Orthotic interventions to improve standing balance in somatosensory loss

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General Discussion

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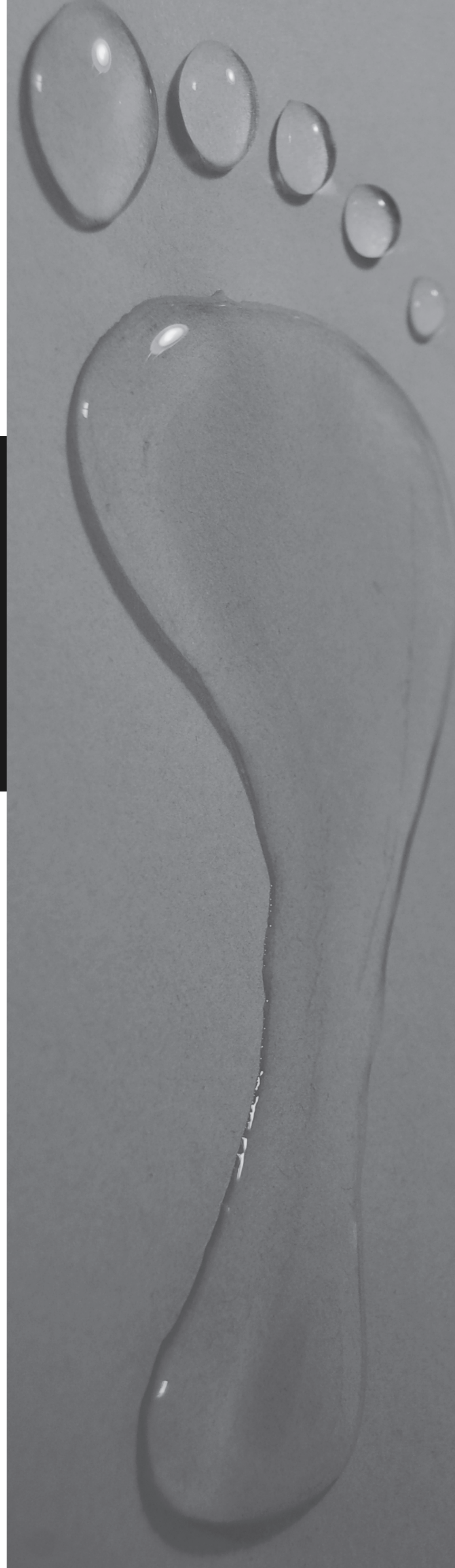

In this thesis ankle and foot appliances to improve standing balance of people with somatosensory loss at their lower limbs were studied. The medical devices which this thesis focused on, were chosen or developed for their tactile or proprioceptive feedback enhancing properties. Enhancing somatosensory 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 C*hapter 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 lightning, 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 disencouraged, 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.

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