelijkheden om de balans te verbeteren met orthesen die de somatosensorische feedback vanuit de onderste extremiteit beogen te verbeteren. In *hoofdstuk 1* worden deze problemen en doelstellingen geïntroduceerd.

In *hoofdstuk 2* wordt een systematisch reviewartikel gepresenteerd betreffende publicaties aangaande de effecten van schoenen en/of (enkel)-voetorthesen op de balans van ouderen (≥ 60 jaar) en patiënten met een perifere neurologische aandoening. De meerderheid van de mensen met een verslechterde balans ten gevolge van perifere neurologisch probleem wordt gevormd door deze twee geïnccludeerde groepen. Voorafgaand aan de systematische review worden de huidige theorieën over de rol van het somatosensorische systeem in de balanscontrole en de manieren waarop (enkel)-voetorthesen de balans kunnen beïnvloeden gepresenteerd. Voor deze systematische review werden publicaties gezocht in Medline, Embase en Recal. In totaal zijn 146 artikelen geïdentificeerd waarvan 18 geselecteerd werden, op basis van titel en abstract. De kwaliteit van deze 18 artikelen werd bepaald door twee onafhankelijke beoordelaars. Zeven van de 18 geselecteerde artikelen zijn geïnccludeerd en gedetailleerd gereviewd, op basis van kwaliteitscriteria. Vanwege dit kleine aantal artikelen en de matige kwaliteit ervan, kunnen geen definitieve conclusies getrokken worden aangaande de effectiviteit van (enkel)-voetorthesen in het verbeteren van de balans van ouderen en mensen met perifere neurologische problematiek. De literatuur geeft wel een aantal aanwijzingen namelijk dat een trainingsprogramma de effectiviteit van een hulpmiddel ten goede komt, inlegzolen die extra somatosensorische informatie geven, kunnen een positief effect hebben op de balans, dikke en zachte zolen lijken een negatief effect te hebben op de balans. Deze bevindingen onderschrijven de theorieën aangaande somatosensorische mechanismen die ten grondslag liggen aan de balanshandhaving. Om het gebruik van (enkel)-voetorthesen ter verbetering van de balans van mensen met somatosensorische problematiek te onderbouwen is meer en kwalitatief beter onderzoek nodig.

Het hierboven beschreven reviewartikel gaf richting aan het onderzoek dat in de volgende hoofdstukken beschreven is. In *hoofdstuk 3* worden de effecten van compressie, aangebracht rond de enkel en voet, op de positiezijn van het enkelgewricht en de balans van ouderen en jong volwassenen bestudeerd. Twaalf zelfstandig wonende ouderen tussen de 77 en 93 jaar oud werden geworven in een seniorenflat. Tevens participeerden 15 jongvolwassenen (19 tot 24 jaar). De compressie rond de enkel en voet werd met behulp van een steunkous aangebracht. De positiezijn werd gemeten met een slope box. De gemiddelde snelheid van de verplaatsing van het aangrijppingspunt van de grondreactiekracht en de effectieve

waarde (root mean square (RMS)) van de snelheid van de verplaatsing in anteroposterior en mediolaterale richting werden gebruikt als uitkomstmaat voor balans. De balansmetingen vonden plaats op een drukplaat. Bij ouderen werd de positiezin verbeterd tot waarden van gezonde jongvolwassenen door het aanbrengen van compressie. De balans van ouderen verslechterde echter door het toepassen van compressie. Bij jongvolwassenen sorteerde compressie geen effect op positiezin en balans.

Het doel van de studie, beschreven in *hoofdstuk 4*, was het bestuderen van de effecten van mechanische ruis, toegepast onder de voetzool door middel van vibrerende zolen, op de balans van mensen met een neuropathie ten gevolge van diabetes mellitus en gezonde mensen. Het werkingsmechanisme waarbij de tactiele sensibiliteit van de voetzool verbetert ten gevolge van het aanbrengen van ruis, is gebaseerd op een fenomeen, genaamd stochastische resonantie. Stochastische resonantie is een verschijnsel, waarbij de toevoeging van ruis een net niet waarneembaar signaal detecteerbaar kan maken. Een mechanisch ruissignaal (vibratie met variërende frequentie) kan toegepast worden op de voetzool, waar op dat moment ook variërende drukkrachten op uitgeoefend worden doordat men staat. Het brein kan de informatie van de twee signalen samen eerder of beter detecteren dan wanneer alleen het druksignaal aanwezig zou zijn. Door stochastische resonantie kan het brein een drukverandering onder de voetzool registreren die zonder het aanbieden van ruis niet of later geregistreerd worden. Onder vier verschillende condities (ogen open of gesloten, wel of geen dubbeltaak of een combinatie van voorgaande) werden gezonde mensen en mensen met een neuropathie gevraagd op een krachtplaat te staan waarop vibrerende inlegzolen geplaatst waren. De proefpersonen stonden gedurende 60 seconden stil op de zolen die - in willekeurige volgorde - de helft van de duur actief waren en de ander helft inactief. De uitkomstmaten voor balans waren gelijk aan die in *hoofdstuk 3*. Bij de mensen met een neuropathie werd een interactie-effect op de balans gevonden tussen vibratie en dubbeltaak. Bij de gezonde mensen werd geen effect van de vibratie gevonden. De vibrerende zolen verbeteren de balans alleen wanneer de aandacht werd afgeleid. Om implementatie in het dagelijks leven mogelijk te maken dienen de vibrerende inlegzolen en de aansturing verbeterd te worden.

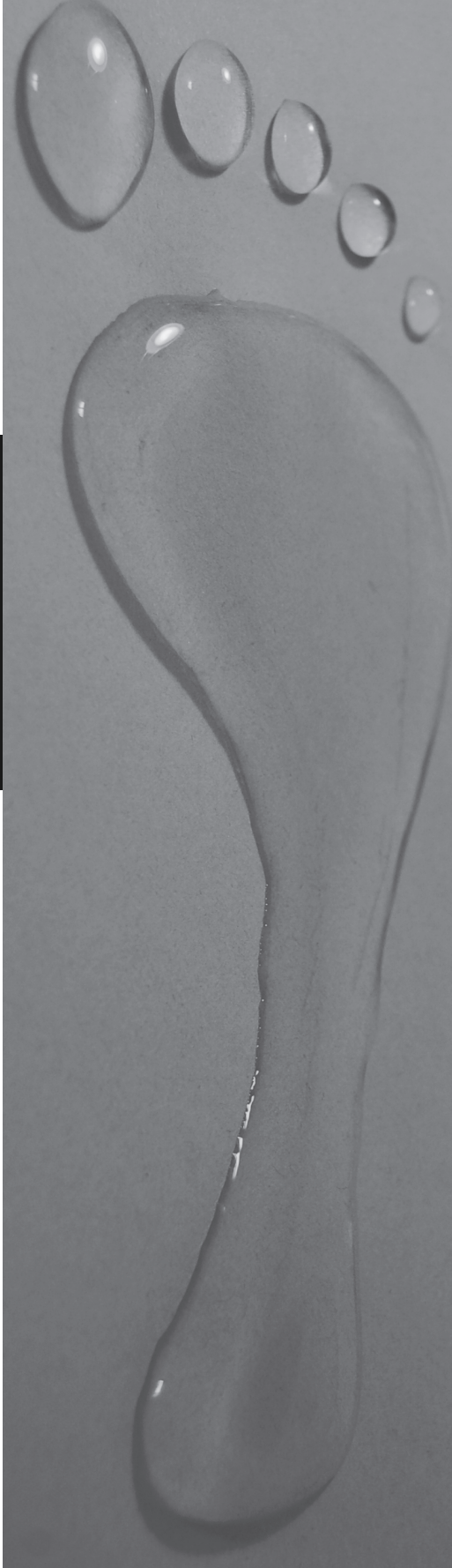
Om de effectiviteit van de vibrerende inlegzolen, gebruikt in *hoofdstuk 4*, te verbeteren, is een verbeterde versie van het vibrerende zolen-systeem ontwikkeld. Deze ontwikkeling staat beschreven in *hoofdstuk 5*. In deze studie werden de eisen die gesteld dienen te worden aan de actuators, het materiaal van de inlegzolen en de aansturing beschreven. Vervolgens werden componenten gezocht die aan deze voorwaarden voldoen. Mogelijke actuators die het mechanische ruissignaal kunnen toepassen onder de voetzool zijn elektromagnetische actuators, piëzo-elektrische actuators of de VBW32 Skin Transducer. De Minimator MR1 van NTI, een draagbare MP3-speler of een speciaal op maat gemaakte ruisgenerator kunnen de actuators voorzien van input. Deze input dient versterkt te worden door een

speciaal op maat gemaakte versterker. De actuatoren kunnen in schuimrubber, siliconen of kurken zool ingebouwd worden.

Het bepalen van de ideale eigenschappen van het mechanische ruissignaal, toegepast onder de voetzool, werd in *hoofdstuk 6* beschreven. Net als in de voorgaande hoofdstukken werd het ruissignaal toegepast door vibrerende zolen met als doel het verbeteren van de balans van mensen met een neuropathie. In een single case experimentele aanpak ($n=5$) werden de effecten van mechanische ruis op de balans bestudeerd. Ruissignalen met drie verschillende amplitudes en drie verschillende frequentiebandbreedtes (negen verschillende interventies) werden toegepast. Met behulp van een krachtplaat werd de gemiddelde snelheid van de verplaatsing van het aangrijpingspunt van de grondreactiekracht bepaald. Ieder ruissignaal werd vergeleken met het interval vlak voor de interventie en het interval direct na de interventie. Bij mensen met een lichte tot matige neuropathie kan het toepassen van mechanische ruis de balans verbeteren. Ruis, gefilterd met een laagdoorlaatfilter met een afsnijfrequentie van 200 Hz lijkt het meest effectief in het verbeteren van de balans. Wanneer deze frequentiebandbreedte wordt toegepast, lijkt het niet uit te maken welke amplitude gekozen wordt.

In *hoofdstuk 7* wordt het in dit proefschrift uitgevoerde onderzoek bediscussieerd. Recente literatuur laat zien dat er meer mogelijkheden zijn om de balans van mensen met somatosensorische problemen te verbeteren door een orthetische interventie. Ook worden andere mogelijkheden om de balans te verbeteren bediscussieerd. Uit dit proefschrift blijkt dat, ondanks dat de positiezin van de enkel bij ouderen verbeterd kan worden door het toepassen van compressie, de balans verslechtert. Inlegzolen die een mechanisch ruissignaal toepassen op de voetzool kunnen de balans van mensen met een neuropathie verbeteren. Deze zolen kunnen echter nog niet in de dagelijkse praktijk worden toegepast. In de toekomst zou onderzoek zich moeten richten op het ontwikkelen van een systeem dat mechanische ruis kan toepassen onder de voetzool. Dit systeem dient in de dagelijkse praktijk gebruikt te kunnen worden. Tevens dient toekomstig onderzoek zich te richten op andere mogelijkheden om de tactiele sensibiliteit van de voetzool te verbeteren.

Dankwoord



Iedereen die ik hieronder noem en iedereen die ik vergeet te noemen: Bedankt voor alle steun die ik heb gehad bij het schrijven van mijn proefschrift en voor de samenwerking in de afgelopen jaren.

Klaas, ik ben je zeer dankbaar voor het bieden van de mogelijkheid om te promoveren op jouw “bruidsschat”. Jouw volle agenda belemmerde je wel eens in de tijd die je aan onderzoek kon besteden, maar tijdens de besprekingen was je altijd even enthousiast. Klaas, ik hoop dat je, nu je geen hoofd van de afdeling meer bent, je wetenschappelijke ambities weet te verwezenlijken.

Jan, jij heb ervoor gezorgd dat ik de afgelopen zes jaar bij het Centrum voor Revalidatie heb kunnen werken en met veel plezier. Ik kijk terug op een mooie en bijzondere samenwerking. De treinreizen die we voor het ORIVO(O) project maakten waren niet alleen gezellig (ik ken inmiddels alle ins and outs van de revalidatiegeneeskunde in Nederland), maar ook momenten om eens goed op de inhoud te focussen. Jan, ik ken niemand die zo goed in timemanagement is als jij. Hoe jij in alle drukte altijd nog wat tijd vrij kan maken is een prestatie. Als nieuw hoofd van de afdeling zal deze eigenschap je zeer goed van pas komen.

Wiebren, ik heb je later in het project gevraagd of je in mijn begeleidingsgroep plaats wilde nemen en ben nog steeds erg blij dat je toen “ja” hebt gezegd. De tijd die je vrij wist te maken voor een inhoudelijk vraag van mij of een dilemma van andere orde, hebben veel invloed op de voortgang gehad. Ook je kennis over bewegingssturing en –registratie heeft veel bijgedragen aan de inhoud van mijn proefschrift. Daarnaast heb ik altijd met veel genoegen met je over de randzaken kunnen kletsen.

At, ook jij bent pas wat later in het project actief betrokken geraakt. Ik waardeer je reactie op elke technische alinea in mijn proefschrift: “dit klopt niet helemaal, mail maar even dan kijk ik er naar”. Van dit aanbod heb ik dan ook ruimschoots gebruik gemaakt. Ook je droge humor tijdens de besprekingen heb ik zeer gewaardeerd.

Graag wil ik de beoordelingscommissie bestaande uit prof. dr. J.E.J. Duysens, prof. dr. L. Peeraer en prof. dr. J.S. Rietman bedanken voor de tijd die ze hebben genomen om mijn proefschrift te lezen en beoordelen.

Koen Vaartjes en Ben Vorenkamp, jullie hebben een heel belangrijke rol in mijn promotieonderzoek gespeeld. De systemen die jullie ontwikkeld hebben zijn de basis voor het onderzoek naar vibrerende zolen geweest! Ik ben jullie veel dank verschuldigd. Ben, ik hoop dat mijn project een interessante samenwerking met Italië voor je op zal leveren. Wim, Wouter en Kimberley, zonder de programma’s die jullie voor mij hebben geschreven had ik mijn onderzoek niet kunnen uitvoeren. Dank! Pieter, ik kon altijd bij je binnenkomen of het ging om statistiek of het weer, ik heb deze samenwerking erg gewaardeerd. Cojanne, dank voor de hulp tijdens het verzamelen van de data voor hoofdstuk 3 en Bart, bedank

voor je hulp bij hoofdstuk 5. Ronald, dank voor je hulp bij de metingen voor hoofdstuk 6. Natuurlijk wil ik ook alle deelnemers aan het onderzoek bedanken voor de medewerking.

Medewerkers van het secretariaat, eerst Klazina, later Gerlinde en Minanda en al heel lang Inge, dank voor al jullie hulp. Medisch secretariaat op de poli, dank voor de lol na de lunch als wij onze post, die er nooit was, kwamen halen.

Promoveren kan eenzaam zijn, maar mijn collega-onderzoekers hebben ervoor gezorgd dat dit bij mij absoluut niet het geval was. Bedankt Bianca, Rients en Sandra, na een paar maanden alleen op een achteraf kamertje was ik erg blij jullie kamergenoot te mogen zijn. Bianca, in de vier jaar dat jij mijn kamergenoot bent geweest was het leven een spreekwoordelijke “bitterbal”. Ik ben erg blij dat wij elkaar lange tijd hebben kunnen steunen. Rients, jij was mijn eerste voorbeeld in het “AIO zijn”. Sandra, ik heb veel bewondering voor je doorzettingsvermogen. Ik kijk terug op een mooie tijd, de lunches, koffie, uitjes en grappen en ook het napraten na zware besprekingen of andere dingen in het leven met jullie en de andere “vakantiegangers” -Anuschka, Carolin, Gerda, Griekke, Jaap, Leontien, Lonneke, Marije, Martin, Mieke en Sippie en Wietske- op de derde verdieping.

Later zijn we verhuisd naar de rest van de afdeling. Dit was niet alleen goed voor de contacten met onze begeleiders maar ook voor het “afdelingsgevoel”. De praatjes op de gang met de fysio’s, staf, assistenten, Evelien, Jannie, MaJo en de andere medewerkers hebben zeker bijgedragen aan een de goede tijd die ik in het UMCG heb gehad.

Henk en Aline, ik kijk terug op een mooie tijd als kamergenoten op de eerste verdieping en een prachtig tripje naar Vancouver samen met Helco en Hein. Cowboy Henk, wat weet jij veel! Aline, hooguit Sandra kan aan jouw doorzettingsvermogen tippen. Gerda, de ene week mijn kamergenoot, de week daarop weer verhuisd (en omgekeerd). Via jou waren we altijd op de hoogte van wat er op de afdeling speelde. Mike and Lauren, after spending some months alone in our big room, I was happy to have your company. Thanks! Lauren, thanks for all the work you did in improving the “written expression” in/of my papers.

Ook op de eerste verdieping was er “de andere kamer”. Lonneke, het was altijd mooi je weekend-verhalen te horen. Martin, oftewel dokter Stenekes, waardering voor jouw andere kijk op de dingen. Carolin, dank voor je hulp bij Matlab-zaken. Corine, de korte periode als collega vond ik erg gezellig. Ik hoop dat het goed met je gaat in je nieuwe stulpje en als moeder. Jaap, via mij aan je baantje gekomen en zelf ervoor gezorgd dat je nu gaat promoveren op het MOS project. Goed werk!

Buiten het werk om heb ik veel lol gehad op het frisbeeveld. GD-ers en ULteam-genoten, dank!

Lieve paps en mams, rest van de familie en Eijgelaars, dank voor al jullie steun en interesse.

Ate, Cornelis en Sjouke, dank voor jullie vriendschap, de vrijdagmiddagborrels en zo veel meer. Dat het maar zo mag blijven, ook al wonen we misschien niet meer bij elkaar om de hoek. Cornelis en Sjouke, met jullie als paranimfen naast me moet het goed komen. We maken er een mooi feest van!

Lieve Janneke, mijn meisje, ik ben heel blij dat ik met jou dit avontuur heb mogen beleven. Op naar het volgende avontuur, **samen!**

CURRICULUM VITAE

Juha Hijmans is op 5 december 1978 geboren in Enschede. Na het behalen van zijn VWO diploma aan het Ichthus College te Enschede in 1997 is hij begonnen aan de studie werktuigbouwkunde aan de Universiteit Twente. In 1998 besloot hij deze studie te verruilen voor de studie Bewegingswetenschappen aan de Faculteit der Psychologische, Pedagogische en Sociologische Wetenschappen van de Rijksuniversiteit Groningen. Voor zijn afstuderen deed hij onderzoek naar het modelleren van gewrichten in mensmodellen. In oktober 2002 behaalde hij zijn diploma in de Bewegingswetenschappen, differentiatie Sport en Lichamelijke Opvoeding. Vanaf december 2002 was hij korte tijd werkzaam aan het Instituut voor Bewegingswetenschappen, Rijksuniversiteit Groningen, als onderzoeker en werkcollege docent. Op 1 februari 2003 werd hij aangesteld als onderzoeker aan het Centrum voor Revalidatie van het Academisch Ziekenhuis Groningen, het latere Universitair Medisch Centrum Groningen (UMCG). Gedurende twee jaar heeft hij in samenwerking met de afdeling Orthopedie van het Academisch Medisch Centrum Amsterdam, Roessingh Research and Development en het Nederlands Paramedisch Instituut richtlijnen ontwikkeld voor het voorschrijven van orthesen. In februari 2004 is hij binnen het Centrum voor Revalidatie, UMCG zijn promotieonderzoek naar de effecten van (enkel-)voet orthesen op de balans van mensen met somatosensorische problematiek gestart. Dit promotieonderzoek heeft uiteindelijk geresulteerd in dit proefschrift.

PUBLICATIONS

Hijmans JM, Postema K & Geertzen JHB (2004). Elbow orthoses: a review of literature. *Prothetics and Orthotics International* 28, 263-272.

Geertzen JHB, Hijmans JM & Van der Linde H. (2005) "Prosthetic prescription in The Netherlands: an interview with clinical experts" by Van der Linde et al. *Prothetics and Orthotics International* 29, 113-114.

Blankevoort L, Geertzen JHB, Heerkens YF, Hijmans JM & Ursum J (2005). Ontwikkeling richtlijnen voor de indicatiestelling en het verstrekingsproces van orthopedische orthesen, eindrapportage. Amsterdam, Groningen en Amersfoort.

Hijmans JM & Geertzen JHB (2006). Development of clinical guidelines for the prescription of orthoses in patients with neurological disorders in The Netherlands. *Prothetics and Orthotics International* 30, 35-43.

Hijmans JM, Geertzen JHB, Dijkstra PU & Postema K (2007). 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. *Gait and Posture* 25(2), 316-323.

Hijmans JM, Geertzen JHB, Schokker B & Postema K (2007). Development of vibrating insoles. *International Journal of Rehabilitation Research* 30, 343–345.

Hijmans JM, Geertzen JHB, Zijlstra W, Hof AL & Postema K (2008). Effects of vibrating insoles on standing balance in diabetic neuropathy. *Journal of Rehabilitation Research and Development*. 45(9), 1442–1450

Hijmans JM, Zijlstra W, Geertzen JHB, Hof AL & Postema K (2009). Foot and ankle compression improves joint position sense but not bipedal stance in older people. *Gait and Posture* 29(2), 322-325

