IMPROVING BALANCE AND GAIT USING BIOMECHANICAL AND ELECTRONIC APPROACHES

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Improving Balance and Gait Using Biomechanical and Electronic Approaches

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CERTIFICATE OF ORIGINALITY

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ABSTRACT

Falls and fall-induced injuries, among elderly people and patients with balance and gait disorders, have been major public health problems globally. Due to aging/pathological related declines in cutaneous plantar surface sensitivity and proprioception, these people have higher chance of falls. Falls may lead to severe injuries, reduced mobility, reduction of quality of life, and even death.

This project aims to employ biomechanical and electronic approaches to solve the above-mentioned critical problems. It improves the balance and gait of elderly people and patients by: 1) providing supplemented sensory information about body posture to users (i.e. biofeedback system integrated with force sensors at plantar surface of foot); and 2) altering the foot plantar pressure and contact area at the foot-floor interface (i.e. custom-fitted orthopaedic insoles with arch supports, metatarsal pads, and heel cups).

Tactile sensation at plantar surface of foot continuously provides useful sensory information about the foot-ground contact characteristics, which contains crucial information about the body movement. Improving plantar pressure sensation could be one potential effective approach to enhance balance and gait, which appears to not have been achieved enough attention before.

This project conducted a series of clinical trials to systematically investigate if plantar pressure sensation, balance and gait could be improved by vibrotactile biofeedback system and orthopaedic insoles, including:

1) Effect of biofeedback system on standing postural balance in healthy young and older adults (Study 1),

2) Effect of biofeedback system on postural balance while standing on a perturbation floor in healthy young adults (Study 2),

3) Effect of biofeedback system on plantar foot loading and gait control in patients with stroke (Study 3), and

4) Effect of orthopaedic insoles on standing postural balance in healthy older adults (Study 4).

This project adopted a step-by-step approach, started from improving postural balance during quite standing, and ended with attempts of improving dynamic balance during walking. All of them are linked together by the theme of improving balance through augmenting plantar pressure sensation. Repeated measures study design has been adopted to compare participant's balance and gait performance between with and without the interventions. Measurement of center-of-pressure parameters during static standing, center-of-mass parameters during standing under balance perturbations, and plantar pressure distribution and spatiotemporal gait parameters during walking, have been employed to objectively assess subject's postural balance and gait control in all experimental conditions of different studies.

The findings of this study supported the effectiveness of vibrotactile biofeedback system and orthopaedic insoles in enhancing balance and gait control in health young and older adults, and patients with stroke, indicating that enhancing/supplementing plantar pressure sensation is one effective approach to improve balance and gait control, which inspires future research in this field. The wearable characteristics of vibrotactile biofeedback systems and orthopaedic insoles also allow them to be used in both indoor and outdoor settings, which further makes them appropriate to be applied as balance aids and balance training devices in daily life in the future. Future studies could consider investigating the effect of them during more complicated tasks, such as ascending/descending stairs and running, in more diverse and representative populations.

PUBLICATIONS ARISING FROM THE THESIS

Peer-Reviewed Journal Papers (SCI)

1. **Ma C.Z.-H.**, Zheng Y.-P., & Lee W.C.-C.* (2018). Changes in gait and plantar foot loading upon using vibrotactile wearable biofeedback system in patients with stroke. *Topics in Stroke Rehabilitation*. 2018, 25 (1): 20-27; DOI: 10.1080/10749357.2017.1380339.
2. **Ma C.Z.-H.**, Wong D.W.-C., Wan A.H.-P., & Lee W.C.-C.* (2018). Effects of orthopaedic insoles on static balance of older adults wearing thick socks. *Prosthetics and Orthotics International*. 2018, 42(3): 357-362; DOI: 10.1177/0309364617752982.
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4. **Ma C.Z.-H.**, Lam W.-K., Chang B.-C., & Lee W.C.-C.* (2018). A systematic review to investigate if it is worth to use insoles in an attempt to improve balance of healthy older adults. *Prosthetics and Orthotics International.* Under review.
5. **Ma C.Z.-H.**, & Lee W.C.-C.* (2017). A wearable vibrotactile biofeedback system improves balance control of healthy young adults following perturbations from quiet stance. *Human Movement Science.* 2017, 55: 54-60; DOI: 10.1016/j.humov.2017.07.006.
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7. **Ma C.Z.-H.**, Wong D.W.-C., Lam W.-K., Wan A.H.-P., & Lee W.C.-C.*. (2016). Balance improvement effects of biofeedback systems with state-of-the-art wearable sensors: a systematic review. *Sensors.* 2016, 16 (4), 434; DOI: 10.3390/s16040434. (**Q1** journal in the category of Instruments & Instrumentation based on its impact factor).

8. Wan A.H.[#], Wong D.W.[#], **Ma C.Z.-H**, Zhang M., & Lee W.C. (2016). Wearable vibrotactile biofeedback device allowing identification of different floor conditions for lower-limb amputees. *Archives of physical medicine and rehabilitation*, 97(7), 1210-1213; DOI: 10.1016/j.apmr.2015.12.016. (**Q1** journal in the category of Rehabilitation and Sport Sciences based on its impact factor).
9. **Ma C.Z.-H.**, Wan A.H.-P., Wong D.W.-C., & Lee W.C.-C.*, Zheng Y.-P. (2015). A vibrotactile and plantar force measurement-based biofeedback system: Paving the way towards wearable balance-improving devices. *Sensors.* 2015, 15, 31709–31722; DOI: 10.3390/s151229883. (**Q1** journal in the category of Instruments & Instrumentation based on its impact factor).

[#] These authors contributed equally to the manuscript.

Conference Full Paper

10. **Ma C.Z.-H.**, Wan A.H.-P., Wong D.W.-C., Zheng Y.-P., Lee W.C.-C.* (2014) Improving postural control using a portable plantar pressure-based vibrotactile biofeedback system. *2014 IEEE Conference on Biomedical Engineering and Sciences*, 8-10 December 2014, Miri, Malaysia. PP 855-860. DOI: 10.1109/IECBES.2014.7047632. (<u>Oral presentation</u>).

Conference Abstracts

11. **Ma C.Z.-H.**, Zheng Y.-P., Lee W.C.-C.* (2018) Smart insole with instant vibrotactile biofeedback of plantar force improve gait of patients with stroke. *Asian Prosthetic and Orthotic Scientific Meeting (APOSM) 2018, 7-9 November 2018*, Bangkok, Thailand. (<u>Oral presentation</u>).
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15. **Ma C.Z.-H.**, Lee W.C.-C., Zheng Y.-P.* (2016) Foot orthosis could improve elderly balance and gait control by changing plantar mechanical stimulations. *Asian Prosthetic and Orthotic Scientific Meeting (APOSM) 2016*, 4-6 November 2016, Seoul, Korea. (Poster presentation).
16. **Ma C.Z.-H.**, Wong D.W.-C., Wan A.H.-P., Elhadi M.M.O., Lee W.C.-C.* (2015) Different arch supports and metatarsal pads of orthopaedic insoles induce different effects on postural balance. *The 10th Beijing International Forum on Rehabilitation*, 11-13 September 2015, Beijing, China. (Oral presentation).
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18. **Ma C.Z.-H.**, Wan A.H.-P., Wong D.W.-C., Zheng Y.-P., Lee W.C.-C.* (2014) Technologies for enhancing elderly balance. *BME 2014 Biomedical Engineering International Conference*, 4-6 December 2014, Hong Kong SAR, China. PP A-1. (Oral presentation).

Book Chapter

19. **Ma C.Z.-H.**, Lee W.C.-C. (2016). Falls in the elderly and balance improvement using biofeedback system integrated with body motion sensors. In: *Bioengineering and Biomechanics Book Series – Biomechanics in Rehabilitation Engineering*. Edited by Y. Fan and M. Zhang. PP 149-165. Shanghai Jiaotong University Press, ISBN 978-7-313-1799-37.

Patent

20. **Ma C.Z.-H.**, Zheng Y.-P. & Huang Z. (2018). Big Data and Machine Learning Based Smart Wearable Biofeedback System for Repetitive Targeted Balance and Gait Training. Chinese patent pending. Filed in August 25, 2018.

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AP	Anterior-Posterior
AREA-CC	The 95% Confidence Circle area
AREA-CE	The 95% Confidence Ellipse area
AREA-SW	Sway Area
ASIS	Anterior Superior Iliac Spine
BBS	Berg Balance Scale
COG	Center of Gravity
COM	Center of Mass
COP	Center of Pressure
FD-CC	Planar Diameter-95% Confidence Circle
FD-CE	Planar Diameter-95% Confidence Ellipse
FO	Foot Orthosis/Orthoses
IMU	Inertial Measurement Units
GRF	Ground Reaction Force
MDIST	Mean Distance
MEMS	Microelectromechanical Systems
ML	Medial-Lateral
MVELO	Mean Velocity
RCT	Randomized Controlled Trial
RD	Resultant Distance
RDIST	Root Mean Square Distance
RMS	Root Mean Square
SD	Standard Deviation
SEBT	Star Excursion Balance Test

S_{max1}	Maximum center of mass displacement opposite to the movement of floor
S_{max2}	Center of mass displacement toward the movement of floor after reaching a new equilibrium position
T_{peak}	Time to reach maximum center of mass displacement opposite the movement of floor (S_{max1})
T_{rec}	Duration between S_{max1} and time S_{max2} for center of mass to reach steady without more displacement

CHAPTER 1. INTRODUCTION

1.1 Falls and the related injuries - a major public health problem

Falls are defined as events that people accidently coming to rest on lower levels, such as ground, excluding those intentional changes in position (World Health Organization Ageing Life Course Unit, 2008).

Falls can cause serious physical and psychological injuries, and can be fatal (Wood, et al., 2011). The burden of the consequences of falls is heavy. According to a report of the World Health Organization, approximately 37.5 million people who experienced falls needed medical care, and 424,000 of them died as results of falls per year (World Health Organization, 2017). Common physical and psychological consequences of falls included reduced lifespan, physical injuries such as fractures and tissue damages, restricted mobility, fear of falls, and social deprivation (Weerdesteyn, et al., 2008a).

1.1.1 Incidence of falls

The risk of falls and consequent injuries increased with aging (Todd & Skelton, 2004). Approximately 30% of people who aged 65 or older and living in the community, and more than 50% of those living in residential care facilities or nursing homes, experienced falls every year (Kannus, et al., 2005; Tinetti, 2003). For those who aged over 75, the rates are even higher (Todd & Skelton, 2004). About 40% of older adults who lived in long-term care institutions and have fallen once tend to experience recurrent falls (World Health Organization Ageing Life Course Unit, 2008). The ratios of falls and consequent injuries are still increasing, due to the continuously increasing proportion of older adults in the whole society (Todd & Skelton, 2004).

In addition to the elderly, patients with neurological conditions also have higher risk of falls. About 50% of adults with long-term neurological conditions, including stroke, vestibular deficits, multiple sclerosis, and spinal cord injury, experienced falls (Saverino, et al., 2014). In patients with stroke, the high risk of falls has been a serious medical complication, with an incidence of up to 73% in the first year since the onset of stroke (Verheyden, et al., 2013). The physical and psychological consequences of falls can be devastating not only in the acute and subacute stages, but also throughout the lifespan post-stroke in the stroke survivors (Weerdesteyn, et al., 2008a).

1.1.2 Consequence of falls and the related injuries

1.1.2.1 Mortality rates arising from falls

Approximately 40% of the injury-related deaths are caused by falls (Rubenstein, 2006). Figure 1-1 shows the rates of fatal falls divided by age and sex groups (Stevens, 2005). For both genders, the rates of fatal falls increase exponentially with aging, and reach the highest point at the age of 85 and over (Stevens, 2005). Rates of fatal falls among men are also higher than those of women among all age groups (Stevens, 2005). This may due to the fact that men tend to have more co-morbid conditions than the women with the same age (Control & Prevention, 2006).

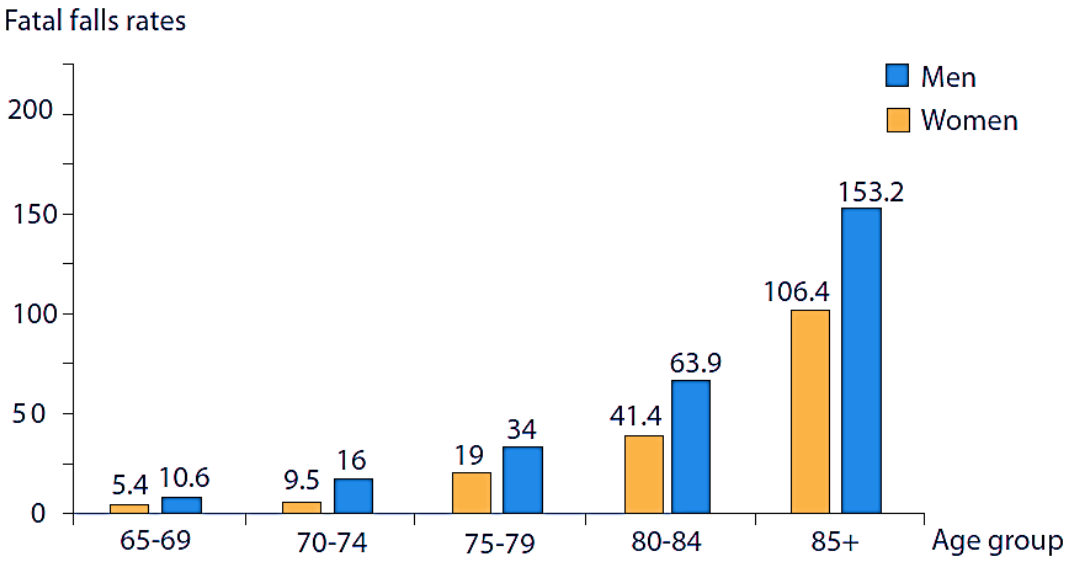


Figure 1-1 Rates of fatal falls by age and sex group (adapted from (Stevens, 2005))

1.1.2.2 Economic burden induced by falls

Medical care costs of fall-induced injuries have been enormous, which burden the family, community and society heavily. The costs related to falls and the consequent injuries can be divided into two categories: direct and indirect costs.

1) **Direct costs**: mainly encompassed the healthcare costs including medications and adequate services, such as <u>labour costs</u> of nursing, physicians, and rehabilitation services; <u>equipment costs</u> of mobility devices (e.g. canes, walking frames, and wheelchairs) and durable medical equipment (e.g. grab bars, toileting devices, and restraints); and <u>utilization costs</u> of the prolonged hospitalization, permanent placement, re-hospitalization, and readmission to nursing facilities (Greene, et al., 2001; Hill, et al., 2007). The average costs of hospitalization for fall-induced injuries have been projected to increase to USD 240 billion by year 2040 globally (World Health Organization Ageing Life Course Unit, 2008).

2) **Indirect costs**: mainly related to the societal productivity losses of activities in which individuals or family care providers would have involved if an individual had not sustained the fall-induced injuries, such as earning losses (World Health Organization Ageing Life Course Unit, 2008). The averaged lost income has been estimated to be approximately US$40,000 per year (World Health Organization Ageing Life Course Unit, 2008).

1.1.2.3 Consequent injuries of falls

Falls, especially the repeated/recurrent falls, have been the main cause of physical and psychological trauma. Approximately 20% of people who experienced falls needed medical care, 5% of them resulted in fracture, and 5% to 10% resulted in other severe injuries, such as joint distortions and dislocations, severe head injuries, and soft-tissue damages (such as bruises and lacerations) (L. Gillespie, et al., 2007; Kannus, et al., 2005). Injury has been the fifth leading cause of death in the elderly people, and most of these injuries were consequences of falls (Kannus, et al., 2005). For example, among the older adults who suffered from a hip fracture, about 25% of them died within half a year since the injury; and for those who survived, the expected lifespan reduced for about 10% to 15% (Gross, et al., 2012), and approximately half of them would never be functional walkers again (C. Freeman, et al., 2002). The duration of hospitalization due to falls is also much longer than those of due to other injuries, ranging from 4 to 15 days (World Health Organization Ageing Life Course Unit, 2008).

Apart from physical injuries, a history of falls is also associated with a number of traumatic psychological consequences, including fear of falling, decreased activity levels, functional dependence on others, depression, social isolation, and decreased quality of life (Gregg, et al., 2000; Gross, et al., 2012; Lord, 2007). These psychological problems, or the so-called “post-fall syndrome”, could also occur even after the recovery of the physical injuries (C. Freeman, et al., 2002).

1.1.3 Risk factors of falls

Since the burden of falls and related injuries is heavy, the risk factors of falls have been widely studied. The exact cause of falls is often difficult to determine, as multiple identifiable risk factors can predispose to falls among most individuals. Studies have indicated that the most important risk factors are accidents, balance and gait disorders, musculoskeletal system degeneration, inappropriate footwear, history of previous falls, visual deficits, depression, cognitive impairment, comorbidity, poly-pharmacy, older age, and environmental factors (Ambrose, et al., 2013).

Generally, risk factors for falls can be categorized as the intrinsic and extrinsic factors as follows (Deandrea, et al., 2010; Lord, 2007):

-<u>Intrinsic factors</u>: included history of falls, advanced age, gender, living alone, ethnicity, impaired mobility and gait, medicines, medical conditions, sedentary behaviour, psychological status, nutritional deficiencies, impaired cognition, visual impairment, foot problems, age-related physiological degenerations, and diseases (Deandrea, et al., 2010; Lord, 2007).

-<u>Extrinsic factors</u>: included hazardous environmental surroundings (such as insufficient light, uneven surfaces, slippery grounds, etc.), inappropriate footwear, and improper walking aids and assisting devices (Deandrea, et al., 2010; Lord, 2007).

Additionally, the Word Health Organization has also encapsulated the risk factors of falls and the interaction among them on falls and fall-related injuries as in Figure 1-2 (World Health Organization Ageing Life Course Unit, 2008).

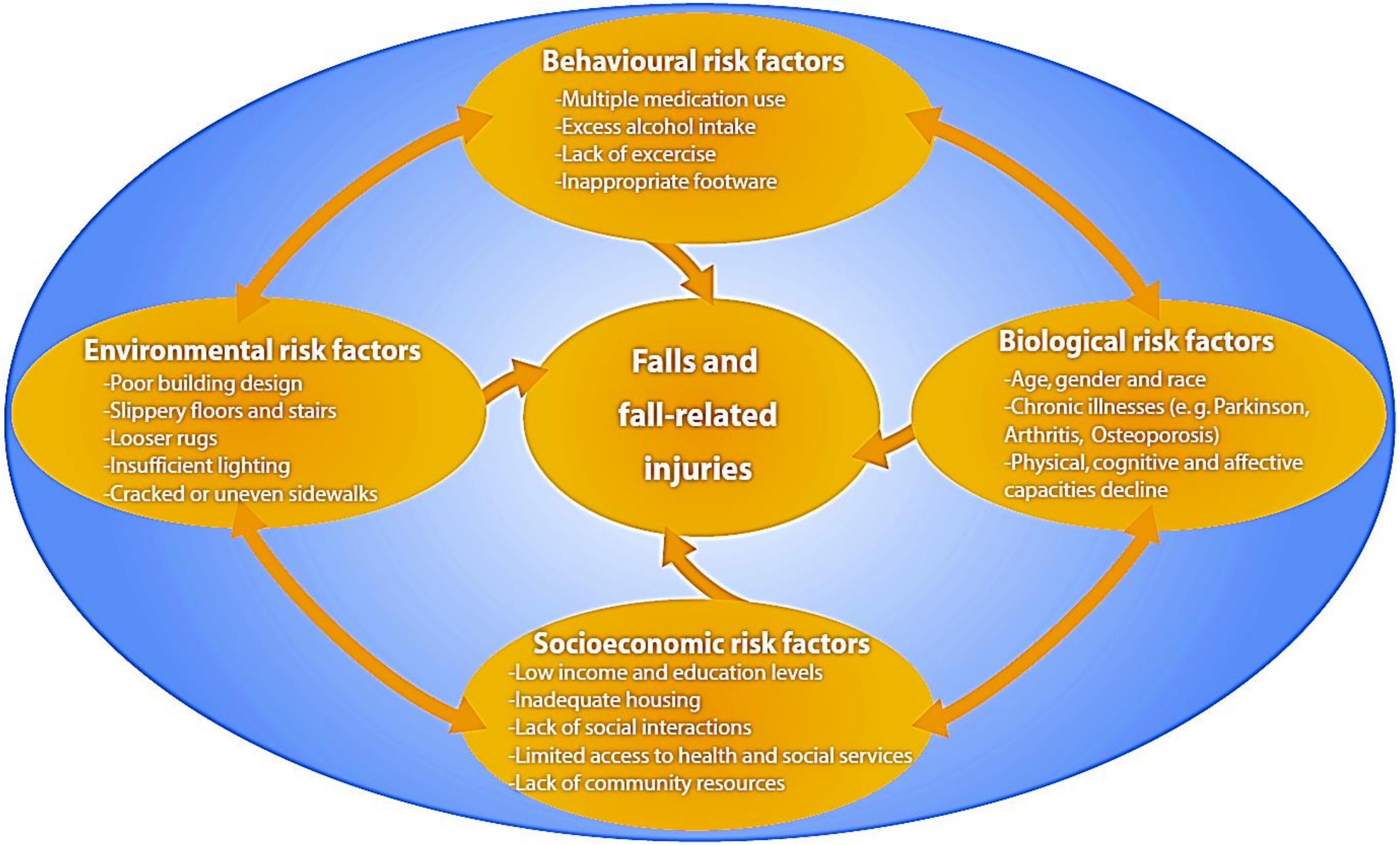


Figure 1-2 Risk factors model for falls in older adults (adapted from (World Health Organization Ageing Life Course Unit, 2008))

As shown in Figure 1-2, the main risk factors have been divided into 4 groups: 1) biological factors, 2) behavioural factors, 3) environmental factors, and 4) socioeconomic factors (World Health Organization Ageing Life Course Unit, 2008):

1) Biological risk factors: included individual characteristics pertaining to the human body, such as non-modifiable biological factors like age, gender and race. Biological factors are also associated with declines in physical and cognitive capacities due to aging and co-morbidity. The interaction of biological factors with behavioural and environmental risks tended to increase the risk of falls (World Health Organization Ageing Life Course Unit, 2008).

2) Behavioural risk factors: embraced modifiable factors concerning the human actions, emotions or daily choices, such as medications and sedentary lifestyle (World Health Organization Ageing Life Course Unit, 2008).

3) Environmental risk factors: consisted of the interplay between an individuals' physical condition and the surrounding environmental hazards, such as narrow steps, slippery surface and insufficient lighting (World Health Organization Ageing Life Course Unit, 2008).

4) Socioeconomic risk factors: included factors that related to societal and individual economic status, such as low income, inadequate housing, limited healthcare facilities, and lack of community resources (World Health Organization Ageing Life Course Unit, 2008).

It can be seen that the biological and behavioural risk factors are similar to the intrinsic factors, while the environmental and socioeconomic factors are more related to the extrinsic factors. Some important risk factors are summarised in the following parts:

1.1.3.1 Accident

Accident is the most common cause of falls and accounts for approximately 30-50% in most cases (Rubenstein, 2006). The occurrence of accidents could be induced by the accumulated negative effects of aging and disease, which lead to an increased individual susceptibility level to the identifiable environmental hazards (Rubenstein, 2006).

1.1.3.2 Balance and gait disorders

Evidence revealed that balance and gait disorders have been the second leading cause of falls, representing for 10-25% in most cases, which just came after accident (Rubenstein, 2006). Balance and gait disorders increase with aging, and have been suggested as an independent risk factor of falls in both older adults (Piirtola & Era, 2006) and patients with neurological deficits (Weerdesteyn, et al., 2008a). Balance disorders and abnormal gait have also appeared to be one of the most consistent predictors of future falls (Ambrose, et al., 2013). Deficits of balance and gait can be caused by many impairments related to aging (Rubenstein, 2006) and stroke (Weerdesteyn, et al., 2008a), including muscle weakness, sensory deficits, and abnormalities of vision and attention.

1.1.3.3 Inappropriate footwear

Footwear can modify the kinematics of foot and ankle complex, which may influence the static and dynamic balance performance that related to the risk of falls (Anna L Hatton, et al., 2013; Menz, et al., 2006). Inappropriate footwear is linked with high rate of falls (Aoki, et al., 2013). Balance can be influenced by the specific design features of footwear, such as heel height, texture, heel counter, and sole (Figure 1-3) (Menant, et al., 2008b). These footwear design characteristics can: 1) redistribute the plantar pressure and reduce pain (Brenton-Rule, et al., 2011; Gross, et al., 2012;

Anna L Hatton, et al., 2013; Landsman, et al., 2009; Mulford, et al., 2008), and 2) compensate or correct foot deformity and put the foot-ankle joint complex in a more stable position (Cobb, et al., 2006; Rome & Brown, 2004; Tochigi, 2003).

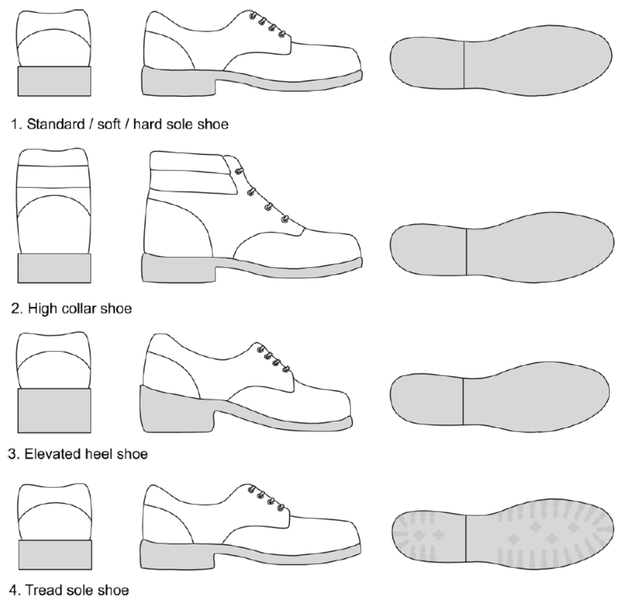


Figure 1-3 Different design features of footwear (adapted from (Menant, et al., 2008a))

Compared with people wearing fastened shoes, people wearing slippers or been barefoot appeared to have higher risks of falls (Ambrose, et al., 2013; Horgan, et al., 2009). High-heeled shoes with heel heights that greater than 2.5 cm (Menant, et al., 2008b; Tencer, et al., 2004) and small contact area at plantar surface (Tencer, et al., 2004) also contributed to higher chance of falls, as compared to the ordinary canvas shoes.

1.1.3.4 Older age

Aging is related to an increased incidence of falls and being seriously injured (Ambrose, et al., 2013; Deandrea, et al., 2010). Compared with young adults, older people had stiffer, less coordinated and more dangerous gait patterns (Tideiksaar, 2010). It is also difficult for an older adult to avoid a fall after an incident trip or slip (Tideiksaar, 2010). This could be caused by age-related declines in posture control, muscle strength, muscle tone, body-orientating reflexes, and height of stepping (Tideiksaar, 2010).

1.1.3.5 History of previous falls

A history of previous falls is related to an increased risk of recurrent falls (Deandrea, et al., 2010). Compared with people without falls, people who had fallen before revealed greater postural sway (Melzer, et al., 2010). Moreover, people with multiple falls also showed more postural sway than those with only single fall (Salgado, et al., 2004).

1.1.3.6 Visual deficits

It has been demonstrated that individuals with visual impairments had higher chance of falls than those with normal vison (E. E. Freeman, et al., 2007).

1.1.3.7 Depression and fear of falling

Experience of falls can induce depression and fear of falling among fallers, which may restrict their activity levels and further increased the risks of falls in return (Ambrose, et al., 2013). There have been strong relationships between fear of falling and poor postural control (Friedman, et al., 2002), slower walking velocity, muscle weakness, abnormal self-rated health status, as well as declined quality of life (Li, et al., 2003). Fear of falling can also be found in people with a history of stroke (Friedman, et al., 2002), and those who taking four or more medications (Friedman, et al., 2002).

1.1.3.8 Cognitive impairment

Cognitive impairment is also related to an increased risk of falls (Ambrose, et al., 2013). More specifically, among all four cognitive domains (i.e. attention especially dual tasking, executive function, information processing, and reaction time), dual tasking performance was found to be the factor that most related to balance and falls (Ambrose, et al., 2013).

1.1.3.9 Comorbidity and poly-pharmacy

Circulatory disease, depression, chronic obstructive pulmonary disease, and arthritis were each related to falls, with an increased falling risk of 32% (Lawlor, et al., 2003). The uprising burden of chronic diseases may also increase the prevalence of falls (Lawlor, et al., 2003; Tinetti, et al., 1995).

In addition to comorbidity, poly-pharmacy is also one major risk factor of falls (Ambrose, et al., 2013). Medications, such as psychotropic medications, diabetic medications, non-steroidal anti-inflammatory drugs (NSAID), and cardiovascular medications, have been found to be associated with an increased risk of falls (Ambrose, et al., 2013). These medications can cause some side effects such as dizziness and confusion, which increased an individual's risk of falls (Ambrose, et al., 2013). People taking two or more prescription drugs were also more prone to falls than those who taking fewer drugs (Ambrose, et al., 2013).

1.1.3.10 Environmental factors

Environmental factors also play an important role in risk of falling. Environmental hazards, including poor lighting and slippery ground, may increase the chance of falling, especially for individuals with visual impairments (Ambrose, et al., 2013).

1.1.4 Interventions to reduce the risk of falls

The aim of fall prevention strategies is to develop interventions that can reduce the chance of falls while maintaining or even improving an individual’s mobility (L. D. Gillespie, et al., 2012). Such interventions can be divided into three groups: 1) single (consisted of only one major category of intervention delivering to all participants), 2) multiple (consisted of a fixed combination of two or more major interventions delivering to all participants), and 3) multifactorial (consisted of more than one main category of interventions, but participants received different combinations of interventions based on an individualized assessment which identified the potential risk of falling) (L. D. Gillespie, et al., 2012).

According to the findings of two Cochrane studies, multifactorial interventions demonstrated significant reductions in both rate of falls and risk of falling, due to the fact that a fall was usually caused by multiple factors (Cameron, et al., 2012; L. D. Gillespie, et al., 2012).

For people who lived in community: 1) multiple-component group exercise, home safety assessment and modification, and treatment of vision problems can significantly reduce both rate of falls and risk of falling; 2) individual risk assessment, gradual withdraw of psychotropic medication, anti-slip shoes, and cardiac pacemaker insertion (among patients with carotid sinus hypersensitivity) can reduce the rate of falls, but not the risk of falling; and 3) vitamin D supplementation, cognitive behavioural intervention, and education about fall prevention can reduce neither the rate of falls nor the risk of fallings (L. D. Gillespie, et al., 2012).

For people who lived in health care facilities and hospitals, the effects of the above-mentioned interventions appeared to be different. No interventions can significantly reduce the rate of falls or risk of falling. Multifactorial interventions and exercise appeared to be effective, but the evidence was rather inconclusive (Cameron, et al., 2012). The interventions of physical exercise and environmental modification are summarized in the following parts:

1.1.4.1 Physical exercise

The efficiency of physical exercise on fall prevention appeared to be influenced by the intensity of exercise. General physical activities, such as walking, could not reduce neither the number of falls nor the risk of falls according to a previous study (L. D. Gillespie, et al., 2012). Gait, balance and functional training, as well as the strength and resistance training helped reduce the rate of falls, but not the risk of falls (Weerdesteyn, et al., 2008b). Exercise classes, home-based exercises containing multiple components, and Tai Chi helped reduce both the rate of falls and risk of falling (Clemson, et al., 2010; Trombetti, et al., 2011). However, such exercise requires a certain duration of time period to achieve the expected effectiveness in prevention of falls (Clemson, et al., 2010; Trombetti, et al., 2011).

1.1.4.2 Environmental modification

Environmental modification at home, or the so-called home safety intervention as shown in Figure 1-4, tended to be more effective in reducing the rate of falls in people with higher risks (Lin, et al., 2007). Such effects also appeared to be more effective when the home safety assessment/interventions were led by an occupational therapist (Pighills, et al., 2011).

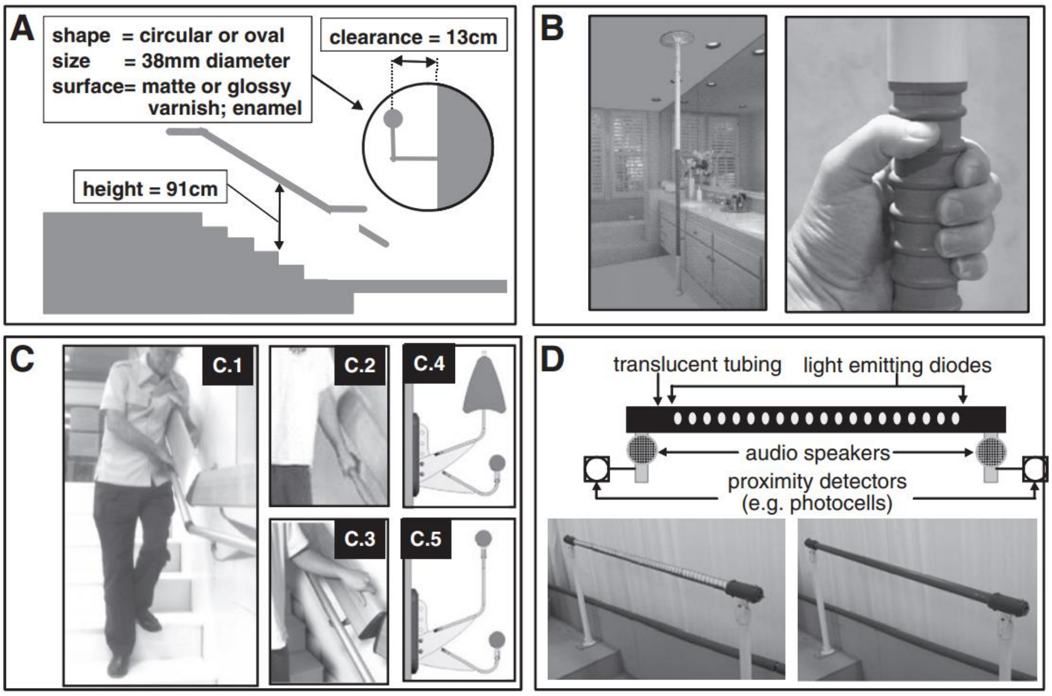


Figure 1-4 Examples of environmental modifications (adapted from (Maki, et al., 2011))

1.2 Aim and Scope

To sum up, falls and fall-induced injuries among elderly people and patients have been major public health problems all over the world. The incidences of falls and consequent injuries have been increasing along with the aging population (Todd & Skelton, 2004). The burden of the consequence of falls is heavy, including significant mortality and morbidity, reduced life span, reduction of quality of life, and huge hospitalization costs (Rubenstein, 2006). Different approaches have been applied in an attempt to prevent falls, including exercises, medications, surgery, nutrition therapy and environmental modification. However, few single approach or program has been identified and approved to be effective so far (L. D. Gillespie, et al., 2012). Physical exercises and environmental modifications have some positive effects, but they require long period of time and large professional manpower to achieve the expected effectiveness.

Meanwhile, balance and gait disorders are the second leading cause of falls, just coming after the accidents (Rubenstein & Josephson, 2002). The normal function of balance control and proprioceptive sensory system requires the normal function of the cutaneous sensation at plantar surface of foot (Höhne, et al., 2012).

Declines in plantar cutaneous sensitivity can lead to balance and gait disorders (Höhne, et al., 2012). Enhancement of the plantar pressure sensation might be one potential effective approach in enhancing balance and gait control in various populations, which has not achieved enough attention before.

1.2.1 Objectives of this project

In views of the above, this reach project sets out to explore and examine, with a considerable breadth and depth, the potential of using the advanced biomechanical and electronic approaches to enhancing/augmenting plantar pressure sensation and balance and gait in healthy young and older adults, and patients with stroke. The objectives of this research project are

1) To explore and identify some smart wearable electronic and biomechanical approaches that could enhance/augment plantar pressure sensation.

2) To evaluate the effectiveness of these approaches on balance and gait control in various populations.

3) To investigate the changes in balance and gait performance upon using these approaches in participants, in an attempt to understand the underlying mechanism and the potential of plantar pressure sensation enhancement on balance and gait control improvements.

This research project hypothesized that the advanced biomechanical and electronic approaches could improve the plantar pressure sensation and balance and gait performance in healthy young and older adults, and patients with stroke. The augmentation of plantar pressure sensation could be achieved not only by measuring the plantar forces via force sensors putting at plantar foot and providing the corresponding biofeedback at other body segments using vibrotactile biofeedback systems (electronic approach), but also by altering the mechanical stimulations at plantar surface of foot using orthopaedic insoles (biomechanical approach).

1.2.2 Research scope

This project briefly reviewed the previous efforts and attempts of preventing falls, and identified that improving balance and gait could be an effective approach in fall prevention. More specifically, balance and gait improvement could be achieved by enhancing/augmenting plantar pressure sensation via some advanced biomechanical and electronic approaches. It is expected that the plantar pressure measurement-based vibrotactile biofeedback system (electronic approach) and orthopaedic insoles (biomechanical approach) have great potential of enhancing/augmenting plantar pressure sensation, which could potentially further improve the balance and gait. Such logic flow of this project is demonstrated in Figure 1-5.

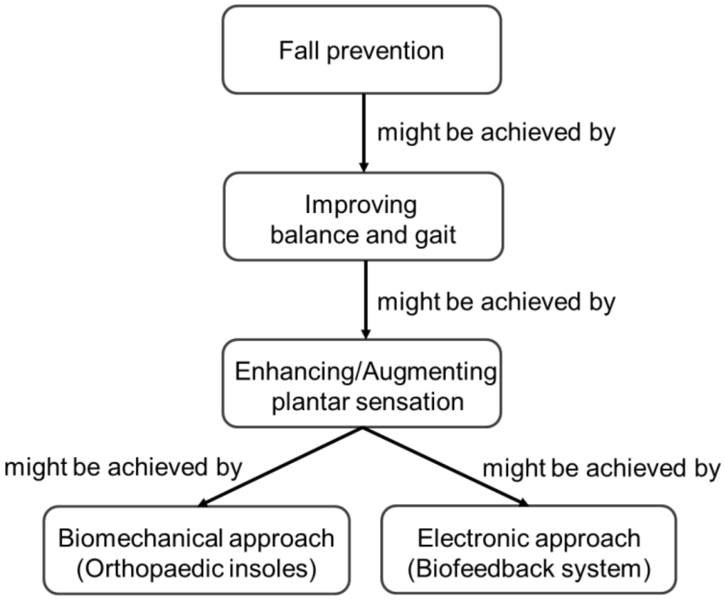


Figure 1-5 Logic flow of this project

To test such hypotheses and achieve the above-mentioned goals, this project first explored the feasibility of using vibrotactile biofeedback systems and orthopaedic insoles to improve static balance during standing in healthy young and older adults, then identified the appropriate design of biofeedback system, and further expanded the efforts by applying the vibrotactile biofeedback systems to improve dynamic balance and gait control in patients with stroke. At the beginning, both orthopaedic insoles and vibrotactile biofeedback system have been designed, developed and investigated for their effects on static balance. Upon careful decision-making, the vibrotactile biofeedback system was then determined as having higher potential on improving dynamic balance, which appears to be more challenging, and was modified to improve dynamic balance and gait thereafter. A series of biofeedback systems that targeted at improving the static postural balance during standing (Study 1), improving the postural balance while subjects standing on a perturbation floor (Study 2), and improving the plantar foot loading and lower-limb motor control during walking (Study 3); as well as the orthopaedic insoles targeted at improving static postural balance

(Study 4), have been developed and investigated (Figure 1-6). The scopes of this study are:

1) Design and development of the biofeedback systems and the orthopaedic insoles that could improve balance.
2) Evaluation of the balance and gait improvement upon using the developed devices, and exploration of the underlying mechanisms.
3) Investigation and validation of the relationship between foot plantar pressure sensation and balance/gait performance, which further potentially helps explain the underlying mechanism of balance and gait improvement upon using the wearable devices.

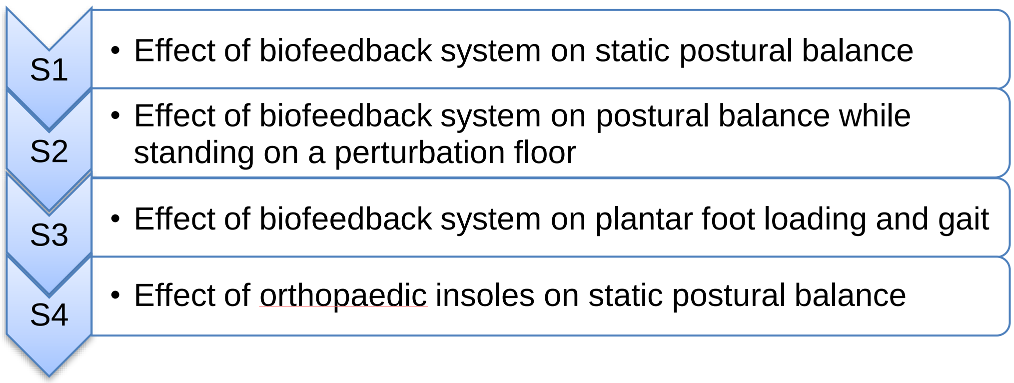


Figure 1-6 The studies involved in this project

1.3 Studies involved in this project

As described in the last session, this project adopted a step-by-step approach, started from improving postural balance during quite standing, and ended with attempts of improving dynamic balance during walking. All of them are linked together by the theme of improving balance and gait control through augmenting plantar pressure sensation. This section introduces each of the four studies involved in this research project.

1.3.1 Improving postural stability by vibrotactile biofeedback system

Some biofeedback systems, as reviewed in (Zijlstra, et al., 2010), have been evolved in an attempt to improve balance of patients with balance disorders. The underlying principle of these devices was to improve balance by supplementing and enhancing the somatosensory input (Zijlstra, et al., 2010). Such devices assessed the user's balance performance first by various instruments, and then provided the corresponding biofeedback reminders to the users. Some systems measured the changes of plantar force using a floor-mounted force-plate (Dozza, et al., 2007b; Hijmans, et al., 2008b; AA Priplata, et al., 2003; Tanaka, et al., 2001; Nicolas Vuillerme, et al., 2007). Some other systems mounted the inertial motion sensors (such as accelerometers and gyroscopes) on user's trunk and head to capture the torso and head tilts in mediolateral and anteroposterior directions (Goebel, et al., 2009; B.-C. Lee, et al., 2012; Nanhoe-Mahabier, et al., 2012; Rossi-Izquierdo, et al., 2013; Sienko, et al., 2008; Sienko, et al., 2013; Sienko, et al., 2012; Wall & Weinberg, 2003; Wall, et al., 2009). The sensors were wired to computers, which analyzed and interpreted the body postures by processing the plantar force and body motion signals, and sent the corresponding control signals to a display (visual feedback) (Chang, et al., 2013; Esculier, et al., 2012; Koslucher, et al., 2012; Nitz, et al., 2010), an audio device (audio feedback) (Dozza, et al., 2005; Dozza, et al., 2007b; Tanaka, et al., 2001), some electrodes (electro-tactile feedback) (Nicolas Vuillerme, et al., 2007), or some vibrators (vibrotactile feedback) (Goebel, et al., 2009; Sienko, et al., 2008; Sienko, et al., 2013; Wall & Weinberg, 2003; Wall, et al., 2009). The feedback devices provided users with the additional augmented sensory information of their body sway. Most biofeedback systems described in the existing literatures were designed for the in-door use at laboratories and clinics only. Patients needed to go to the clinics and laboratories to receive the balance training which usually lasted for at least 2 weeks as reviewed in (Zijlstra, et al., 2010).

Conducting balance training at home (or the so-called home-based balance training) contributed to high continuity and adherence of training (Madureira, et al., 2007). Good compliance rates of home-based balance training programs have been achieved (Davis, et al., 2009; Liu-Ambrose, et al., 2008). However, whether the training device is convenient to use could affect the compliance in the elderly and patients. Large sensing/feedback elements and the need of wired connection to a computer would discourage people from using the devices at home. Making the biofeedback systems portable and convenient to use is necessary to allow them to be used at home. While the current advanced technologies enable the microprocessors to be small and light-weight which allow them to be wearable, little attempts have been made to turn the biofeedback systems from hospital training instruments into wearable devices. Thin-film in-shoe force sensors are ideal for the wearable purpose. They are obviously smaller and lighter than any floor-mounted force plates. In addition, it is possible for the thin-film sensors together with the associated electronic components for power supply, force and motion analysis, and data transmission to be mounted at the shoes. The replacement of trunk-mounted inertial motion sensors with in-shoe force sensors would reduce the total weight of electronic components to be worn at the upper body. While some mobile in-shoe force measurement systems have been used to measure the plantar pressure distribution with success as shown in (Putti, et al., 2007; Ramanathan, et al., 2010), those devices did not provide the real-time feedback regrding the changes of plantar forces to users. With current wireless data transmission technology, considerations can be made to put force sensors at plantar foot and attach the vibrators at other body regions while maintaining the connection with sensors wirelessly.

The objectives of this study are 1) to present a wearable biofeedback system, which measured and analyzed the changes in plantar forces and wirelessly sent control signals to the vibrators located at the trunk, and 2) to report the findings of an experiment conducted to evaluate the effects of the use of this system on static postural balance, as assessed by measuring the movements of COP, of young and elderly people whose plantar tactile sensory input was experimentally reduced.

1.3.2 Improving postural balance while subjects under balance perturbation using vibrotactile biofeedback system

Sufficient balance control needs to be maintained during standing and walking on both static and moving support surfaces (F. B. Horak, 2006; Schoneburg, et al., 2013). Balance perturbation, which can be generated by translation of the support surface and sudden push/pull of the body (Mansfield, et al., 2015), poses great challenges to balance control (Sturnieks, et al., 2013). Trajectory of the body's center of mass (COM) provides important information regarding the control of balance (Lafond, et al., 2004). Large displacement of COM and slow reaction time in response to a floor translation perturbation have been suggested to be linked to higher risk of falls (Owings, et al., 2001).

Following the perturbation of the floor, three stages happened: 1) initial body tilt towards the opposite side of translation, 2) process of returning to postural equilibrium (recovery period, voluntary postural adjustment), and 3) reaching a new equilibrium position (Maki & McIlroy, 2007). Our central nervous system interprets the signals received from somatosensory, visual, and vestibular systems to detect the changes in postural equilibrium during sudden perturbations (Maki & McIlroy, 2007). It then gives a postural response by transmitting signals to the muscles (S. Park, et al., 2004). During quiet standing, a sudden perturbation of the floor can provoke an ankle strategy (activation of plantarflexors, dorsiflexors, invertors and evertors of the foot) and a hip strategy (activation of hip flexors, extensors, abductors and adductors) to control the body movements (Jones, et al., 2008), and these induce changes in force distributions under the feet (F. Yang & Pai, 2007). Tactile sensory input from the plantar foot is one crucial element for balance (Oliveira, et al., 2011), as it provides the information for necessary adjustments of body posture and motion for maintaining balance (Eils, et al., 2004). Plantar pressure sensation could be reduced by soft foot-supporting materials (S. D. Perry, et al., 2000), aging (Bretan, et al., 2010) and neuropathy (Jaiswal, et al., 2013). Providing additional feedback regarding the changes in plantar force distribution could possibly be useful to improve balance following perturbations.

Some biofeedback systems have been developed, but there were limited indications suggesting these systems improved balance in response to perturbations. A biofeedback system developed by Sienko *et al.* (2012) provided subjects with instant vibrotactile clues when the measured degree of trunk inclination, which was provoked by a perturbation of the floor, exceeded certain thresholds. They reported reduction of recovery time but increase of body tilt after providing the clues (Sienko, et al., 2012). Rocchi *et al.* (2008) delivered auditory biofeedback to subjects standing on an unstable floor when the sensed trunk acceleration exceeded specific ranges. They found the changes of postural sway in both forward-backward and mediolateral directions were inconsistent among subjects (Rocchi, et al., 2008). Determining the appropriate thresholds of provoking biofeedback has been difficult. In addition, these studies used inertia motion sensors that were attached to the trunk to detect body motion. These tended to add weight and bulkiness to the entire trunk-mounted devices. Delivering biofeedback based on the plantar force measurement could be a good alternative option. This can augment plantar pressure sensation which is important for balance control (Oliveira, et al., 2011), and potentially makes the monitoring of floor perturbations more sensitive as it directly measures the forces acting on plantar surfaces of feet. Thin-film plantar force sensors embedding into the shoes can also potentially reduce the size and mass of the device that is mounted to the trunk (C. Z.-H. Ma, et al., 2015; C. Z.-H. Ma, et al., 2016b). So far, such kind of biofeedback systems with plantar force sensors were only configured for the use in static floor conditions (C. Z.-H. Ma, et al., 2015; C. Z.-H. Ma, et al., 2016b; C. Z. Ma, et al., 2014a).

This preliminary study attempted to reduce the COM displacement and reaction time in response to the perturbation floor by developing and investigating a new wearable vibrotactile biofeedback system integrated with plantar force measurement. Four directions of translational perturbations were studied, including forward, backward, to the left and right sides, with the biofeedback system turned on and off. If the system is proven effective in improving balance control in a simple perturbation floor condition, future studies can look into the possibilities of its application in fall prevention in real life conditions, such as standing in buses or trains that suddenly decelerate or accelerate.

1.3.3 Improving gait and plantar foot loading using vibrotactile biofeedback system

Stroke is a leading cause of neurological impairment (Whitall, 2004) and chronic motor disability (Bath & Bath, 2004) in adults. Motor impairments of lower limbs can lead to difficulty in locomotion and activities of daily living, and consequently influence an individual’s quality of life (Kim, et al., 2014). People with stroke generally walk with higher gait asymmetry (G. Chen, et al., 2005), energy consumption (Kramer, et al., 2016) and risk of falls (Batchelor, et al., 2012). Abnormal motion of the ankle-foot complex contributes to the deterioration of the overall balance performance and gait pattern (Paton, et al., 2014). Deformities at the ankle-foot complex are common, due to the muscle spasticity (Lawrence & Botte, 1994) and muscle imbalance (Reynard, et al., 2009). The foot at the affected side of patients with stroke tends to be more plantar-flexed and inverted than non-stroke people (Forghany, et al., 2014). Recovery of walking ability by addressing the ankle-foot deformity helps patients with stroke to regain the independence in daily life, and is one of the main rehabilitation training goals (Peurala, et al., 2014).

Plantarflexion deformity can increase the chance of falls, as the feet tend to drag over the floor during swing phase (Bakheit, 2012). Fortunately, ankle-foot orthoses have been used successfully to correct plantar-flexion deformity after stroke (Mulroy, et al., 2010). Correcting varus deformity has been more difficult, because of the lack of lever arm that provides sufficient corrective eversion moment at foot. Abnormally high degree of foot inversion during gait could put excessively more strains on muscles and tendons (Kaplan, et al., 2003), and more plantar forces at the lateral side of paretic foot (de Haart, et al., 2004). Such musculoskeletal overloading could lead to soft tissue damage and structural deformity at the foot, leading to foot pain (Burns, et al., 2005). Foot inversion also reduces the total contact area with ground during mid-stance and the propulsive force during push-off phases of the gait (J. Perry & Burnfield, 2010). Foot pain together with the altered foot biomechanics could disturb gait, and consequently predispose the individuals with higher risk of falls (Mickle, et al., 2010). Previous studies have concluded that increased foot inversion is associated with decreased postural stability (Cobb, et al., 2004; L.-C. Tsai, et al., 2006), which is a crucial indicator of increased risk of falls (Moghadam, et al., 2011). Reducing the degree of abnormal foot inversion is required to relieve muscle stress and foot pain, which could improve walking performance and reduce risk of falls in patients with stroke (Kaplan, et al., 2003).

Various interventions have been used to relieve varus deformity for patients with stroke, but with some limitations (Reynard, et al., 2009). Local botulinum toxin injection has the limitations of high cost and transient nature that requires repetitive injections (Ozcakir & Sivrioglu, 2007). Patient's compliance of wearing ankle-foot orthosis has been low, and therefore leading to a high financial loss for society and a waste of therapeutic effort as reviewed in (Swinnen & Kerckhofs, 2015). Physiotherapy which provides repetitive verbal reminders of putting the foot in a better position during gait requires intensive manpower (Hesse, 2003).

Wearable biofeedback systems have great potential of facilitating home-based trainings in patients, which contribute to high level of continuity, adherence, and compliance rates of training in patients (Davis, et al., 2009) and save the expertise human resources. Biofeedback systems, with the use of sensors (force sensors, accelerometers, gyroscopes and magnetometers) and feedback modalities (screens, speakers and vibrators), were used in the elderly (C. Z.-H. Ma, et al., 2015; C. Z. Ma, et al., 2014a; Wall III, 2010), healthy young adults (C. Z.-H. Ma, et al., 2015; C. Z. Ma, et al., 2014a; N. Vuillerme & Cuisinier, 2008), patients with vestibular disease (Sienko, et al., 2012; Wall III, 2010), patients with Parkinson's disease (Byl, et al., 2015), and lower limb amputees (M.-Y. Lee, et al., 2007; Wan, et al., 2016). Regarding stroke patients, researchers have detected stance time using foot switches (M. R. Afzal, et al., 2015; Sungkarat, et al., 2011), ground reaction forces using force sensors (Byl, et al., 2015) and body sway using smartphones (Muhammad Raheel Afzal, et al., 2015) and inertial motion sensors (Byl, et al., 2015). Upon giving some instant feedback based on the sensor measurements, some improvements in the amount of body sway (N. Vuillerme & Cuisinier, 2008; Wan, et al., 2016), the symmetries in weight-bearing and stance/swing time between two legs (Byl, et al., 2015; M.-Y. Lee, et al., 2007), as well as the scores in standard clinical tests were noted (N. Vuillerme & Cuisinier, 2008). However, there is a lack of comprehensive understanding on how biofeedback systems could influence the spatial-temporal and kinematic gait parameters of stroke patients. In addition, little attempt has been made to address the negative effects of varus deformities on gait through biofeedback.

This study aimed to: (1) develop and present a biofeedback system that reminds stroke patients with flexible foot varus deformity to increase loading at the medial aspect of the foot of the affected side during gait; and (2) report the effects of using such biofeedback system on gait parameters and plantar pressure distribution. It is hypothesized that instant vibrotactile biofeedback of plantar force at the medial and lateral forefoot could improve plantar loading at the medial aspect of the affected foot and the gait pattern of stroke patients with flexible foot varus deformity.

1.3.4 Improving postural stability by orthopaedic insoles

Orthopaedic insoles are conventionally used to treat foot pain and correct foot deformity in patients (Conceição, et al., 2014). Some studies reported that balance could be improved by reducing foot pain (de Morais Barbosa, et al., 2013), correcting foot deformities (Gross, et al., 2012; Takata, et al., 2013), and putting the foot and ankle joint in a more stable position (T.-h. Chen, et al., 2014; Hamlyn, et al., 2012) upon using orthopaedic insoles. However, it is not known if these balance improving effects can still be retained in people without any foot pain or deformity.

Orthopaedic insoles may also have some positive effects on balance for people without foot pain or deformity. Previous studies measuring the plantar pressure distribution indicated that orthopaedic insoles increased the contact area between the foot and the support surface (T.-h. Chen, et al., 2014; Gross, et al., 2012). In addition, orthopaedic insoles redistributed the plantar pressure by increasing the pressure over the metatarsal shafts, and reducing the pressure over the heel and the metatarsal heads which are the common painful sites (Bus, et al., 2004). It just happens that the metatarsal shaft region has been shown to have higher tactile sensitivity than the heel and the metatarsal heads (Hennig & Sterzing, 2009). The increased contact area and the elevated pressure over some more tactile sensitive regions could enhance the plantar tactile input, which gives the traditional orthopaedic insoles the potential to improve balance of people with deficits of plantar tactile sensation. Scientific methods have not yet confirmed about this.

Wearing thick socks and multiple layers of socks could improve comfort (Menant, et al., 2008b) and protect the feet from frostbite during cold weather (Kuklane, 2009). However, the use of socks could be linked to an increased risk of falls (Menant, et al., 2008b; Y.-J. Tsai & Lin, 2013). The reason behind this phenomenon could be that the soft materials under the feet could attenuate the plantar tactile sensory input (Menant, et al., 2008b; Y.-J. Tsai & Lin, 2013), which is crucial for balance control. This mechanism could also explain the poorer postural stability caused by wearing shoes with soft soles (Menant, et al., 2008b) and standing on a soft foam surface (Patel, et al., 2008b).

This study evaluated the effects of wearing thick socks on postural balance of healthy older adults without foot pain or deformity, then further investigated if orthopaedic insoles could produce any significant changes in postural balance while wearing socks. Postural balance was assessed by measuring the movement of center of pressure (COP). It was hypothesized that the conventional orthopaedic insoles could improve the postural balance of older adults, which was adversely affected by the use of socks. This study potentially uncovers the balance improving effects of traditional orthopaedic insoles and sheds new light on the application of a low-cost and practical solution for improving balance.

1.4 Significance of the project

Falls and fall-induced injuries have been a major public health problem all over the world. The burden of the consequence of fall is heavy, including injures, reduced mobility, social isolation, depression, reduction of life quality, and even death. Costs of the medical care for fall-related injuries are also enormous.

The significance of this research lies in its vast potential of preventing falls and relevant burden faced by many people. This research used the advanced technology to improve and augment the plantar pressure sensation of subjects, and assessed the balance and gait control of subjects with and without the developed approaches. Upon been proved to be effective, the novel wearable biomechanical and electronic approaches could facilitate the individuals with balance and gait disorders to be able to engage into activities that are traditionally inappropriate for them. This will improve their health, quality of life, and life span. It is also highlighted that such approaches could also be modified to be applied in other populations that were not involved in this research, such as amputees, patients suffered from diabetes, spinal cord injury, cerebral palsy, and vestibular disease.

1.5 Outline of thesis

The chapters of this thesis are organized as follows:

Chapter 1 INTRODUCTION: the current chapter. This chapter examines the potential of improving balance by augmenting plantar pressure sensation, followed by the aim and scope of this project. Thereafter, this chapter introduces the four studies involved in this project. The significance of this project is also provided.

Chapter 2 LITERATURE REVIEW: this chapter begins with a review of balance and gait disorders and the tactile sensation at plantar foot, in an attempt to identify the feasibility of improving balance by augmenting plantar pressure sensation. Thereafter, the available balance assessing methods and instruments are reviewed and summarized accordingly. Two reviews of the effect of biofeedback system and insoles on balance and gait in various populations are then presented, respectively. This helps to explore the possible device designs that may enhance the plantar pressure sensation.

Chapter 3 RESEARCH METHOD: this chapter presents the developments and investigations on the effects of biomechanical (orthopaedic insoles) and electronic (vibrotactile biofeedback systems) approaches that are involved in this project in details. The design details of vibrotactile biofeedback system and orthopaedic insoles with arch supports, metatarsal pads and heel cups are described. The details of subject recruitments and experimental design are provided as well.

Chapter 4 RESULTS: this chapter presents the results of effects of vibrotactile biofeedback system and orthopaedic insoles on postural stability and gait, respectively.

Chapter 5 DISCUSSIONS AND SUGGESTIONS FOR FUTURE RESEARCH: this chapter starts with the separate summaries and discussions of effects of various vibrotactile biofeedback systems and orthopaedic insoles of each study. Then a more general discussion of the whole research project, as well as its implications and perspectives are summarized thereafter. Suggestions on further developments of the vibrotactile biofeedback system and orthopaedic insoles, as well as some future research directions are also highlighted in this chapter.

Chapter 6 CONCLUSIONS: this chapter summarises the key findings of this project and its clinical implications regarding the balance and gait improvement.

CHAPTER 2. LITERATURE REVIEW

2.1 Chapter summary

This chapter begins with a review of literatures on balance and gait disorders, as well as the plantar pressure sensation. This is then followed by a summary of the assessing methods of balance, and instruments used for balance assessment. This justifies the choice of balance and gait outcome measures adopted in this project. The review of research and literatures on the effect of insoles (biomechanical approach) on static and dynamic balance, and the review of research and literatures on the effect of wearable biofeedback systems (electronic approach) on static and dynamic balance are then presented. The purpose of these two reviews is to provide a comprehensive understanding of previous research in this area, as well as to provide the rationale for the choice of potential biomechanical and electronic approaches in the present project.

2.2 Balance and gait disorders- a leading cause of falls

2.2.1 Balance and gait disorders

Balance and gait disorders have been identified as the second leading cause of falls, just coming after the accident (Rubenstein & Josephson, 2002). Balance control, defined as the ability of maintaining the body’s center of mass (COM) within the base of support (Hrysomallis, 2011), is important for preventing falling. Sufficient balance control needs to be maintained during the standing and walking on both static and moving support surfaces (F. B. Horak, 2006; Schoneburg, et al., 2013).

Body’s ability of keeping balance relies on the normal function of central nervous and musculoskeletal systems, which requires adequate vision, proprioceptive feedback, vestibular input, muscle strength, and joint flexibility to detect and correct the balance displacement (Tideiksaar, 2010). Dysfunctions of visual, vestibular and proprioceptive sensory systems could lead to balance and gait disorders (Jacobson & Shepard, 2009). More specifically, deficits of balance and gat control could be caused by the declines in plantar cutaneous sensitivity and proprioception (Bretan, et al., 2010; Hennig & Sterzing, 2009).

Walking is an important activity in daily life, and poor gait pattern leads to increased risk of falls (Verlinden, et al., 2013). People with poor balance or having difficulty in walking are more likely to fall (Ambrose, et al., 2013). The gait pattern of people with poorer gait reveals decreased walking velocity, decreased step length, decreased height of step, stiffer and less coordination, and poorer postural control (Tideiksaar, 2010). Smaller foot-floor contact area during walking (Hertel, et al., 2002) and lower gait symmetry (Kamphuis, et al., 2013) are also associated with poorer balance, and higher risk of falls (Cheng, et al., 2001; Kamphuis, et al., 2013).

It can be summarized that the risk of falls can be influenced by balance and gait control. Improving balance and gait could potentially be one appropriate approach to reduce the risk of falls.

2.2.2 Factors affecting balance and gait control

Multiple factors contribute to balance and gait disorders, such as muscle weakness, deficits in sensory systems, physiological and pathological aging, and abnormal ankle-foot motion. More detailed descriptions of these factors are summarized below.

2.2.2.1 Muscle weakness

Upper and lower limb muscle weakness could lead to postural instability (Orr, 2010) and difficulty in rising from a chair (Meijer, et al., 2009), resulting in an increased risk of falls (Yamada & Demura, 2009). With declined muscle strength and endurance, it would be hard for a person to avoid a slip, stumble or trip (Tideiksaar, 2010). Trip or slip could be caused by the interruption of one foot during swing phase, and being barefoot or wearing footwear with low frictional resistance during stance phase of gait (Tideiksaar, 2010).

2.2.2.2 Physiological and pathological aging

Balance and gait control can also be affected by physiological degeneration. Loss of back muscle strength and reduced flexibility of spine could lead to poor posture and balance impairment (Tideiksaar, 2010); while degenerative joint changes lead to increased joint stiffness and pain, decreased mobility, gait and balance impairments (Tideiksaar, 2010).

In addition to physiological aging, some age-related medical conditions like arthritis, osteoporosis, diabetes, prior cerebra-vascular disease (CVD) and impaired vision are also associated with increased risks of falls (Ambrose, et al., 2013). All these age-related physiological and pathological changes would increase the tendency of falls among people (Tideiksaar, 2010).

2.2.2.3 Abnormal ankle-foot motion

Abnormal motion of the ankle-foot complex deteriorates the overall balance performance and gait pattern (Paton, et al., 2014). Abnormally high degree of foot inversion during gait could put excessively more strains on muscles and tendons (Kaplan, et al., 2003) and more plantar forces at the lateral side of the paretic foot (de Haart, et al., 2004). Such musculoskeletal overloading could lead to soft tissue damage and structural deformity at the foot, leading to foot pain (Burns, et al., 2005). Foot inversion also reduces the total contact area with ground during the mid-stance phase of gait (J. Perry & Burnfield, 2010). Foot pain together with the altered foot biomechanics could disturb gait, and consequently predispose the individuals with higher risk of falls (Mickle, et al., 2010). Previous studies concluded that increased foot inversion is associated with decreased postural stability (Cobb, et al., 2004; L.-C. Tsai, et al., 2006), which is a crucial indicator of higher risk of falls (Moghadam, et al., 2011).

2.2.2.4 Peripheral neuropathy

Peripheral neuropathy is a major public health concern, affecting almost 30% of the population aged over 65 (Mold, et al., 2004). Common symptoms of peripheral neuropathy consist of tactile and proprioceptive sensory loss, sensation dysesthesia, and chronic pain at the lower extremity (McKinney, et al., 2014). Patients with peripheral neuropathy, especially those who have primary sensory deficits, have been found to exhibit abnormal balance and gait pattern (Allet, et al., 2008).

2.2.2.5 Visual impairments

Visual impairments, such as declines in visual acuity, contrast sensitivity and visual fields, tend to increase the likelihood of slips and strips (Wood, et al., 2011). These visual problems increase the probability of falls by arising the difficulty of detecting obstacles, decreasing the adjusting ability of eyes regarding different levels of light and darkness, reducing the ability of seeing objects on the pathway but outside an individual's visual field, and reducing the depth perception (Tideiksaar, 2010).

Upon summarizing the contributing factors of balance and gait disorders, the evaluation methods of balance and gait are reviewed and presented in the following contents.

2.3 Evaluation of balance performance

Assessment of balance control is important to evaluate the risk of falling, and can be grouped into the categories of assessments of static balance, dynamic balance and balance perturbation. Static balance control tasks require the subjects to establish a stable base of support, and try to maintain the body movement within this base of support during the assessment (Gribble, et al., 2012). Meanwhile, dynamic balance control tasks need the subjects to do some degrees of body movements without compromising the established base of support, which more closely mimic the demands of physical activities than the static balance control tasks (Gribble, et al., 2012). In addition, balance control could also be assessed by requiring the subject to perform some balance tasks with additional balance perturbations, which make the balance control more challenging by interfering with subject's original balance control during the assessment (F. B. Horak, 2006).

The assessments under static balance, dynamic balance, and balance perturbation conditions are reviewed and summarized in the following parts.

2.3.1 Static balance

2.3.1.1 Romberg test

Romberg test can evaluate the function of lower limb proprioceptive spinal reflex arcs by placing subjects in a challenging postural position and only allowing the use of proprioceptive and vestibular inputs to maintain the upright position (Jacobson & Shepard, 2009). Patients with proprioceptive impairments could stand steadily and comfortably with eyes open, but would reveal an increased postural sway or even falls when their eyes are closed (Jacobson & Shepard, 2009). When performing the test, subjects are first required to stand with eyes open, feet together (to narrow the area of base of support), and arms crossed on the chest with the palm of each hand touching the opposite shoulder (Figure 2-1). Then subjects would be instructed to close eyes and maintain the current posture. Subjects shall be protected by an examiner when the eyes are closed. The postural stability can be assessed by measuring the direction and amplitude of postural sway during the assessment. The changes in postural stability, direction of sway, and direction of falls could be recorded either by the examiner, instruments, or both, when subjects keeping their eyes closed (Jacobson & Shepard, 2009).

Figure 2-1 Romberg test

2.3.1.2 Tandem standing test

Tandem standing test is the “sharpened” or “challenging” version of Romberg test. It requires the subjects to stand in the Tandem position, which is to stand with the heel of the front foot touching the toe of the back foot (Furman & Cass, 2003). In this standing position, the proprioceptive sensory input from ankle joints would become more discordant comparing with the vestibular and visual sensory inputs. This makes this test more sensitive to dysfunction of the proprioceptive sensory systems in subjects (Furman & Cass, 2003).

2.3.1.3 Limits of Stability (LOS) test

Limits of stability (LOS) test requires the subjects to stand quietly first, then lean their trunk forward as far as possible while maintaining the maximum leaning position without loss of balance (Juras, et al., 2008). Subject's maximum forward leaning distance is measured to evaluate the balance control. A longer leaning distance represents better static balance control (Juras, et al., 2008). Additionally, a floor-mounted force plate could also be used to measure the range of center of pressure (COP) displacement during this test (Juras, et al., 2008).

2.3.2 Dynamic balance

2.3.2.1 Star Excursion Balance Test (SEBT)

The Star Excursion Balance Test (SEBT) shows high reliability and validity in identifying the dynamic balance deficits in individuals with a variety of lower limb conditions (Gribble, et al., 2012). It requires the subjects to stand with one foot (stance leg) fixed at a point, and the other leg (non-stance leg) to reach maximally to the touching points along 8 designated lines on the ground (Gribble, et al., 2012). The 8 lines are 45 degrees to each other and extending from a same center point (Gribble, et al., 2012). Each reaching direction demands for the combined movements in sagittal, frontal and horizontal planes. As shown in Figure 2-2, the names of reaching directions are oriented to the stance leg, including anterior, anteromedial, anterolateral, medial, lateral, posterior, posteromedial, and posterolateral (Gribble, et al., 2012).

During the test, subjects are instructed to: 1) reach as far as possible with the non-stance leg along each reaching line, 2) lightly touch the line with the most proximal portion of the reaching foot, while without shifting weight or coming to rest on the non-stance leg, then 3) return the non-stance leg to the beginning position, i.e. in the center of the grid, and reassume a bilateral stance (Gribble, et al., 2012).

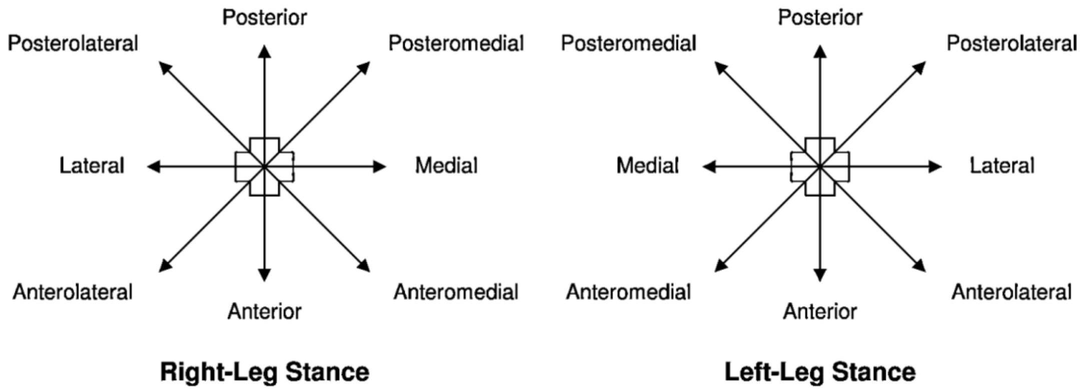


Figure 2-2 Orientation of the eight reaching directions in Star Excursion Balance Test (adapted from (Gribble, et al., 2012))

The measurement outcome from the SEBT is the maximal averaged distance that subjects can reach along the eight directions without violating any of the instructions. A longer reaching distance indicates better dynamic postural control (Gribble, et al., 2012). With appropriate instructions and normalization of the reaching distance, this assessment can be used to compare between the pre- and post-interventions to quantify the improvements in postural control (Gribble, et al., 2012). The reaching distance is recommended to be normalized by expressing as a percentage of the leg length (Gribble, et al., 2012).

Concerning a participant's reaching distance in one given direction is shown to be highly correlated with the reaching distance in the other 7 directions, it has been recommended that the assessment of reaching distances in only 3 directions (anterior, posteromedial, and posterolateral, Figure 2-3) is already sufficient enough to evaluate the dynamic balance (Hertel, 2008). This modification could substantially reduce the duration of the assessing time (Gribble, et al., 2012).

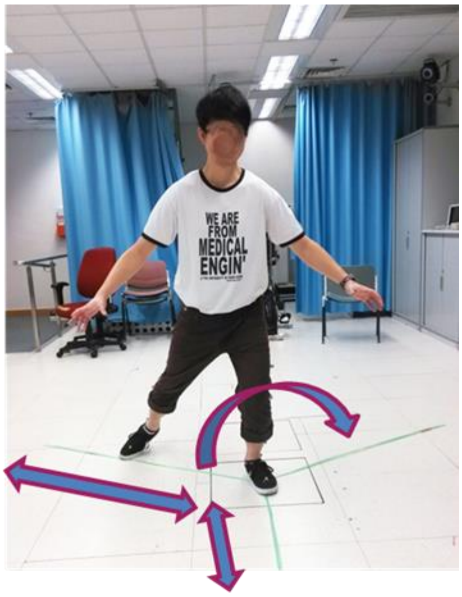


Figure 2-3 Orientation of the three reaching directions (anterior, posteromedial, and posterolateral) in Star Excursion Balance Test

2.3.2.2 Tandem gait assessment

As shown in Figure 2-4, tandem gait is a walking pattern with the heel of the front foot touching the toe of the back foot for each walking step (Dozza, et al., 2007a). Generally, subjects are required to walk 10 steps during the assessment. The spatial-temporal gait parameters and displacement of center of mass (COM) could be captured to evaluate the balance control during the assessment (Dozza, et al., 2007a).

Figure 2-4 Tandem gait

2.3.2.3 Berg Balance Scale (BBS)

Berg Balance Scale (BBS) is a balance assessment questionnaire that measures the examiner’s subjective perceived balance ability of the subjects while subjects performing each of the 14 daily activities, including transferring, standing unsupported, rising from a sitting position to a standing position, tandem standing, turning 360°, and single-leg standing (Schlenstedt, et al., 2015). The score is given based on the assessor’s perception of subject’s balance while subjects performing the test (Schlenstedt, et al., 2015).

2.3.2.4 Timed Up and Go (TUG) test

Timed Up and Go (TUG) test is commonly employed to detect dynamic balance deficits in patients and elderly people. When performing this test, subjects are required to stand up from an armchair, walk ahead for a distance of 3 meters, turn around, walk back to the chair, and sit down (Steffen, et al., 2002). A score of 1 to 5 is given based on the assessor's perception of subject's risk of falling during the test (Steffen, et al., 2002).

2.3.3 Balance perturbation

In addition to the conventional static and dynamic balance assessments, balance control could be made more challenging by adding some perturbations, examples are involving some cognitive demanding tasks, and providing some unstable support surfaces, devices, or environments. Some common perturbations include requiring the subjects to stand/walk on a foam pad (Patel, et al., 2008a; Patel, et al., 2008b) or a moving support surface (F. B. Horak, 2006), be pushed/pulled suddenly during quite standing without prior notice (Matjacic, et al., 2013), and perform some dual tasks while trying to maintain the balance (van Iersel, et al., 2007).

During a sudden perturbation, our central nervous system is involved to detect and predict the changes in postural equilibrium upon receiving signals from somatosensory, visual, and vestibular sensory systems (F. Horak & Kuo, 2000), and give postural response by transmitting signals to the muscles (S. Park, et al., 2004). The reaction time and postural sway during the balance perturbation could be used to assess an individual's balance control (Owings, et al., 2001).

2.4 Biomechanical measurements of balance and gait

Both instrumented and non-instrumented tests can be employed to evaluate the static and dynamic balance. Common instrumented tests measure the subject's postural stability during standing/walking and the gait pattern using force plates, inertial motion sensors attached to human body, and some infra-red cameras together with the reflective markers adhering to the body bony landmarks. Non-instrumented tests mainly consist of some clinical tests, balance assessing scales, and questionnaires as mentioned in the previous section. Sometimes, both instrumented and non-instrumented approaches are used to obtain a more comprehensive understanding of the balance performance. Some commonly used instrumented tests are summarized in the following part.

2.4.1 Center of pressure (COP)

While maintaining the position of center of pressure (COP) within the area of base of support is one of the key balance features (Hernandez, et al., 2012), evaluating movement of COP is a key assessing method to quantify the static balance performance (Moghadam, et al., 2011). COP is defined as the position of the global ground reaction force vector that adapts to the body sway (Ruhe, et al., 2010).

During bipedal static support, the displacement of COP that captured by force platform was calculated as in Equation 2-1:

$$COP_x = \frac{-M_y + F_x \times Z_0}{F_z} + X_0 \quad \text{and} \quad COP_y = \frac{M_x + F_y \times Z_0}{F_z} + Y_0$$

Equation 2-1

where M is the moment, F is the reaction force, x, y, and z are the anteroposterior (AP), mediolateral (ML), and vertical directions, respectively, and X_0, Y_0, Z_0 are the offset distances from the geometric center of the force platform (Lafond, et al., 2004).

The plantar force measured by multiple force sensors could also be used to calculate the location and trajectory of center-of-pressure (COP) as in Equation 2-2:

$$COP_x = \frac{\int [x \times p(x)] dx}{\int [p(x)] dx} \quad \text{and} \quad COP_y = \frac{\int [y \times p(y)] dy}{\int [p(y)] dy}$$

Equation 2-2

where P is the pressure at plantar surface of each foot, $p(x)$, $p(y)$ is the pressure depends on the distance x and y from a reference line, x, y is the anteroposterior and mediolateral distance from a reference line, and $\int[\,]dx$, $\int[\,]dy$ is the integration of a continuous function.

Parameters derived from the COP signal can provide the objective information on the postural control mechanism, which can be used to detect the balance deficit, predict the risk of falls, and evaluate the efficiency of balance training programs and interventions (Palmieri, et al., 2002). Larger COP-based parameters are typically described as deteriorated postural stability (Chaudhry, et al., 2011).

To evaluate balance by analyzing the COP parameters, evidence revealed that an experimental protocol of a 90s' data acquisition with eyes closed and an instruction of "standing as still as possible" could produce a high test-retest reliability (Ruhe, et al., 2010).

2.4.2 Center of mass (COM)

Center of mass (COM) is defined as the point equivalent of the total body mass in a global reference system, and is the weighted average of each body segment's COM in a three-dimensional space (Lafond, et al., 2004). Measurement of COM displacements, using either the optical motion capture system integrated with cameras and reflective markers adhered to the body bony landmarks (Caudron, et al., 2014; Nataraj, et al., 2012) or the inertial motion sensors attached to the posterior trunk that near the COM (Franco, et al., 2013; Grewal, et al., 2015; Nanhoe-Mahabier, et al., 2012), are common methods to assess the postural balance. When employing a optical motion capture system, the estimation of COM requires an accurate anthropometric model, which composes of several body segments such as head, trunk, upper limbs and lower limbs; as well as a full kinematic description of each marker that attached to the distal and proximal bony landmarks of the body segments (Lafond, et al., 2004). The reflective markers are usually attached to the lateral side of joints to facilitate the capture of the cameras. Common bony landmarks that used to adhere the reflective markers consist of acromion, anterior superior iliac spine (ASIS), knee joint center, lateral malleolus, suprasternal, styloid process, tip of the second toe, greater trochanter, and xyphiod (Lafond, et al., 2004). With a sufficient anthropometric model, the location of COM could be calculated as in Equation 2-3:

$$COM = \frac{1}{N}\sum_{i=1}^{n} COM_i \times m_i$$ **Equation 2-3**

where M is the total body mass, m_i is the mass of the ith body segment, COM_i is the coordinate of the ith body segment, and N is the number of body segments defining the body COM (Lafond, et al., 2004). Generally, an inverted pendulum model is adopted to evaluate the static postural stability, which requires the vertical projection of COM on ground to be within the area of base of support in static condition (A. Hof, et al., 2005).

Additionally, some researchers also proposed the use of extrapolated COM (XcoM), based on the inverted pendulum theory, to evaluate the postural balance in dynamic conditions (A. Hof, et al., 2005; A. L. Hof, 2008). The extrapolated COM is defined as the COM position plus the COM velocity multiplied by a parameter related to the subject's leg length. The XcoM usually moves away from the COP, and the COM ultimately follows the displacement of XcoM. To maintain balance, the position of the vertical projection of COM plus its velocity times a factor $\sqrt{l/g}$ should be within the base of support, where l being the leg length and g being the acceleration of gravity (A. Hof, et al., 2005; A. L. Hof, 2008). The position of XcoM can be calculated as in Equation 2-4:

$$XcoM = x + \frac{v_x}{\omega_0}$$ **Equation 2-4**

where $XcoM$ is the extrapolated center of mass, x is the projection of the COM position on the ground, v_x is the velocity of COM, $\omega_0 = \sqrt{g/l}$ is the Eigen-frequency of the inverted pendulum, l is the leg length, and g is the acceleration of gravity (A. Hof, et al., 2005; A. L. Hof, 2008). Larger COM- and XcoM- based outcome measures indicate poorer balance control in static and dynamic situations, respectively (A. Hof, et al., 2005; A. L. Hof, 2008).

Trajectory of COM also provides important information regarding the control of balance when a sudden perturbation is added. Following perturbation of the floor, three stages happened: 1) initial body tilt to the opposite side of translation, 2) process of returning to postural equilibrium (recovery period, voluntary postural adjustment), and 3) reaching a new equilibrium position (Maki & McIlroy, 2007). Larger displacement of COM and slower reaction time in response to the perturbation have been suggested to be linked with higher risk of falls (Owings, et al., 2001).

2.4.3 Plantar pressure distribution

While the force plate-captured COP movements could be used to indicate the static balance control during standing, some in-shoe plantar pressure measurement systems incorporating numerous force sensors at plantar surface of each foot could be used to monitor the COP trajectory during walking and evaluate the dynamic balance control (Putti, et al., 2007; Ramanathan, et al., 2010).

In addition to the COP trajectory, the regional plantar loading pattern could also be used to evaluate the dynamic balance and gait. Plantar pressure measurement has revealed high repeatability (Putti, et al., 2007) and validity (Price, et al., 2016) in previous studies. A number of studies have employed plantar pressure measurement to objectively quantify the gait patterns and assess the foot function by investigating the pressure distribution at specific foot regions during walking in hemiplegic patients (C. Chen, et al., 2007; Femery, et al., 2002; Hillier & Lai, 2015; N. K. Lee, et al., 2013; M. Park, et al., 2010; J. K. Yang, et al., 2014). For example, the supinated foot posture influences the plantar pressure distribution at forefoot and midfoot, leading to higher plantar pressure at the lateral side and lower plantar pressure at the medial side (Chuckpaiwong, et al., 2008; Femery, et al., 2002).

2.4.4 Gait parameters

Gait analysis is a common method to assess an individual's walking ability. Common gait parameters used to assess balance and gait include the spatiotemporal gait parameters such as speed, step length, stride length, cadence, stance time, swing time, and stride time; as well as the kinematic and kinetic data such as angles, moments, and powers of lower limb joints (J. Perry & Burnfield, 2010). These gait parameters could be measured by the three-dimensional motion capture systems and the floor-mounted force platforms.

During the data collection, an instruction of walking in self-selected comfortable speed could reduce the artificial alteration of gait pattern in subjects as shown in a previous study (Jordan, et al., 2007). Standardization of shoe models is recommended during the measurement.

2.5 Instruments for assessing postural balance and gait

Balance and gait can be assessed by the wearable sensors attaching to human body and the motion capture systems together with floor-mounted force plates.

2.5.1 Wearable sensors

Inertial motion sensors and plantar force sensors are common wearable sensors that can be used to objectively measure and evaluate the human body motion. Their characteristics of small size and light weight allow them to be wearable on human body. Inertial motion sensors could detect the postural sway by measuring the linear acceleration, angular velocity, and direction (relative to the earth) of the body movements. Plantar force sensors could detect the postural sway and gait variability by measuring the plantar loading, COP trajectory at plantar surface of foot, and the stance/swing time during walking. The range, average, and standard deviation of these parameters are calculated to evaluate the degrees of postural sway and gait variability. Generally, increases in postural sway and gait variability are interpreted as a deterioration of balance performance (Putti, et al., 2007; Ramanathan, et al., 2010). An overview of these wearable sensors is summarized in Table 2-1, including the type and location of the sensor, and the outcome measurement. More detailed descriptions of the sensing mechanism of each sensor are summarized in the following texts.

Table 2-1 Overview of wearable sensors

Type of wearable sensor		**Outcome measurement**	**Location of sensor**
Inertial motion sensor	Accelerometer	Linear acceleration in a three-dimensional space	Body segment
	Gyroscope	Angular velocity: extent and rate of rotation in a three-dimensional space (roll, pitch, and yaw)	Body segment
	Magnetometer	Direction: absolute angular movements relative to the Earth's magnetic field	Body segment
Planter force sensor		Plantar force/pressure	Plantar surface of foot

2.5.1.1 Inertial motion sensors

State-of-the-art inertial measurement units (IMU), based on the microelectromechanical systems (MEMS), could incorporate up to all nine axes of sensing in a single integrated circuit package. They consist of a tri-axial accelerometer, a tri-axial gyroscope, and a tri-axial magnetometer, which measure the linear acceleration, angular velocity, and direction, respectively (O'Donovan, et al., 2007). Such information could be further processed to reveal the orientation/inclination of human body and body segments. Inertial motion sensors were shown to be able to identify the increased trunk (Nanhoe-Mahabier, et al., 2012) and head (Halická, et al., 2014) inclination, and the decreased coordination among lower-limb joints (Grewal, et al., 2015), which are interpreted as poorer balance performance generally. The detailed sensing mechanism of each sensor, as well as the working mechanism after incorporating them together are described below.

Accelerometers

A tri-axial accelerometer could detect the acceleration of X, Y, and Z movements in a three-dimensional space. The underlying mechanism is that an accelerometer independently measures the respective acceleration, or the so-called "g-force", in each of the three directions as a vector quantity. The output of an accelerometer is normally expressed as in Equation 2-5:

$$\vec{a} = \vec{g} + \overrightarrow{a_l} + \vec{\varepsilon}$$

Equation 2-5

where $\vec{a}$ is the output of an accelerometer, $\vec{g}$ is the gravity acceleration, $\overrightarrow{a_l}$ is the linear acceleration, and $\vec{\varepsilon}$ is the noise in a sensor coordinate frame (Zhu & Zhou, 2004).

Based on the detected changes of magnitude and direction of the g-force, the direction of linear movement of an object could then be obtained (Woodman, 2007). This is how the body-mounted accelerometers detect the moving direction of various body segments.

Gyroscopes

Gyroscopes could measure the extent and rate of rotation in a three-dimensional space (roll, pitch, and yaw) (Woodman, 2007). They are designed based on the theory of Coriolis effect, which states that in a frame of reference rotating at angular velocity, a mass moving with velocity experiences a force as shown in Equation 2-6:

$$\overrightarrow{F_c} = -2m(\vec{\omega} \times \vec{\vartheta})$$ **Equation 2-6**

where ω represents the angular velocity, m represents the mass, ϑ represents the velocity, and F_c represents the experienced force of the mass (Woodman, 2007).

A gyroscope involves a spinning disc of which the axis of rotation is free to assume any orientation. The orientation of this axis is not affected by the instantaneous tilting or rotation of the mounted object according to the conservation of angular momentum, which allows the gyroscopes to detect the movement in a relatively short time period more accurately than using accelerometers within a three-dimensional space (Luinge & Veltink, 2005).

Magnetometers

Magnetometers could provide the direction information or the absolute angular movements relative to the Earth's magnetic field (Zhu & Zhou, 2004). The detected vector component of a magnetic field consists of declination (the angle between the horizontal component of the field vector and the magnetic north) and inclination (the angle between the field vector and the horizontal surface) (Zhu & Zhou, 2004).

Integrated sensing mechanism

Either a tri-axial accelerometer or a tri-axial gyroscope could already be able to provide the orientation information of an object. However, the accelerometer only measures linear acceleration along one or several axes, and the measured signal may be biased by the gravity (Woodman, 2007). It also has high level of signal noise at the onset of acceleration (Luinge & Veltink, 2005; Zhu & Zhou, 2004). The gyroscope measures the instantaneous angular velocity accurately, but additional errors will accumulate over a period of time or even seconds when the object is not undergoing any rotations (Woodman, 2007), leading to an inaccurate measurement of pitch/roll angle relative to the horizon during a relatively long time period (Zhu & Zhou, 2004). Thus, to achieve accurate and sufficient measurements of orientation in both short and long time periods, both accelerometers and gyroscopes are needed to calibrate each other (Luinge & Veltink, 2005). However, combining accelerometers and gyroscopes together could only provide the information of fully six degrees of freedom of body motion (orientation) in a three-dimensional space, and could not provide the absolute direction information relative to the Earth's magnetic field (Woodman, 2007). An additional magnetometer measuring direction is needed to help measure the body segment's motion more clearly by adding an universal reference (Zhu & Zhou, 2004).

2.5.1.2 Plantar force sensors

In addition to the inertial motion sensors measuring the body inclination directly, force sensors putting at the plantar surface of foot can measure the plantar force/pressure information, which could be further analysed to assess the balance performance. Common parameters derived from plantar force measurement to assess balance are center of pressure (COP) trajectory, and variability of plantar loadings.

Parameters calculated based on the trajectory of COP during standing (Ruhe, et al., 2010) and walking (Hass, et al., 2004), such as mean velocity and range, could be used to evaluate the postural stability. Capability of maintaining a good postural stability is a key factor to assess the risk of falls (Moghadam, et al., 2011). Increase of COP displacements is generally interpreted as an overall deterioration of postural stability during standing and walking (Chaudhry, et al., 2011). In addition, the step-by-step COP variability during walking is also associated with dynamic balance performance, and greater COP variability generally indicates poorer balance (O'Connor & Kuo, 2009).

In addition to the COP variability, gait variability could also be determined by calculating the variation of stance and swing time, and weight-bearing symmetry that measured by the force sensors putting under the left and right feet (M.-Y. Lee, et al., 2007). The timing of the force applications at plantar surface of heel and forefoot could be measured to calculate the stance and swing time. Symmetry of stance and swing time between two legs is an important parameter of assessing dynamic balance performance during walking (M.-Y. Lee, et al., 2007).

2.5.2 Optical motion capture system and force plates

Three-dimensional motion capture systems and floor-mounted force plates have been commonly used to measure the movement of COP, COM, and spatiotemporal gait parameters.

During the measurement, some reflective markers are adhered to some body bony landmarks. The movements of these reflective markers are captured by infra-red cameras for further analysis of body movement (Caudron, et al., 2014; Nataraj, et al., 2012). The estimation of body motion requires an accurate anthropometric model, which composes of several body segments such as head, trunk, upper limbs and lower limbs; as well as a full kinematic description of each marker that attached to the distal and proximal bony landmarks of body segments (Lafond, et al., 2004). These reflective markers are generally attached to the lateral side of joints to facilitate the capture of cameras. Common bony landmarks used to adhere the reflective markers consist of acromion, anterior superior iliac spine (ASIS), posterior superior iliac spine (PSIS), knee joint center, lateral malleolus, suprasternal, styloid process, tip of the 2^{nd} toe, greater trochanter, and xyphoid (Lafond, et al., 2004).

2.6 Review of the effect of biofeedback system on balance

2.6.1 Introduction

Since the lack of balance during standing and walking is one of the leading causes of falls, some researchers have been developing some new methods to monitor balance performance and providing various corresponding biofeedback information, in an attempt to prevent falls. Some of these devices consisted of wearable sensors to monitor balance status with high level of accuracy and reliability; while some other devices delivering biofeedback to augment somatosensory input based on the instrumented measurement devices, such as a force plate (Nicolas Vuillerme, et al., 2007), or a motion capture system (Nitz, et al., 2010).

Wearable sensors including inertial motion sensors (Goebel, et al., 2009; B.-C. Lee, et al., 2012; Nanhoe-Mahabier, et al., 2012; Rossi-Izquierdo, et al., 2013; Sienko, et al., 2008; Sienko, et al., 2013; Sienko, et al., 2012; Wall & Weinberg, 2003; Wall, et al., 2009) and plantar force sensors (Anna L Hatton, et al., 2013; M.-Y. Lee, et al., 2007; Sungkarat, et al., 2011) have been used to detect body sway, acting as a real-time balance monitoring device or a rehabilitation training tool. These devices mounted inertial motion sensors (accelerometers, gyroscopes and magnetometer) on user’s trunk, head, or lower limbs to capture torso, head or other body segments’ tilts in mediolateral and anteroposterior directions (Goebel, et al., 2009; B.-C. Lee, et al., 2012; Nanhoe-Mahabier, et al., 2012; Rossi-Izquierdo, et al., 2013; Sienko, et al., 2008; Sienko, et al., 2013; Sienko, et al., 2012; Wall & Weinberg, 2003; Wall, et al., 2009); and put foot switches or force sensors on top of shoe insoles (M.-Y. Lee, et al., 2007; Sungkarat, et al., 2011). The sensors were connected to computers, which analyzed body postures by interpreting the plantar force and body motion signals and sent control signals to a display (visual feedback) (Chang, et al., 2013; Esculier, et al., 2012; Koslucher, et al., 2012; Nitz, et al., 2010), an audio device (audio feedback) (Dozza, et al., 2005; Dozza, et al., 2007b; Tanaka, et al., 2001) (Figure 2-5), or some vibrators (vibrotactile feedback) (Goebel, et al., 2009; Sienko, et al., 2008; Sienko, et al., 2013; Wall & Weinberg, 2003; Wall, et al., 2009) (Figure 2-6). The application of these devices including healthy young (Franco, et al., 2013) and older adults (Chiari, et al., 2005), patients with stroke (Sungkarat, et al., 2011), diabetic neuropathy (Grewal, et al., 2013), Parkinson’s disease (Nataraj, et al., 2012), vestibular loss (Janssen, et al., 2010), multiple sclerosis, and lower limb amputees (M.-Y. Lee, et al., 2007). The underlying mechanism of these devices is to capture the body motion through inertial sensors or plantar force sensors, and provide corresponding body motion reminder through different kinds of biofeedback. High satisfactory level of accuracy and usability of these devices was founded (Giggins, et al., 2014; Leardini, et al., 2014).

Electrotactile feedback (Tyler et al. 2003, Vuiller me et al.2007)

Visual feedback (Nits et al. 2010)

Auditory feedback (Dozza et al. 2005)

Figure 2-5 Previous design of electro-tactile, visual and auditory biofeedback systems

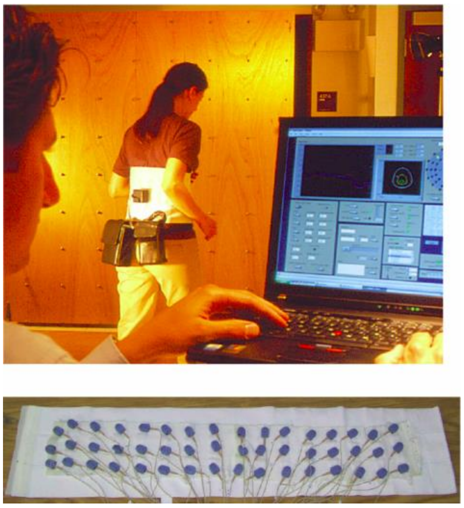


Figure 2-6 Previous design of vibrotactile biofeedback system (adapted from (Wall III, 2010))

A better understanding of the effective design of previous devices can shed new lights on future design of devices involving wearable sensors to improve balance and reduce falls. This review considered both the plantar force sensors and inertial motion sensors that are wearable. The objectives of this review are to 1) examine the effectiveness of different wearable motion sensors on monitoring balance performance; 2) identify key design features of biofeedback systems using wearable motion sensors that effectively improve balance performance; 3) summarize characteristics of previous clinical trials that evaluated the effectiveness of these devices; and 4) suggest potential future design of wearable biofeedback systems that could improve balance using wearable motion sensors.

2.6.2 Methods

2.6.2.1 Inclusion criteria

Types of participants

This review considered studies that included healthy adults, as well as patients with balance disorders, including stroke, neuropathy, lower-limb amputation, vestibular diseases, cerebral palsy, spinal cord injury, and Parkinson's disease. Studies were included in this review only if the participants were adults aged 18 years and over.

Types of sensors and biofeedback

This review considered studies that used wearable sensors to detect balance and provided instant biofeedback based on the detected information. The sensors included wearable inertial motion sensors (accelerometers, gyroscopes, and magnetometers), and foot switches and force sensors placed at plantar surface of foot.

Studies that provided visual, auditory, electro-tactile and vibrotactile biofeedback were included in this review.

Types of intervention outcomes

This review considered studies that included the following intervention outcome measures: 1) instrumented measurements, including displacement of COP, COM, plantar pressure distribution, spatial-temporal and kinematic gait parameters, using either the wearable sensors integrated in the biofeedback systems or extra sensors that were not part of the biofeedback system; and 2) non-instrumented measurements, including standard clinical assessments, questionnaires, and verbal reports.

Types of studies

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

This review also considered descriptive epidemiological study designs including case series, individual case reports and descriptive cross-sectional studies for inclusion.

2.6.2.2 Exclusion criteria

Studies were excluded if they: 1) involved non-wearable sensors; 2) involved no balance outcome measures; 3) involved study protocols not relating to balance; 4) did not provide sufficient biofeedback information; 5) were conference papers, and 6) were review articles.

2.6.2.3 Search strategy

Published studies were searched following the guidelines of the standardized critical appraisal instruments from the Joanna Briggs Institute Meta-Analysis of Statistics Assessment and Review Instrument (JBI-MAStARI). A three-step search strategy was employed. An initial search of MEDLINE only was undertaken to analyze the words contained in the titles and the abstracts, and the index terms that were used to describe the articles. The aim of this search was to identify appropriate keywords (Step 1). A second search was then undertaken to use all identified keywords to search across all included databases to identify papers that suitable for this review (Step 2). Thirdly, the reference lists of all identified reports and articles were also searched for more relevant studies (Step 3). Studies published in English and published from 1993 to 2013 were included in this review.

The keywords that been identified in Step 1 and used for paper searching were: sensors, wearable sensors, force sensors, inertial motion sensors, accelerometer and gyroscope, sensory augmentation, sensory stimulation, biofeedback, balance, balance training, and postural stability.

The databases been searched in Step 2 included: Web of Science, MEDLINE, and Google Scholar.

2.6.2.4 Data collection and data synthesis

Qualitative data were extracted from papers and summarized according to the following characteristics: methodological quality and level of evidence; study design; sample size; sample characteristics (age and gender); key characteristics of the device; follow-up time; static and dynamic balance outcome measures; and results. Data synthesis using a meta-analysis was not possible due to the variety of study designs, methodologies, and outcome measures.

2.6.3 Results

2.6.3.1 Sample characteristics

As shown in Table 2-2, sample characteristics varied across studies. Sample size ranged from 1 (Nataraj, et al., 2012) to 35 (Sungkarat, et al., 2011). Subjects were predominantly males. Subjects recruited in the included studies consisted of healthy young and older adults, patients with diabetes, Parkinson’s disease, stroke, spinal cord injury, vestibular loss, and amputees. The inclusion and exclusion criteria regarding physical and cognitive functioning were different, as well as the clinical tests to evaluate these characteristics. Most studies did not specify the cognitive status of subjects; only two of them verified that subjects did not have cognitive disorders with clinical assessments (Nanhoe-Mahabier, et al., 2012; Sungkarat, et al., 2011). Physical status of subjects were mainly assessed by clinical tests, including Modified Ashworth Scale (Sungkarat, et al., 2011), Air Force Class III equivalent physical examination (Mulavara, et al., 2011), as well as self-reported independent walking abilities (Nanhoe-Mahabier, et al., 2012; Sungkarat, et al., 2011). The history of falls was only specified in one publication (Janssen, et al., 2010). The initial balance performance of subjects also varied across studies, though most studies involved subjects who encountered balance disorders (Table 2-2).

Table 2-2 Subject characteristics (n=11).

Study	Sample size (gender,F/M)	Group (sample size, n): mean (SD) age, years	Sample characteristics		
			Physical	Cognitive	Fall history
(Franco, et al., 2013)	20 (11/9)	Intervention (20): 26.5 (3.7)	Healthy young subjects with no history of sensory or motor problems, neurological diseases, or disorders.	Not specified	Not specified
(Grewal, et al., 2013)	29 (4/25)	Intervention (29): 57.0 (10.0)	-Patients with type 2 diabetes and peripheral neuropathy -With no medical condition other than diabetes that may alter the patient's balance -With no previous professional balance training.	Not specified	Not specified
(Nanhoe-Mahabier, et al., 2012)	20 (4/16)	Intervention (10): 59.3 (2.0) Control (10): 58.6 (2.5)	-Patients with PD. -With no causes of balance impairment other than PD, able to walk without walking aids, and no severe co-morbidity.	No cognitive dysfunction	Not specified
(Nataraj, et al., 2012)	1 (1/0)	Intervention (1): nil (nil)	Patient with thoracic-4 level complete paraplegia.	Not specified	Not specified
(Sungkarat, et al., 2011)	35 (11/24)	Intervention (17): 52.1 (7.2) Control (18): 53.8 (11.2)	-Patients with first episode of unilateral stroke with hemiparesis; orpington prognostic score at initial assessment between 3.2 and 5.2 (moderately severe); able to walk at least 10m with or without assistance; stable medical condition; and to participate. -Patients without any comorbidity or complication that would preclude gait training, severe leg spasticity (Modified Ashworth Scale ≥3(Sungkarat, et al., 2011)), neglect, or missed more than three training sessions.	No impaired cognition and/or communication	Not specified
(Alahakone, et al., 2010)	6 (3/3)	Intervention (6): 23.2 (nil)	Healthy young subjects	Not specified	Not specified
(Janssen, et al., 2010)	20 (8/12)	Intervention (10): 63.1 (9.3) Control (10): 40-65	Patients with severe bilateral vestibular losses (flexia or hyporeflexia). With severe balance problems	Not specified	>5 times falls per year
(Giansanti, et al., 2009)	9 (nil)	Intervention (9): 55.0 (33-71)	Healthy subjects	Not specified	Not specified
(M.-Y. Lee, et al., 2007)	7 (2/5)	Intervention (7): 38.9 (14.1)	Lower-limb amputees with no orthopaedic or neurological conditions, disabling arthritis, uncorrected visual problems, dizziness or vertigo, use of assistive walking devices, joint injury, or joint implants	Not specified	Not specified
(Chiari, et al., 2005)	9 (nil)	Intervention (9): 55.0 (33-71)	Healthy subjects	Not specified	Not specified
(Wall III, et al., 2001)	6 (4/2)	Intervention (6): 24.8 (22-29)	Healthy subjects	Not specified	Not specified

2.6.3.2 Types of sensors

Table 2-3 summarizes the types of wearable sensors and biofeedback adopted in the biofeedback systems. Generally, inertial motion sensors were used to measure the postural sway or lower-limb joint co-ordinations in mediolateral and anteroposterior directions during standing and walking (Alahakone, et al., 2010; Chiari, et al., 2005; Franco, et al., 2013; Giansanti, et al., 2009; Grewal, et al., 2013; Janssen, et al., 2010; Nanhoe-Mahabier, et al., 2012; Nataraj, et al., 2012; Wall III, et al., 2001). Some studies put the inertial motion sensors at the lower back near the location of COM to assess postural sway (Alahakone, et al., 2010; Franco, et al., 2013; Giansanti, et al., 2009; Nataraj, et al., 2012); at the shank, thigh and lower back in an attempt to estimate the lower-limb joint co-ordinations by measuring joint angles (Grewal, et al., 2013); or at the head and trunk to measure the inclination of head and torso (Chiari, et al., 2005; Janssen, et al., 2010; Mulavara, et al., 2011; Wall III, et al., 2001). Most studies developed a new device consisted of various inertial motion sensors (Grewal, et al., 2013; Nanhoe-Mahabier, et al., 2012), while some studies directly used the smartphones equipping with inertial motion sensors to do the measurements (Franco, et al., 2013).

Force sensors were attached to the plantar surface of foot to measure the ground-reaction-force information, which were processed and used to estimate the weight bearing asymmetry between the affected and sound sides (Sungkarat, et al., 2011); and assess the temporal step-to-step gait variability by detecting the gait phases, mainly the heel-strike and toe-off (B.-C. Lee, et al., 2012). One study put only one plantar force sensor at heel to evaluate the weight bearing symmetry between two legs during standing (Sungkarat, et al., 2011), while some other studies put two or more force sensors at heel, metatarsal heads, and toes to detect the postural sway during standing and gait phase transitions (M.-Y. Lee, et al., 2007).

2.6.3.3 Types of biofeedback

Different kinds of biofeedback have been provided to users, based on the processed body motion information measured by the wearable sensors (Table 2-3). Single and multiple biofeedback information were provided, including visual (Alahakone, et al., 2010; M.-Y. Lee, et al., 2007), auditory (Chiari, et al., 2005; Franco, et al., 2013; Giansanti, et al., 2009; Sungkarat, et al., 2011), vibrotactile (Alahakone, et al., 2010; Janssen, et al., 2010; Nanhoe-Mahabier, et al., 2012; Wall III, et al., 2001), and electro-tactile (M.-Y. Lee, et al., 2007; Mulavara, et al., 2011; Nataraj, et al., 2012). The visual biofeedback information were usually shown on a large screen (Alahakone, et al., 2010; M.-Y. Lee, et al., 2007). The auditory biofeedback usually delivered through a headphone. Meanwhile, the electro-tactile and vibrotactile feedbacks were usually provided through electrical and vibrating stimulators directly to the surface of skin, except one study adopted surgically implanted stimulators at user's bilateral muscle groups of the trunk and lower limb (Nataraj, et al., 2012). Head and trunk tilts in mediolateral and anterolateral directions during standing were considered in the setting of these devices.

Table 2-3 Device characteristics (n=11).

Study	Type of sensors	Location of sensors	Type of biofeedback	Function of device
(Franco, et al., 2013)	-Accelerometer -Magnetometer -Gyroscope of a smartphone	Posterior side of L5	Auditory	Monitor the trunk angular evolution during bipedal stance and improve user's balance through auditory biofeedback by earphone
(Grewal, et al., 2013)	-Accelerometer -Magnetometer -Gyroscope	Shank, thigh and lower back	Visual	Monitor the sway of COM, hip and ankle in the mediolateral and anteroposterior directions
(Nanhoe-Mahabier, et al., 2012)	-Angular velocity sensors	Lower back at level L1-L3	Vibrotactile	Deliver vibrotactile feedback of trunk sway to head
(Nataraj, et al., 2012)	-Accelerometer	Pelvis and torso	Electrotactile	-Estimate COM acceleration using inputs from body-mounted accelerometer measurements. -Deliver stimulation via surgically implanted intramuscular electrodes to bilateral muscle groups of trunk and lower limb
(Sungkarat, et al., 2011)	Plantar force sensors	Heel of the paretic foot	Auditory	-Rehabilitation and gait training based on footswitch and the amount of weight bearing at the paretic limb
(Alahakone, et al., 2010)	-Accelerometer -Gyroscope -Temperature sensor	Lower back	Vibrotactile & Visual	-Measure the ML trunk tilt angles -Custom-developed software for data processing, data display and feedback generation
(Janssen, et al., 2010)	-Accelerometer	Head or upper trunk	Vibrotactile	-Detect head or body tilt -Deliver vibrotactile biofeedback to the waist.
(Giansanti, et al., 2009)	-Accelerometer -Gyroscope	Body center of mass (COM).	Auditory	Assess the trunk sway and provide biofeedback information
(M.-Y. Lee, et al., 2007)	Plantar force sensors	Heel and the 3rd MT head of the prosthetic foot	Visual-auditory	-Detect heel strike and toe off. -Provide visual-auditory biofeedback on a screen
(Chiari, et al., 2005)	-Accelerometer	Trunk	Auditory	-Measure the linear accelerations of the trunk in anteroposterior and mediolateral directions -Provide audio-biofeedback via headphones
(Wall III, et al., 2001)	-Accelerometer -Gyroscope	Head	Vibrotactile	Measure lateral head tilt and mount vibrotactile elements on the body to display head tilt

2.6.3.4 Assessment of balance performance

The outcome measures of balance performance incorporated in these studies varied with respect to the assessment specificity (Table 2-4). Of all the eleven studies that were reviewed, nine assessed the static balance only (Alahakone, et al., 2010; Chiari, et al., 2005; Franco, et al., 2013; Giansanti, et al., 2009; Grewal, et al., 2013; Janssen, et al., 2010; Nanhoe-Mahabier, et al., 2012; Nataraj, et al., 2012; Wall III, et al., 2001), two assessed both static and dynamic balance (M.-Y. Lee, et al., 2007; Sungkarat, et al., 2011), and none of them assessed the dynamic balance during walking only. Most studies evaluated the immediate effects of these devices by comparing the balance ability between pre- and post- interventions. Only one study assessed the long-term effect of the devices, which allowed and instructed the users to use the devices for three weeks (Sungkarat, et al., 2011). Some of the studies recruiting healthy subjects required the subjects to stand with their eyes closed on a perturbation floor (Franco, et al., 2013; Giansanti, et al., 2009; Mulavara, et al., 2011; Wall III, et al., 2001), or a soft foam surface (Mulavara, et al., 2011) to make the maintenance of balance more challenging.

Both instrumented and non-instrumented tests were used for balance evaluation. These studies used device-contained wearable sensors only (Franco, et al., 2013; Giansanti, et al., 2009; Nanhoe-Mahabier, et al., 2012), external assessing devices (e.g., force platform, motion capture system) only (Chiari, et al., 2005; Janssen, et al., 2010; M.-Y. Lee, et al., 2007; Nataraj, et al., 2012; Sungkarat, et al., 2011), or both of them to evaluate balance performance (Alahakone, et al., 2010; Wall III, et al., 2001). Of the studies incorporating instrumented tests, four assessed postural stability during standing using a floor-mounted force platform (Chiari, et al., 2005; Janssen, et al., 2010; Mulavara, et al., 2011; Wall III, et al., 2001), three assessed postural control during standing and/or walking using a motion capture system (M.-Y. Lee, et al., 2007; Nataraj, et al., 2012; Sungkarat, et al., 2011), and six assessed static and dynamic postural sway using the self-contained inertial motions sensors or force sensors in the fabricated biofeedback systems (Alahakone, et al., 2010; Franco, et al., 2013; Giansanti, et al., 2009; Mulavara, et al., 2011; Nanhoe-Mahabier, et al., 2012). Of the studies incorporating non-instrumented tests, questionnaires and clinical tests, such as Berg Balance Scale and Timed Up and Go test, were used (Sungkarat, et al., 2011). Generally, the non-instrumented tests were used as a secondary assessment of balance, in addition to the instrumented tests (Sungkarat, et al., 2011).

Table 2-4 Study outcome characteristics (n=11).

Study	Assessment point	Outcome measures	Measurement tool	Results	Balance improvement
(Franco, et al., 2013)	1) Pre-test 2) Post-test	-Postural stability during standing	-Inertial motion sensors	Improved postural balance in the medial-lateral direction.	Yes, static balance
(Grewal, et al., 2013)	1) Pre-test 2) Post-test	-Postural stability during standing	-Inertial motion sensors	- Significant reduction of COM sway after training. - Significant improvement in postural coordination between the ankle and hip joints.	Yes, static balance
(Nanhoe-Mahabier, et al., 2012)	1) Pre-test 2) Post-test	-Postural stability during standing	-Angular velocity sensors	Significantly greater reduction in ML and AP postural sway in the feedback group subjects.	Yes, static balance
(Nataraj, et al., 2012)	1) Pre-test 2) Post-test	-Postural stability during standing	Motion capture system using reflective markers	Controlled stimulations based on the COM acceleration improved standing performance more and reduced the upper limb loading required to resist internal postural disturbances.	Yes, static balance
(Sungkarat, et al., 2011)	1) Pre-test 2) 3 weeks (60mins×5 days/week)	Single support time asymmetry ratio, and amount of load at paretic leg	-Motion capture system -Clinical tests: BBS, TUG	The experimental group demonstrated significant increase in weight-bearing symmetry compared with the control group.	Yes, static and dynamic balance
(Alahakone, et al., 2010)	1) Pre-test 2) Post-test	ML trunk sway during tandem Romberg standing tests	-Inertial motion sensors -Web camera for sighted tests	- Feedback was triggered 100% of the time when trunk tilt exceeded the defined threshold. - Significant reduction in trunk tilt angle.	Yes, static balance
(Janssen, et al., 2010)	1) Pre-test 2) Post-test	Body sway during standing (COP)	-Force plate	- No significant change in body sway path was observed using biofeedback in six subjects. - In four patients, body sway path decreased significantly using biofeedback and sensor on the head in all three activation modes, whereas with sensor on the trunk only one patient showed a significant improvement in sway path in all three activation modes. -However, the improvement with true biofeedback was only observed in those subjects where an improvement was present in placebo mode as well.	Partially yes, static balance
(Giansanti, et al., 2009)	1) Pre-test 2) Post-test	Changes in angular sway and kinetic energy variables	-Inertial motion sensors	Significantly reduced pitch, roll and angular velocity with eyes open/closed while standing on a foam surface.	Yes, static balance
(M.-Y. Lee, et al., 2007)	1) Pre-test 2) Post-test	Treadmill ambulatory gait performance	-Motion capture system	Improved gait performance with visual-auditory biofeedback of heel contact and push-off.	Yes, dynamic balance
(Chiari, et al., 2005)	1) Pre-test 2) Post-test	-Postural stability during standing	-Force plate	Improved balance upon using the audio-biofeedback system and this improvement was greater when the subject's balance was challenged by absent or unreliable sensory cues.	Yes, static balance
(Wall III, et al., 2001)	1) Pre-test 2) Post-test	-Lateral head sway -Postural stability during standing	-Inertial motion sensors -Force plate	Reduced lateral postural sway upon using the head tilt information.	Yes, static balance

2.6.3.5 Summarization on the effectiveness of the devices

Except one study reporting only 4 out of 10 subjects showed balance improvements upon using the biofeedback system integrated with inertial motion sensors (Janssen, et al., 2010), all the remaining ten studies concluded that providing biofeedback information based on the measurements of wearable sensors significantly enhanced either static or dynamic balance, or both of them immediately or in longer follow-up time period (Table 2-4). An overview of the effectiveness of the biofeedback devices on static and dynamic balance is summarized in Figure 2-7. There is a general trend that biofeedback systems with inertial motion sensors were able to enhance static balance, while those with plantar force sensors were able to enhance dynamic balance (Figure 2-7).

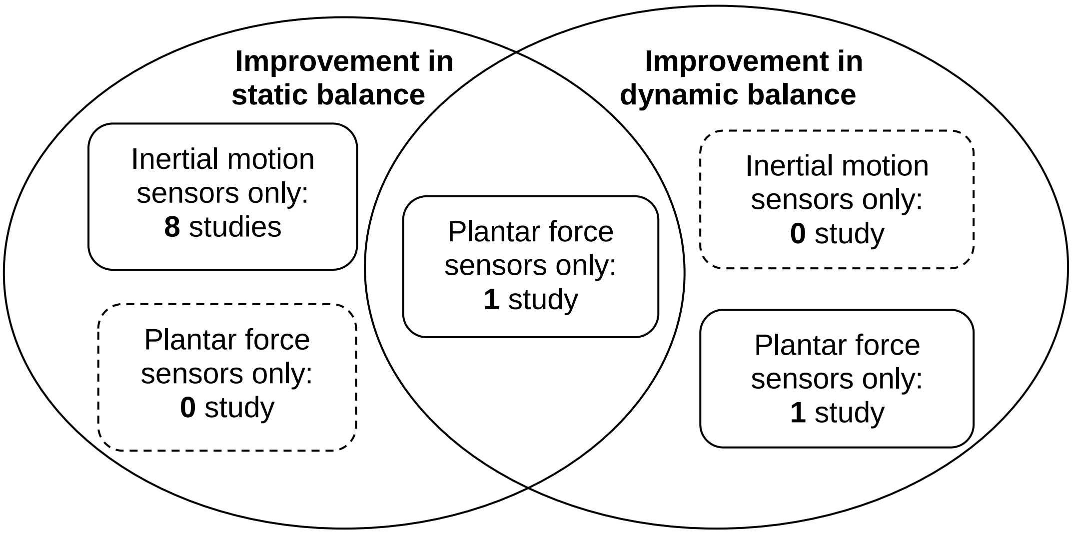


Figure 2-7 Overview of effectiveness of the devices and type of sensors

The detailed design features of previous biofeedback systems are summarized as follows, in an attempt to facilitate a better understanding and broader knowledge about the previous efforts of balance improvements upon using biofeedback systems, and shed new lights on future studies.

Effect of biofeedback systems with inertial motion sensors on static balance

Wall III et al. (2001) developed a prototype that measured the lateral head tilt using one gyroscope and one linear accelerometer (Wall III, et al., 2001) (Figure 2-8). The accelerometer and gyroscope were attached to the left side of head, with their sensitive axes parallel to the user's naso-occipital and intra-aural axes, respectively. Two vibrators were attached to the lateral trunk. The vibrators were activated in response to the head tilt, with a vibrational frequency of 250 Hz. A larger angle of head lateral tilt led to larger magnitude of vibration. No vibration would be generated if the angle of lateral head tilt was less than a threshold value of 0.5 °. Healthy young subjects were recruited in this study. With the use of the device, their overall lateral postural sway was reduced during standing. The dimension of the entire instrument was 6.6×1.8×4.4 cm^3.

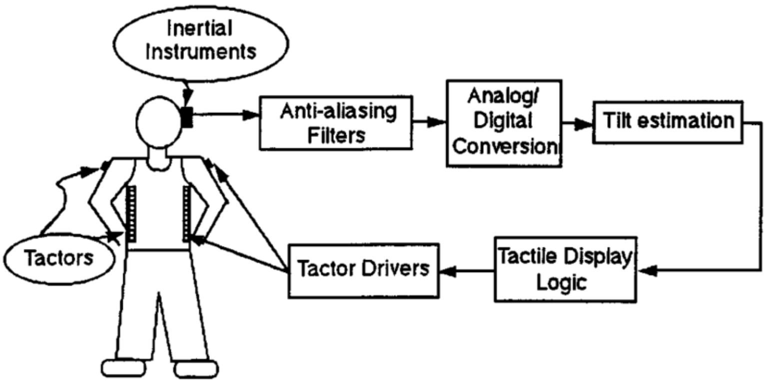


Figure 2-8 Diagram of prototype balance prosthesis with head-mounted sensors (adapted from (Wall III, et al., 2001)).

Chiari et al. (2005) developed an audio-biofeedback system with two linear uni-axial accelerometers (Chiari, et al., 2005). The whole prototype weighed about 100 grams. The micromechanical instruments were packaged into a 7.5×7.5×3.5 cm^3 electronic module. The accelerometers measured the linear accelerations of trunk in anteroposterior and mediolateral directions. Auditory biofeedback reminding of the trunk sway was delivered via a pair of headphones. If the user's postural sway exceeded an allowable threshold during standing, various sound levels of auditory feedback, ranging from 5mV rms to 50mV rms, that corresponded to the degrees of pitch and roll would be provided via the headphones. Healthy young and older subjects were recruited in this study. Their COP movements during quiet standing were reduced upon using the biofeedback system.

Giansanti et al. (2009) presented an audio-biofeedback system with three uni-axial accelerometers and three uni-axial gyroscopes (Giansanti, et al., 2009) (Figure 2-9). The inertial motion sensors were placed at the level of COM at posterior lower back to measure the 3D linear and angular trunk kinematics. A laptop recorded and processed the motion signals and delivered the auditory feedback to a pair of headphones. Continuous auditory spatial clues about the anteroposterior and lateral trunk movements were provided to the users. The right and left output channels of the headphones were modulated independently. Forward body movements increased the frequency, while backward movements decreased the frequency of the sound pitch. At the same time, the mediolateral movements were recognized by the balance between left and right audio channels: i.e. lateral movements produced a volume increase in the contralateral channel. An inverted pendulum model was adopted to define a subject-specific reference region, which formed by a ±1° vertical projection of the COM from the natural upright posture (Mayagoitia, et al., 2002). The values obtained from the model were directly used to set the threshold of anterior movement threshold, and were multiplied by 2/3 to set the thresholds of posterior and lateral movements (Giansanti, et al., 2009). Healthy young and older subjects participated in this study, and revealed significantly reduced postural sway with eyes open and closed while standing on a soft foam surface upon using the device.

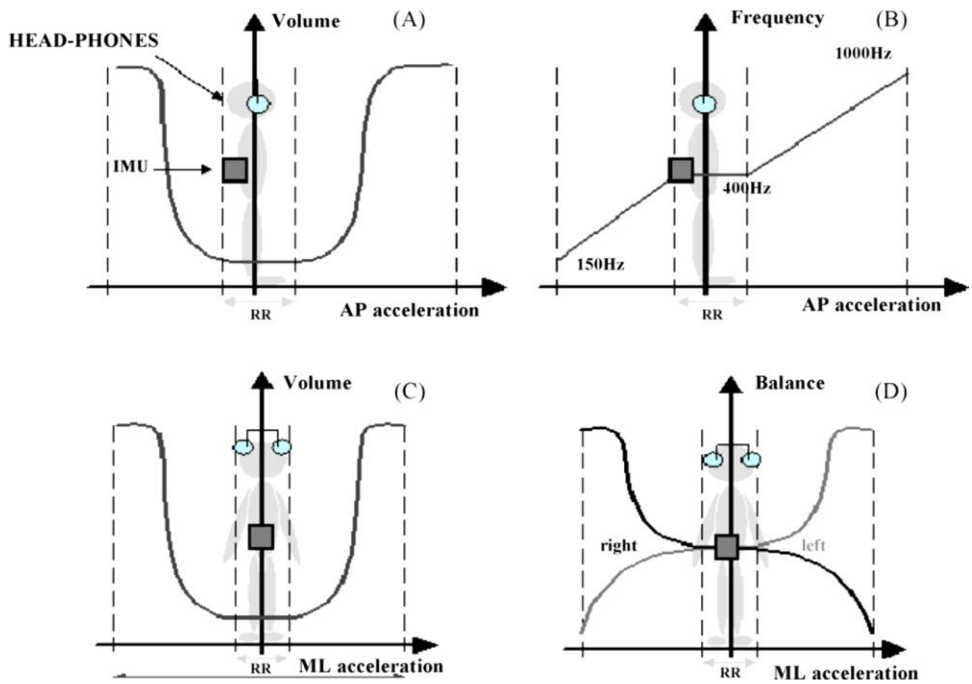


Figure 2-9 Volume and frequency modulation functions based on AP movements (A and B). Volume and stereo balance modulation functions based on ML movements (C and D) (adapted from (Giansanti, et al., 2009)).

Janssen et al. (2010) developed a vibrotactile biofeedback system with three uni-axial linear accelerometers orthogonal to each other (Janssen, et al., 2010) (Figure 2-10). A total of 12 actuators were equally distributed on an elastic band that fastened at subject's waist to deliver vibrotactile biofeedback. When the body's tilt angle exceeded 2° relatively to a subject-specific reference vector, the corresponding actuator would be activated and would not be deactivated until the magnitude of tilting angle decreased within 1.5°. The battery pack and processor unit weighed 330g and 240g, respectively. Patients with severe bilateral vestibular loss were recruited in this study. However, only 4 out of 10 subjects revealed reduced postural sway during standing upon using the device, while the rest of them did not reveal any improvements of standing balance.

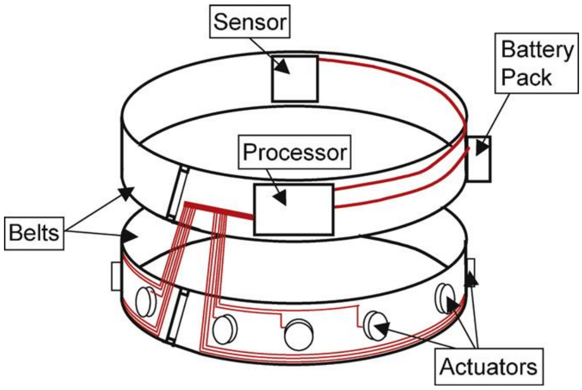


Figure 2-10 Schematic overview of the ambulatory vibrotactile biofeedback (AVBF) system (adapted from (Janssen, et al., 2010)).

Alahakone et al. (2010) developed a vibrotactile biofeedback system with a tri-axial accelerometer, a tri-axial gyroscope, a temperature sensor, and an on-board processor with sensor-fused algorithms (Alahakone, et al., 2010) (Figure 2-11). The unit measured the linear acceleration, velocity, Euler angles, and angular velocities of the trunk. The resolution of the sensor was 0.1°, and the sensor package supported a full 360° measurement of the orientation range over all axes. Two vibrators were mounted at the left and right sides of trunk to provide clues of the lateral postural sway, and were activated once the postural sway exceeded a threshold of 2° postural pitch/roll. The magnitude of vibration was proportional to the magnitude of postural pitch and roll: 1) low vibration corresponded to the postural sway between 2° and 7°, 2) moderate vibration corresponded to the postural sway between 7° and 12°, and 3) high vibration corresponded to the postural sway beyond 12°. Additionally, two visual indicators of the vibrators were also shown on a display, with darker colors representing larger magnitudes of vibrations. Healthy young subjects participated in this study. They revealed significant reduction of trunk tilting angle upon using the biofeedback system during standing.

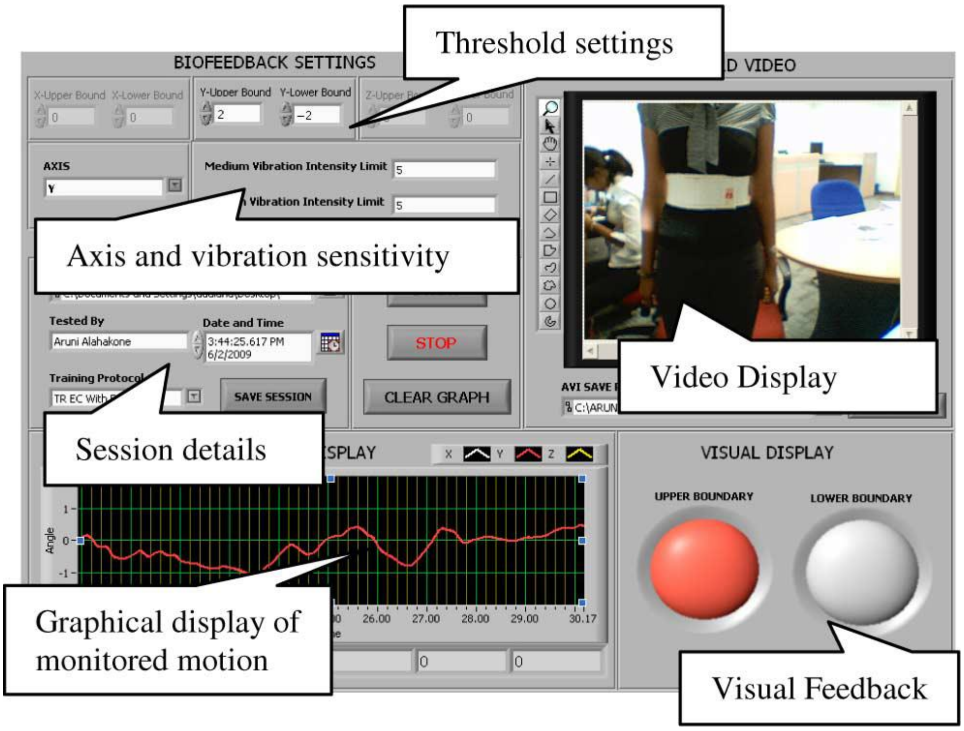


Figure 2-11 Software tools for therapeutic monitoring (adapted from (Alahakone, et al., 2010)).

Nataraj et al. (2012) developed an electrotactile biofeedback system based on the 3D acceleration analysis of COM (Nataraj, et al., 2012) (Figure 2-12). Two tri-axial accelerometers were used to estimate the COM movement: one was put at the anterior midpoint of anterior superior iliac spines (ASIS); and the other at a point on posterior torso between the sacrum and right shoulder which was 40% closer to the right shoulder. The accelerometers were calibrated at each anatomical landmark to remove the effect of gravitational acceleration. Intramuscular electrodes were surgically implanted to the user's bilateral muscle groups of the lower limb. Ground electrodes were placed at the skin of abdomen, kneecap, and ASIS. The maximum COM acceleration during quiet standing was firstly captured by the accelerometers, which was then multiplied by 15% to set the threshold of allowable anteroposterior and lateral postural sway. The subject's standing balance performance was evaluated by measuring the weight-bearing of upper-limb using force sensors at the left and right handrails. Reduced upper-limb weight-bearing indicated improved standing balance. During the assessment, balance perturbation was provided by requiring the patient to move an object over a level surface using the non-dominant hand. Electrical stimulations were provided to subject through the surface and surgically implanted electrodes during balance perturbation. One patient with thoracic-4 level complete paraplegia participated in the study. Significantly reduced upper-limb weight-bearing was found with this device, which indicated improved balance performance.

Figure 2-12 Subject with spinal cord injury undergoing internal perturbations by volitionally moving object over level surface with one arm while stabilizing with the other arm. (adapted from (Nataraj, et al., 2012)).

Nanhoe-Mahabier et al. (2012) developed a vibrotactile biofeedback system integrated with two gyroscopes (Nanhoe-Mahabier, et al., 2012) (Figure 2-13). The gyroscopes were put at the lower back and at the level of L1-L3 to measure the mediolateral (roll) and anteroposterior (pitch) movements of the trunk. A total of 8 vibrators were equally distributed at head. A 90% range of the peak-to-peak pitch and roll values was determined by excluding the extreme 5% of the measured values, and was then multiplied by 40% to set the thresholds for allowable body pitch and roll movements. Once the subject’s body movements exceeded this threshold, a continuous vibration with consistent magnitude and a frequency of 250Hz would be provided. Patients with Parkinson's disease were recruited in this study. Upon using the device, subjects revealed significant reduction of anteroposterior and mediolateral postural sways during quiet standing.

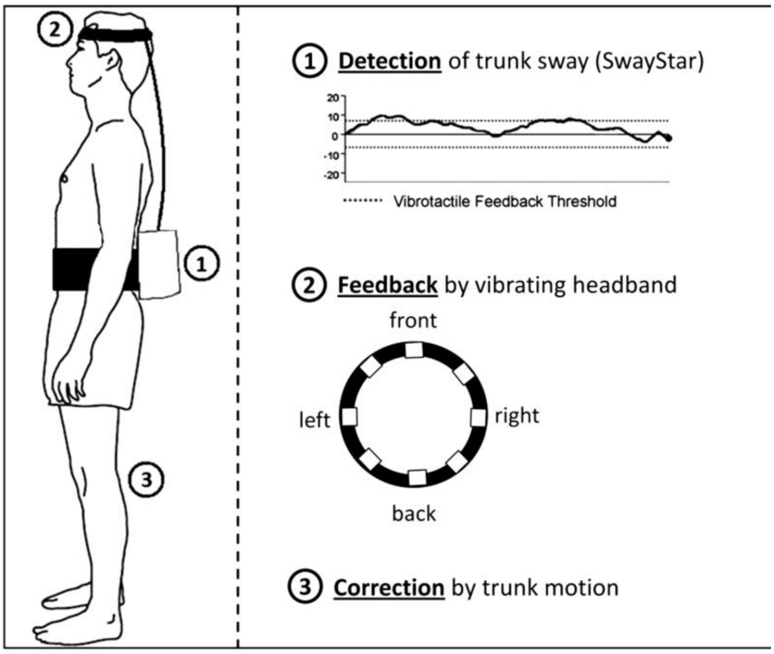


Figure 2-13 Schematic illustration of the SwayStar and biofeedback system. (adapted from (Nanhoe-Mahabier, et al., 2012)).

Franco et al. (2013) developed a smartphone-based auditory biofeedback system with a tri-axial accelerometer, a tri-axial gyroscope, and a tri-axial magnetometer that equipped in a smartphone (Franco, et al., 2013). The smartphone was mounted at the low back and at the level of L5 to measure the lateral postural sway, with auditory biofeedback delivered through a pair of earphones. A threshold of 1° of the trunk tilting was determined as the allowable trunk movement during standing. Once the body sway to the left or right side exceeded the threshold, auditory feedback would be delivered to the corresponding left or right earphones. Healthy young adults were recruited in this study. They were found to have reduced lateral postural sway during standing with this device been in use.

Grewal et al. (2013) developed a visual biofeedback system based on the tri-axial accelerometers, gyroscopes, and magnetometers (Grewal, et al., 2013) (Figure 2-14). The inertial motion sensors were placed at the shank, thigh and lower back of the subject. The control of coordination of the lower limbs were trained by a point-to-point ankle reaching task, with visual biofeedback provided by a laptop screen putting in front of the subjects. Visual feedback of the joint locations was displayed as a simple lower limb stick model on a screen to help visualize the error of joint motion during the training. Patients with diabetic peripheral neuropathy were recruited in this study. They were found to have less postural sway and improved coordination between ankle and hip joints while standing with this device turned-on.

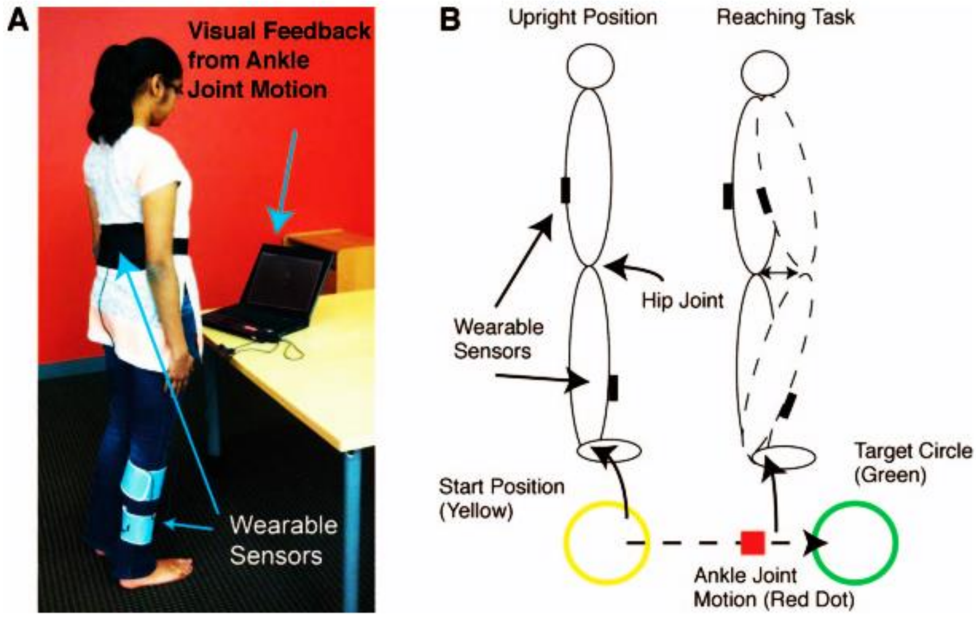


Figure 2-14 An illustration of sensor-based exercise training including an ankle-reaching task and a visual biofeedback of ankle motion. (adapted from (Grewal, et al., 2013)).

Effect of biofeedback systems with inertial motion sensors on dynamic balance

None of the involved studies have attempted to enhance dynamic balance with inertial motion sensors.

Effect of biofeedback systems with plantar force sensors on static balance

None of the involved study aimed to enhance static balance with plantar force sensors.

Effect of biofeedback systems with plantar force sensors on dynamic balance

Lee et al. (2007) developed a biofeedback system providing visual-auditory feedback based on the measurement of plantar force sensors (M.-Y. Lee, et al., 2007) (Figure 2-15). Two force sensors were put at the heel and forefoot of a prosthetic foot to detect gait phases of heel-strike and toe-off during walking. The visual-auditory feedback provided amputees with clues about the correct occurrence of heel strike and toe-off. Auditory biofeedback was provided via two loudspeakers once the detected plantar forces exceeded the subject-specified thresholds, which were determined and adjusted by a physician based on the amputee's plantar pressure distribution pattern. The activation of each loudspeaker corresponded to the measurement of one force sensor. Additional visual biofeedback was also delivered via a screen placed in front of the subjects, which demonstrated the real-time plantar foot pressure distribution, as well as the occurrence of heel-strike and toe-off as detected by the two force sensors. Lower-limb amputees were recruited in this study. They revealed significant reduction of stance time asymmetry during treadmill walking with this device.

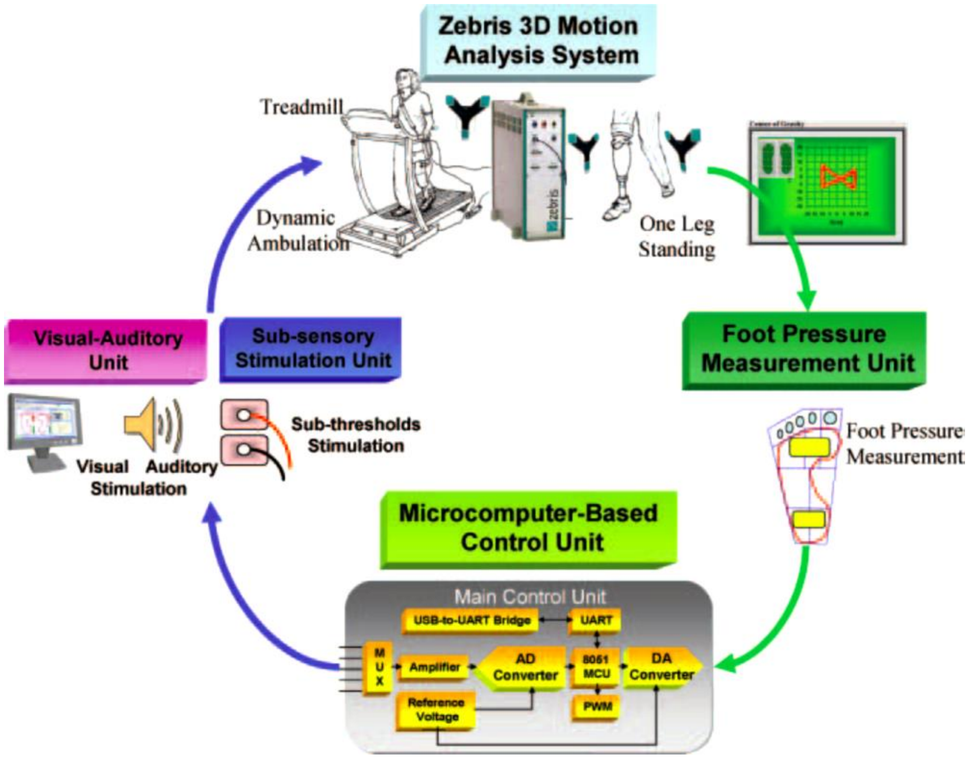


Figure 2-15 System architecture of the proposed sensory compensation biofeedback system (adapted from (M.-Y. Lee, et al., 2007)).

Sungkarat et al. (2011) developed an auditory biofeedback system with a force sensor embedded in the heel of the insole at the paretic side, and a foot switch attached to the non-paretic side of patients with stroke (Sungkarat, et al., 2011) (Figure 2-16). Auditory feedback corresponding to the amount of weight bearing at the paretic side during stance training (detected by the plantar force sensor), and the stance time of non-paretic side during gait training (detected by the foot switch) were provided. Biofeedback was initiated when the weight bearing of paretic limb during standing, and the swing time of non-paretic limb during walking exceeded the pre-set thresholds, instead of comparing to the condition of contralateral legs. The recruited patients with stroke revealed significant increase of weight-bearing symmetry during standing and walking upon using this device.

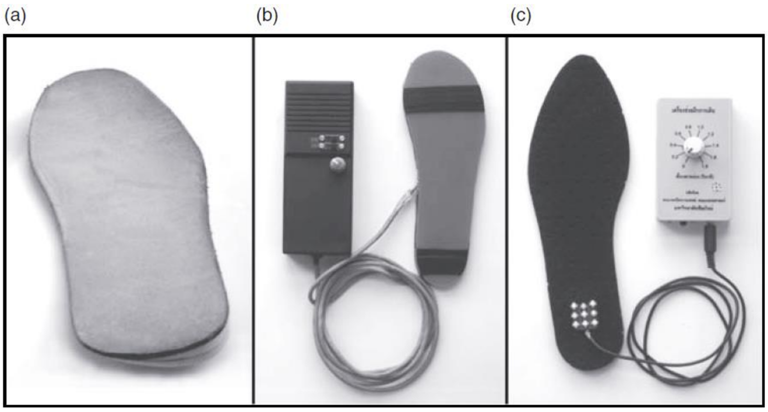


Figure 2-16 Devices used in the insole shoe wedge and sensors (I-ShoWS) set-up. (a) Shoe-wedge; (b) force sensor; and (c) foot switch (adapted from (Sungkarat, et al., 2011)).

2.6.4 Discussion

This review demonstrates the potential of biofeedback systems with wearable sensors on enhancing static and dynamic balance performance in patients and aged population. Furthermore, this review exams the specific design features of biofeedback systems that may impact the efficacy of balance improvement.

2.6.4.1 Effectiveness

Overall, evidence supports the effectiveness of biofeedback systems in enhancing static and dynamic balance among healthy adults and patients with balance disorders. Subjects in these studies included lower limb amputees, patients with stroke, Parkinson’s disease, and healthy young and older adults. Significantly reduced postural sway, weight bearing asymmetry, and gait variability were achieved upon using the biofeedback systems.

2.6.4.2 Wearable sensors

The wearable sensors included in this review could be divided into two categories: 1) inertial motion sensors, including accelerometers, gyroscopes, and magnetometers; and 2) force sensors. Inertial motion sensors attaching to body segments could capture the changes in tilting of head, trunk and limbs, which could be furthered processed to analysis the overall postural stability and joint angles (Sienko, et al., 2013). Force sensors attaching to the plantar surface of foot could capture the ground reaction force, which could be processed to estimate the changes of foot-ground contact information and detect certain gait phases (initiation of movements such as heel contact and toe-off), as well as gait pattern (weight-bearing symmetry) (Sungkarat, et al., 2011). To assess the balance and gait abnormalities, only relying on clinical doctors and therapists' knowledge and experience might not be highly accurate and comprehensive (Byl, et al., 2015; Liu, et al., 2012; Zhang, et al., 2014). It has been recommended that supplementing some computerized devices could assist clinical doctors and therapists with more accurate information of the kinematics and efficiency of movements (Byl, et al., 2015). Further optimizations of the devices included in this review would provide opportunities to achieve this extensively in the near future.

Inertial motion sensors were mainly used to capture the tilting of body segments, which could be used to reflect the overall postural stability. Some studies put inertial motion sensors at the lower back and near the location of center of mass (COM) to assess postural sway (Alahakone, et al., 2010; Franco, et al., 2013; Giansanti, et al., 2009; Nataraj, et al., 2012); at the lower back, thigh, and shank in an attempt to estimate the sway of COM and joint angles (Grewal, et al., 2013); and at the head and trunk to measure the stability of head and torso (Chiari, et al., 2005; Janssen, et al., 2010; Mulavara, et al., 2011; Wall III, et al., 2001). Most studies developed new devices consisted of various inertial motion sensor modalities (Grewal, et al., 2013; Nanhoe-Mahabier, et al., 2012), while some other studies used the smartphones equipping with inertial motion sensors directly (Franco, et al., 2013).

Although the inertial motion sensors could do the angular measurements accurately, however, it is hard for them to measure the kinematics of movement, especially the movement initiation. These problems could be eased by force sensors putting at the plantar surface of foot to supplement/enhance the proprioception. Plantar force sensors attaching to the bottom surface of foot could measure the ground reaction force, which can be processed to estimate the weight bearing asymmetry between left and right lower limbs (Sungkarat, et al., 2011), as well as to detect the gait phases, such as heel strike and toe-off (M.-Y. Lee, et al., 2007). Previous studies have attempted to put only one sensor at heel to the evaluate weight bearing symmetry (Sungkarat, et al., 2011), and put two force sensors at heel and forefoot to detect the gait phase transitions of heel-strike and toe-off (M.-Y. Lee, et al., 2007). These strategies are helpful to improve balance by compensating the absent or declined plantar pressure sensation in amputees (M.-Y. Lee, et al., 2007) and patients with neurological problems (Sungkarat, et al., 2011). With the current state-of-the-art technology, some thin-film force sensors could be inserted into insoles or shoes to develop some smart shoes. This kind of design could allow the users to use the biofeedback system anytime at anywhere. With larger number of force sensors been used, it would also be more feasible to measure the trajectory of center of pressure (Putti, et al., 2007; Ramanathan, et al., 2010), which is an important indicator of balance performance and risk of falls (Hernandez, et al., 2012; Moghadam, et al., 2011).

2.6.4.3 Biofeedback information

Considering wearable sensors could monitor the body motion accurately and reliably, some additional real-time biofeedback could be provided. So far, single and multiple biofeedback modalities have been provided, including visual (Alahakone, et al., 2010; M.-Y. Lee, et al., 2007), auditory (Chiari, et al., 2005; Franco, et al., 2013; Giansanti, et al., 2009; Sungkarat, et al., 2011), vibrotactile (Alahakone, et al., 2010; Janssen, et al., 2010; Nanhoe-Mahabier, et al., 2012; Wall III, et al., 2001), and electrotactile (M.-Y. Lee, et al., 2007; Mulavara, et al., 2011; Nataraj, et al., 2012). Comparing with visual feedback shown on a large screen (Alahakone, et al., 2010; M.-Y. Lee, et al., 2007), the visual feedback shown on a smaller display and the auditory biofeedback delivered through a pair of earphones make the devices more portable. The electrotactile and vibrotactile feedback further improve this design by providing electrotactile or vibrotactile stimulations to the surface of skin. It has been suggested that the tactile feedback does not hinder daily tasks of speaking, eating, seeing and hearing, since the tactile stimulation is received at user's skin (Janssen, et al., 2010; Wall III, 2010). With the non-invasive stimulations and easy-to-operate device settings, the user's acceptance of these devices has been suggested to be excellent, which implies that such biofeedback devices could potentially be used as balance and gait control aids in the near future (Crea, et al., 2015; Leardini, et al., 2014).

2.6.5 Summary

A synthesis of research examining the effect of biofeedback systems on static and dynamic balance performance based on body motion information measured by wearable sensors suggests that most of these devices are effective. Inertial motion sensors were mainly used to capture the body motion in static conditions, while plantar force sensors allowed the assessment of weight-bearing asymmetry in static conditions and temporal gait variability in dynamic conditions. A variety of feedback were delivered to the users, including visual, auditory, vibrotactile and electro-tactile. The design of these devices could be further optimized by applying some state-of-the-art technologies to make the devices more lightweight, with more powerful processing capacities, smaller size, and higher usability. Some smart products could be integrated and connected with wearable sensors wirelessly to compute body balance and provide various biofeedback information. These devices have a good potential to be used as laboratory- and home-based rehabilitation training devices, as well as balance aids in daily life. Numerous various populations could be benefit from these devices in the future. To achieve these goals, further optimizations of such devices are required.

2.7 Review of the effect of insoles on balance

2.7.1 Introduction

Foot supports the whole-body weight and is an important contact surface of human body to the ground. The sensation at plantar surface of foot is important to maintain balance control. Insoles and footwear are important interface between the feet and ground. Footwear with different properties have been developed with the associated effects been investigated, in an attempt to find the optimized design for enhancing balance, and ultimately reduce falls. Insole is an important design element of footwear. The effects of insoles on standing/static (Corbin, et al., 2007; Hijmans, et al., 2008b; Hijmans, et al., 2007; Palluel, et al., 2008; Palluel, et al., 2009; AA Priplata, et al., 2003; Takata, et al., 2013; Van Geffen, et al., 2007; C.-C. Wang & Yang, 2012) and walking/dynamic (Hartmann, et al., 2010; Anna L Hatton, et al., 2012; Stephen, et al., 2012) balance have been attracting increasing attention these years. These insoles could be categorized as vibrating insoles, textured insoles, and orthopaedic insoles.

Vibrating insoles worked by sending some mechanical noise signals to the plantar foot surface (Figure 2-17 and Figure 2-18). The piezoelectric actuators (vibrators) were inserted into a piece of flat insole using standard manufacturing process. These actuators can be driven by electrical circuit and supplied by a battery. Such vibrating insoles can propagate vibrating signals to the plantar foot surface and enhance sensory inputs through the vibrators. Certain levels of random mechanical interference (or the so-called ‘noise’) can enhance the detection and transmission of weak signals via a phenomenon called stochastic resonance (SR), which results from the concurrence of a threshold, a subthreshold stimulus, and noise (Attila Priplata, et al., 2002). Declined cutaneous plantar sensory sensitivity and proprioception leaded to increased sensory threshold and lots of undetected sub-threshold information at plantar foot (AA Priplata, et al., 2003). With the combination of the original weak input signals and additional noise signal provided by vibrating insoles, an increase of signals would occur, in which condition the signals can across the sensory threshold. The threshold-crossed sensory signals can then serve to generate appropriate motor function outputs for balance control (Figure 2-18) (Galica, et al., 2009; AA Priplata, et al., 2003; Attila Priplata, et al., 2002; A. A. Priplata, et al., 2006). Previous literatures have shown that the imperceptible vibratory noise applied to the feet can improve balance in young and older adults (AA Priplata, et al., 2003), and patients with diabetic neuropathy and stroke (Sejdić & Lipsitz, 2013). It has also shown that this approach can significantly reduce the variability of stride, stance, and swing time during walking in recurrent elderly fallers (Galica, et al., 2009).

Textured insoles attached some flexible or rigid components such as small cylinders to flat insoles. It has been suggested that these insoles could enhance sensory input via the enhanced tactile stimulation of plantar cutaneous mechanoreceptors (Anna Lucy Hatton, et al., 2011), and thus enhance postural balance in short-term time period (Qiu, et al., 2013). Some studies also reported that adhering a flexible plastic tube with a diameter of 3 mm (referred as a “ridge”) to the margin of insoles can enhance balance (Maki, et al., 2011; S. D. Perry, et al., 2008) (Figure 2-19). It has been suggested that this “ridge” design can remind users of the condition whenever the COM reached the limits of base of support, which could improve balance performance (Maki, et al., 2011; S. D. Perry, et al., 2008).

Orthopaedic insoles with arch supports, metatarsal pads and heel cups are commonly prescribed to correct/compensate foot deformity and relieve pain. Besides pain relief, these design features increased the contact area between the foot and support surface (Committee, 2008). The increased contact area enlarged the base-of-support and provided a larger surface area for sensory input, which may potentially enhance the balance (Gross, et al., 2012). Arch support and heel cup can also facilitate the stabilization of ankle-foot complex (Anna L Hatton, et al., 2013). All these factors provide orthopaedic insoles the potential of balance improvements.

This review included papers investigating the effect of insoles on static and dynamic balance in adults, in an attempt to: (1) review the mechanism of enhancing balance upon the usage of various insoles; (2) summarize the key design concepts of each type of insoles; (3) examine the effectiveness of various insoles in enhancing balance performance; and (4) suggest future potential design features of insoles that could potentially enhance balance in various populations.

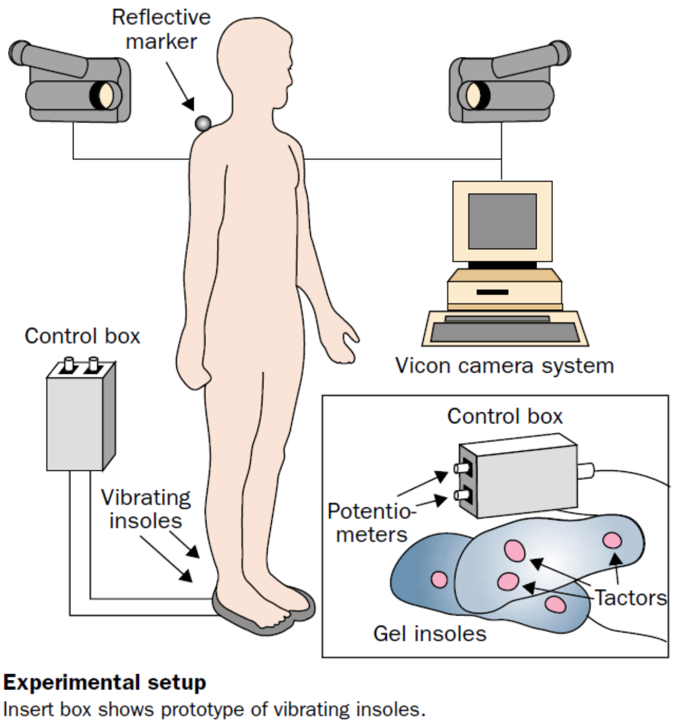


Figure 2-17 Example of the design of vibrating insoles (adapted from (AA Priplata, et al., 2003))

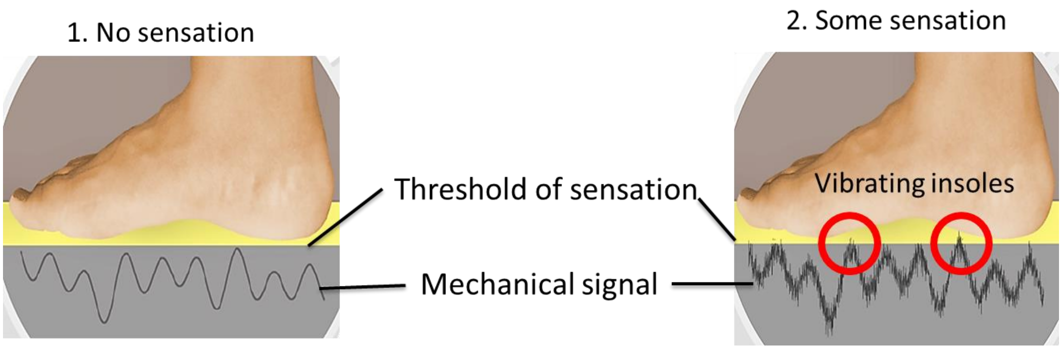


Figure 2-18 Underlysing mechanism of vibrating insoles (adapted from (Harry, et al., 2005))

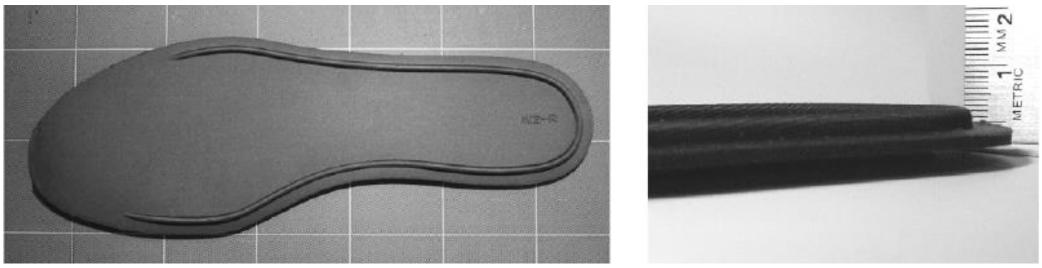


Figure 2-19 Prototype of "Sensor Sore" (adapted from (S. D. Perry, et al., 2008))

2.7.2 Methods

2.7.2.1 Inclusion criteria

Types of participants

This review considered studies that included healthy older adults, and patients with poor balance control, including diabetic neuropathy, strokes, and Parkinson's diseases.

Types of interventions

This review considered studies that evaluated the effect of textured insoles, vibrating insoles, and orthopaedic insoles on static or dynamic balance.

Types of intervention outcomes

This review considered studies that included the following outcome measures relating to balance performance: 1) instrumented/objective measurements, including displacement of center of pressure (COP), center of mass (COM), gait parameters; and 2) non-instrumented/subjective measurements, including clinical tests, questionnaires, and verbal reports.

Types of studies

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

This review also considered descriptive epidemiological study designs including case series, individual case reports and descriptive cross-sectional studies for inclusion.

2.7.2.2 Exclusion criteria

Studies were excluded if they: (1) contained no insole intervention; (2) involved no balance outcome measure; (3) contained study protocol not relating to balance; (4) were review article; (5) were conference papers; (6) provided interventions that were not insoles; and (7) were non-English papers.

2.7.2.3 Searching strategy

The search strategy aimed to find published studies following the guidelines of the standardized critical appraisal instruments, i.e. the Joanna Briggs Institute Meta-Analysis of Statistics Assessment and Review Instrument (JBI-MAStARI). A three-step searching strategy was utilized in this review. An initial limited search of MEDLINE was undertaken followed by analysis of the words contained in the title and abstract, and of the index terms used to describe article to identify the keywords for literature search (Step 1). A second search using all identified keywords were then undertaken across all included databases (Step 2). Thirdly, the reference lists of all identified articles were searched for additional studies (Step 3). Studies published in English and published from 1993 to 2013 were considered for inclusion in this review.

The databases been searched included: Web of Science, MEDLINE, and Google Scholar.

The keywords been used in Step 2 were: insole, foot orthosis/orthoses, shoe insert, balance, static balance, dynamic balance, postural stability, and postural control.

2.7.2.4 Data collection and data synthesis

Qualitative data were extracted from papers and included in this review using the standardized data extraction tool from JBI-MAStARI. The extracted data included specific details about the interventions, populations, study methods, and outcomes of significance to the review question and specific objectives. Quantitative data were not possible to be pooled in statistical meta-analysis due to the various study designs.

Studies were summarized according to the following characteristics: study design; sample size; sample characteristics (age, gender, and fall history); key characteristics of the insoles; follow-up time; static and dynamic balance outcome measures; and balance improvement results. Data synthesis using a meta-analysis was not possible due to the variety of study designs, methodologies, and outcome measures.

2.7.3 Results

A total of nineteen publications met the inclusion criterial and were included in this review.

2.7.3.1 Sample characteristics

As shown in Table 2-5, the subjects recruited in the included studies consisted of healthy young and elderly adults, elderly fallers, patients with diabetic neuropathy, moderate loss of plantar cutaneous sensitivity that unrelated to neuropathy, stroke, and Parkinson' Disease. The sample size ranged from 12 (Simeonov, et al., 2011) to 80 (Jenkins, et al., 2009). Subjects were predominantly males. The inclusion and exclusion criteria regarding the subject's physical and cognitive functioning were different. Most studies required the subjects to be able to walk 10 m without assisting devices and follow the study instructions. The self-reported history of falls was specified in 8 publications, among which, three studies claimed subjects shall have no history of falls (Palluel, et al., 2008; Palluel, et al., 2009; A. A. Priplata, et al., 2006), one study claimed subjects shall experience at least one fall before the experiment (Gross, et al., 2012), and another four studies claimed subjects shall experience at least two falls before the experiment (Galica, et al., 2009; Anna L Hatton, et al., 2012; C.-C. Wang & Yang, 2012; Wei, et al., 2012). The initial balance performance also varied across studies, though most studies recruited subjects with balance disorders (Table 2-5).

2.7.3.2 Type of insoles and balance outcome measurements

Table 2-5 summarizes the types of insoles been developed and investigated in the involved studies. Different insoles have been applied to improve balance, including textured insoles, vibrating insoles, and orthopaedic insoles.

Some studies investigated the effect of hardness of insole materials on balance, including soft, medium, and rigid hardness (Iglesias, et al., 2012; Qiu, et al., 2012; Van Geffen, et al., 2007). Some other studies attached small pyramidal peaks, nubs, spikes, grids or dimples to the upper surface of the insole (Anna L Hatton, et al., 2012; Palluel, et al., 2008; Palluel, et al., 2009; Qiu, et al., 2013; Wilson, et al., 2008). Some researchers also attempted to attach a small tube at the margin of the upper insole surface, which were claimed to be able to remind the users about the relative position of foot to the insole (Jenkins, et al., 2009; S. D. Perry, et al., 2008). Vibrating insoles attached vibrators at the plantar surface of foot. The location of vibrators included the first metatarsal head, the fifth metatarsal head, and the heel (Galica, et al., 2009; Hijmans, et al., 2008b; AA Priplata, et al., 2003; A. A. Priplata, et al., 2006; Simeonov, et al., 2011; Stephen, et al., 2012; C.-C. Wang & Yang, 2012; Wei, et al., 2012). Orthopaedic insoles have also been applied to enhance balance, and the design of which was custom-made insoles (Gross, et al., 2012).

The outcome measures of balance performance adopted in these studies varied with the assessment specificity (Table 2-6). Of all the involved nineteen studies, thirteen assessed static balance only (Hijmans, et al., 2008b; Iglesias, et al., 2012; Palluel, et al., 2008; Palluel, et al., 2009; AA Priplata, et al., 2003; A. A. Priplata, et al., 2006; Qiu, et al., 2012; Qiu, et al., 2013; Simeonov, et al., 2011; Van Geffen, et al., 2007; C.-C. Wang & Yang, 2012; Wei, et al., 2012; Wilson, et al., 2008), four assessed dynamic balance only (Galica, et al., 2009; Jenkins, et al., 2009; S. D. Perry, et al., 2008; Stephen, et al., 2012), and the remaining two assessed both static and dynamic balance (Gross, et al., 2012; Anna L Hatton, et al., 2012). Most studies evaluated the immediate effect of insoles on balance by comparing the balance performance pre- and post- interventions. Only three of them evaluated the long-term effect, and the intervention time lasted from 1 day to 12 weeks (Gross, et al., 2012; S. D. Perry, et al., 2008; Wilson, et al., 2008).

Both instrumented and non-instrumented tests were used for balance assessment. Of the studies incorporating instrumented tests, eleven assessed postural stability during standing using a force plate (Anna L Hatton, et al., 2012; Hijmans, et al., 2008b; Iglesias, et al., 2012; Palluel, et al., 2008; Palluel, et al., 2009; Qiu, et al., 2012; Qiu, et al., 2013; Van Geffen, et al., 2007; C.-C. Wang & Yang, 2012; Wei, et al., 2012; Wilson, et al., 2008), three assessed postural balance during standing using a motion capture system (AA Priplata, et al., 2003; A. A. Priplata, et al., 2006; Simeonov, et al., 2011), two assessed dynamic balance during walking using in-shoe plantar pressure measurement insoles (Galica, et al., 2009; Stephen, et al., 2012), and four assessed dynamic balance during walking using motion capture systems (Anna L Hatton, et al., 2012; Jenkins, et al., 2009; S. D. Perry, et al., 2008; Stephen, et al., 2012). Of the studies incorporated non-instrumented tests, questionnaires and clinical tests, such as Time Up and Go (TUG) test, 1-leg stance, tandem stance, tandem gait, and alternating step test, were used (Gross, et al., 2012). Generally, the clinical tests were used as a secondary assessment of balance, except one study adopted the clinical test only to assess both static and dynamic balance (Gross, et al., 2012).

Table 2-5 Study characteristics (n=19)

Author Year	Subjects	Sample size (EG/CG)	Mean age (years)	Fall history	Intervention	Follow-up
(Qiu, et al., 2013)	-Healthy elderly -PD patients	20/20	69/69	Not specified	1) Barefoot 2) Smooth insoles 3) Textured insoles	Immediate effect
(Wei, et al., 2012)	-Healthy young -Healthy elderly	14/26	22/59	≥2 falls a year	-Vibrating insoles	Immediate effect
(C.-C. Wang & Yang, 2012)	-Healthy young -Elderly fallers	16/26	25/83	Faller	-Vibrating insoles	Immediate effect
(Stephen, et al., 2012)	Healthy elderly	29	72	Not specified	-Vibrating insoles	Immediate effect
(Qiu, et al., 2012)	-Healthy young -Healthy elderly	10/7	27/72	Not specified	1) Barefoot 2) Soft textured insoles 3) Rigid textured insoles	Immediate effect
(Iglesias, et al., 2012)	Healthy elderly	22	85	Not specified	1) Barefoot 2) Soft textured insoles 3) Rigid textured insoles	Immediate effect
(Anna L Hatton, et al., 2012)	Elderly fallers	30	79	≥2 falls previously	1) Smooth insoles 2) Textured insoles	Immediate effect
(Gross, et al., 2012)	Elderly fallers	13	81	≥1 falls previously	-Custom foot-orthosis	- Immediate effect -2 weeks
(Simeonov, et al., 2011)	-Elderly construction workers -Young construction workers	6/6	27/51	Not specified	-Vibrating insoles	Immediate effect
(Palluel, et al., 2009)	-Healthy young -Healthy elderly	17/10	24/69	No	-Spike insoles	Immediate effect
(Jenkins, et al., 2009)	-PD patients -Age-matched controls	40/40	65/65	Not specified	1) Textured insole 2) Conventional flat insole	Immediate effect
(Galica, et al., 2009)	-Healthy young -Healthy elderly -Elderly fallers	12/18/18	26/77/78	≥2 falls previously	-Vibrating insoles	Immediate effect
(Wilson, et al., 2008)	-Healthy female	10/10/10/10	51	Not specified	1) Control 2) Grid insoles 3) Dimple insoles 4) Plain insoles	-Immediate effect -4 weeks
(S. D. Perry, et al., 2008)	-Elderly with moderate loss of plantar cutaneous sensitivity (unrelated to peripheral neuropathy)	20/20	70/69	Not specified	1) Textured insole 2) Conventional flat insole	- Immediate effect -12 weeks
(Palluel, et al., 2008)	-Healthy young -Healthy elderly	19/19	26/69	No	-Spike insoles	-Immediate effect -5 min

Author Year	Subjects	Sample size (EG/CG)	Mean age (years)	Fall history	Intervention	Follow-up
(Hijmans, et al., 2008a)	-Patients with neuropathy -Non-disabled	17/15	40-60	Not specified	-Vibrating insoles	Immediate effect
(Van Geffen, et al., 2007)	-Healthy -Diabetic patients with neuropathy	10/30	27-51/37-82	Not specified	1) Barefoot 2) Flat insole 3) Soft hardness flat insoles 4) Rigid hardness flat insoles	Immediate effect
(A. A. Priplata, et al., 2006)	-Healthy elderly -Patients with diabetic neuropathy -Patients with stroke	12/15/15	73/60/61	No	-Vibrating insoles:	Immediate effect
(AA Priplata, et al., 2003)	-Healthy young -Healthy elderly	15/12	23/73	Not specified	-Vibrating insoles	Immediate effect

Table 2-6 Study outcomes (n=19)

Author Year	Outcome measures	Measurement tool	Results	Balance improvement
(Qiu, et al., 2013)	-COP during standing	-Force plate	- Textured insoles reduced medial-lateral sway in the PD group while subjects standing on a firm surface. -Only the textured insole decreased medial-lateral sway in the PD group, with and without visual input.	Yes, static balance
(Wei, et al., 2012)	-COP during standing	-Force plate	-The balance stability of 61.5% elderly subjects is improved after the intervention.	Yes, static balance
(C.-C. Wang & Yang, 2012)	-COP during standing	-Force plate	-Vibrating insoles enhanced balance in elderly fallers, especially in the AP direction, for a short time duration (30 s)	Yes, static balance
(Stephen, et al., 2012)	-Spatial gait variability -3D position data of the feet	-In-shoe force sensors -Motion capture system	-Applying stochastic-resonance mechanical vibrations on the plantar surface of the foot reduced gait variability	Yes, dynamic balance
(Qiu, et al., 2012)	-COP during standing	-Force plate	-Both textured insole surfaces reduced postural sway for the older group especially in more challenging balance tasks (eyes closed on a foam surface).	Yes, static balance
(Iglesias, et al., 2012)	-COP during standing	-Force plate	-Both hard and soft insoles decreased postural sway compared with the barefoot condition. -More rigid insole reduced more postural sway. -The rigid insole was also effective when visual sensory input was removed.	Yes, static balance
(Anna L Hatton, et al., 2012)	-Standing balance -Gait parameters	-Force plate -Motion capture system	-Wearing textured insoles significantly lowered the gait velocity, step length and stride length. -No significant differences were found in any of the balance parameters	No, static and dynamic balance
(Gross, et al., 2012)	-1-leg stance time -Tandem stance time -Tandem gait -Alternating step tests	-Clinical tests	-Significantly reduced one-leg stance times and tandem stance times after using foot orthosis immediately and for 2 weeks. -Significantly increased steps taken for the tandem gait test and alternating step test after using foot orthosis immediately and for 2 weeks.	Yes, dynamic balance
(Simeonov, et al., 2011)	-Trunk angular displacement during standing	-Motion capture system	-The supra-sensory vibration had a destabilizing effect significantly.	No, static balance
(Palluel, et al., 2009)	-COP during standing	-Force plate	-The spike insoles improved postural sway -Elderly subjects were particularly perturbed when the tactile sensitivity enhancement device was removed.	Yes, static balance
(Jenkins, et al., 2009)	-Spatio-temporal parameters of gait	-Motion capture system	-Significant increase in single-limb support time.	Yes, dynamic balance
(Galica, et al., 2009)	-Stride, stance, and swing time variability	-In-shoe force sensors	-Vibrating insoles significantly reduced the variability of stride, stance, and swing time in elderly recurrent fallers. -Elderly non-fallers also demonstrated significant reductions in stride and stance time variability.	Yes, dynamic balance
(Wilson, et al., 2008)	-Standing postural stability	-Force plate -Motion capture system	-Postural stability variables demonstrated no significant differences between the four insole conditions.	No, static balance

Author Year	Outcome measures	Measurement tool	Results	Balance improvement
(S. D. Perry, et al., 2008)	-Lateral stability -Kinematic data	-Motion capture system	-Significantly improved postural stability during gait immediately, and after 12 weeks of wearing the insole. -Initial reports of discomfort in 10 cases, and one subject could not tolerate the textured insoles	Yes, dynamic balance
(Palluel, et al., 2008)	-COP during standing	-Force plate	-Significant improvement of quiet standing in the elderly and young subjects.	Yes, static balance
(Hijmans, et al., 2008a)	-COP during standing	-Force plate	-Vibrating insoles improved standing balance in subjects with neuropathy.	Yes, static balance
(Van Geffen, et al., 2007)	-COP during standing	-Force plate	-No significant effects of insoles on postural stability were found in diabetic patients and control group.	No, static balance
(A. A. Priplata, et al., 2006)	-Postural stability during standing	-Motion capture system	-Statistically significant reduction in each of the eight sway parameters in subjects with diabetic neuropathy, subjects with stroke, and the elderly.	Yes, static balance
(AA Priplata, et al., 2003)	-Postural stability during standing	-Motion capture system	-Application of noise resulted in a reduction in seven of eight sway parameters in young participants and all of the sway variables in elderly participants.	Yes, static balance

2.7.3.3 Summary on the effectiveness of insoles on balance improvement

There were one study reported that vibrating insoles did not enhance static balance in construction workers (Simeonov, et al., 2011), two studies reported that textured insoles did not enhance static balance in in healthy middle aged females (Wilson, et al., 2008) and patients with diabetic neuropathy (Van Geffen, et al., 2007), and another one study reported that textured insoles did not improve either static or dynamic balance in elderly fallers (Anna L Hatton, et al., 2012). The remaining fifteen studies reported that orthopaedic insoles, vibrating insoles, and textured insoles could enhance either static or dynamic balance, or both of them immediately or in longer follow-up time period significantly (Figure 2-20). An overview of the effectiveness of insoles on static and dynamic balance is summarized in Figure 2-20.

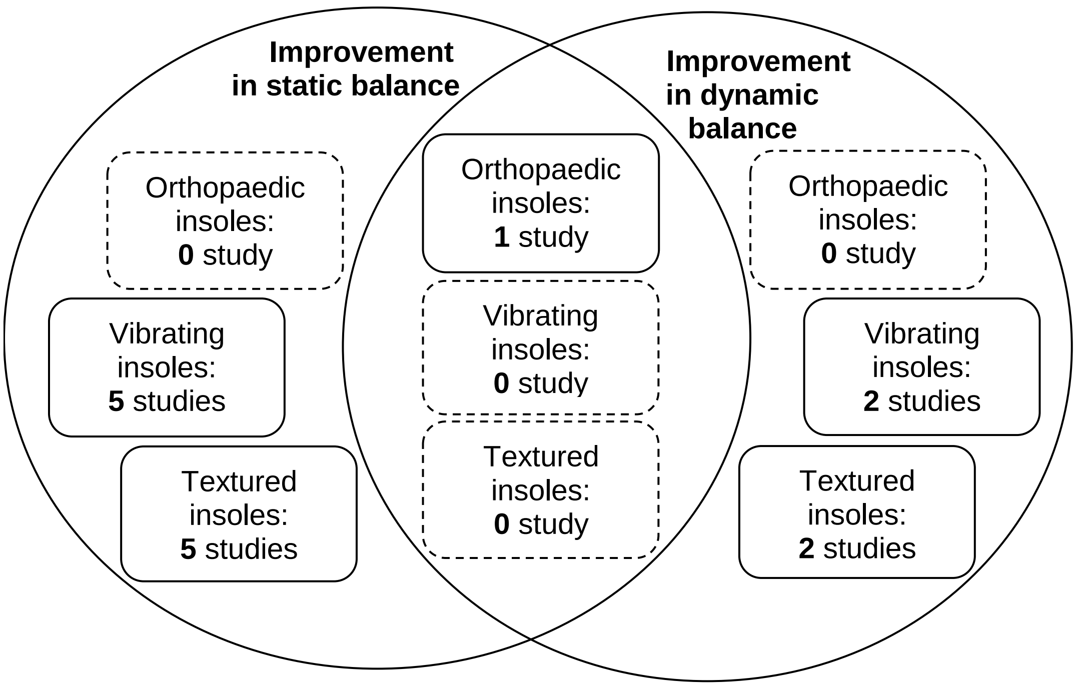


Figure 2-20 Overview of effectiveness of the insoles

2.7.3.4 Effect of vibrating insoles on static balance

A total of six reviewed studies investigated the effect of vibrating insoles on static balance. Among them, except one study found vibrating insoles providing supra-sensory threshold vibration did not reduce postural sway in young and older construction workers (Simeonov, et al., 2011), all the other studies reported that vibrating insoles significantly improved the postural stability. The vibrators were attached at the first and fifth metatarsal heads, and heel. Sub-sensory vibration was provided to subjects throughout the experiment. Healthy young and older adults (AA Priplata, et al., 2003; Wei, et al., 2012), elderly fallers (C.-C. Wang & Yang, 2012), patients with stroke (A. A. Priplata, et al., 2006), and patients with diabetic neuropathy (Hijmans, et al., 2008b; A. A. Priplata, et al., 2006) were recruited, and revealed significant improvement of postural stability in anteroposterior and mediolateral directions while standing with the vibrating insoles.

2.7.3.5 Effect of vibrating insoles on dynamic balance

A total of two studies evaluated the effect of vibrating insoles on dynamic balance. The vibrators were attached at the first and fifth metatarsal heads, and heel. Sub-sensory vibration was provided to the subjects' soles of feet during walking throughout the experiment. Healthy young and older adults (Galica, et al., 2009; Stephen, et al., 2012) and elderly recurrent fallers (Galica, et al., 2009) were recruited, and revealed significant reduction of gait variability and improvement of clinical balance test results. Particularly, the dynamic balance improvement in recurrent fallers (6.3%) was higher than non-fallers (5.8%) upon wearing the vibrating insoles (Galica, et al., 2009).

2.7.3.6 Effect of textured insoles on static balance

A total of seven involved publications investigated the effect of textured insoles on static balance. Among them, except two studies reported no improvement of postural stability in healthy females (Wilson, et al., 2008) and patients with diabetic neuropathy (Van Geffen, et al., 2007), all the other studies concluded that textured insoles enhanced the postural stability during standing. The design of the textured insoles varied across the study. Some studies only investigated the effect of soft, medium and rigid insole hardness on balance (Iglesias, et al., 2012; Qiu, et al., 2012; Qiu, et al., 2013), and found that all these textured insoles reduced the postural sway significantly. Additionally, more rigid insoles also appeared to reduce more postural sway in subjects (Iglesias, et al., 2012). In addition to evaluating the effect of insole hardness on balance, some other studies also attempted to fabricate the upper surface of insoles with different textures, including the equally distributed comprised granulations (height: 3.1 mm; diameter: 5mm) made of 270 density Ethylene Vinyl Acetate (EVA) and compliant ridges (height: 3.1 mm; width: 3.1mm) at the lateral perimeter and around the heel (Qiu, et al., 2013), and the spikes (density: 4 spikes/cm^2; height: 5mm; diameter: 3mm) made of semi-rigid polyvinyl chloride (PVC) (Palluel, et al., 2008; Palluel, et al., 2009). Healthy young and older adults (Iglesias, et al., 2012; Palluel, et al., 2008; Palluel, et al., 2009; Qiu, et al., 2012), and patients with Parkinson’s Disease (Qiu, et al., 2013) were recruited. Significant reduction of postural sway was found while subjects standing with the textured insoles.

2.7.3.7 Effect of textured insoles on dynamic balance

A total of three involved studies investigated the effect of textured insoles on dynamic balance. Except one study reported no balance improvement in elderly fallers upon using the textured insoles with small pyramidal peaks made of medium density EVA (thickness: 3 mm and Shore value A50) (Anna L Hatton, et al., 2012), the remaining two studies reported that textured insoles improved dynamic balance significantly. These two studies fabricated insoles with different upper surface textures, including equally distributed (2.5 mm center-to-center distance) (Jenkins, et al., 2009), and a raised ridge (height: 2.5 mm) around the perimeter (S. D. Perry, et al., 2008). Elderly subjects with moderate loss of plantar cutaneous sensation (S. D. Perry, et al., 2008) and patients with Parkinson's Disease (Jenkins, et al., 2009) were recruited, and revealed significantly improved postural stability and reduced gait variability during walking while wearing the textured insoles.

2.7.3.8 Effect of orthopaedic insoles on static balance

None of the reviewed studies evaluated the effect of orthopaedic insoles on static balance.

2.7.3.9 Effect of orthopaedic insoles on dynamic balance

One reviewed study evaluated the effect of orthopaedic insoles on dynamic balance. This study used the custom-made insoles to correct and compensate subject's foot deformity (Gross, et al., 2012). Recurrent elderly fallers were recruited, and revealed significantly improved dynamic balance while wearing orthopaedic insoles as assessed by non-instrumented clinical tests, both immediately and after a 2-week intervention (Gross, et al., 2012).

2.7.4 Discussion

This review of literatures about insoles with different designs demonstrates the potential of applying insoles to enhance static and dynamic balance performance in older adults and patients. This review also builds on previous research by examining the specific design features of insoles that may affect the efficacy of balance improvement. The insoles that appeared in the reviewed studies could be divided into three categories: (1) custom-made orthopaedic insoles; (2) vibrating insoles with vibrators at the first and fifth metatarsal heads, and heel; and (3) textured insoles with different hardness and texture patterns on the upper surface of insoles.

2.7.4.1 Effectiveness

In general, evidence supports the effectiveness of insoles in enhancing static and dynamic balance in healthy young and older adults and patients with balance disorders. Except one study showed that vibrating insoles providing sub-threshold vibrations did not enhance the static balance of young and elderly construction workers (Simeonov, et al., 2011), one study showed that textured insoles with medium hardness grids and dimples on upper surface could not enhance the static balance of healthy middle aged females immediately or after a 4-week intervention of wearing textured insoles (Wilson, et al., 2008), one study did not support the effect of textured insoles with soft or rigid hardness in enhancing static balance in patients with diabetic neuropathy (Van Geffen, et al., 2007), and another one study did not support the effect of textured insoles with medium hardness small pyramidal peaks in improving dynamic balance of elderly fallers (Anna L Hatton, et al., 2012). The remaining fifteen studies supported the effectiveness of custom-made orthopaedic insoles, vibrating insoles, and textured insoles in enhancing static and dynamic balance. The subjects in these studies involved healthy young and elderly adults, elderly fallers, patients with diabetic neuropathy, moderate loss of plantar cutaneous sensitivity that unrelated to neuropathy, stroke, Multiple Sclerosis, and Parkinson' Disease.

It has been generally reported that textured insoles can enhance the balance of older adults (Iglesias, et al., 2012; Palluel, et al., 2008; Palluel, et al., 2009; S. D. Perry, et al., 2008; Qiu, et al., 2012; Qiu, et al., 2013). One possible reason could be that the hardness of insoles and insole textures influences mechanical stimulations at plantar foot and affects postural stability. Adding various textures to insoles was demonstrated to increase sensory afferent feedback via enhanced tactile stimulation of plantar cutaneous mechanoreceptors (Anna Lucy Hatton, et al., 2011). However, the sparsely distributed textured patterns may not be able to provide sufficient sensory augmentation for balance improvement, as one reviewed study found that the small pyramidal peaks distributed 2.5 mm center-to-center distance did not enhance neither static nor dynamic balance of the elderly fallers (Anna L Hatton, et al., 2012). Wearing more rigid insoles, without causing discomfort, also lead to greater postural stability in individuals (Iglesias, et al., 2012). Since more rigid insoles tend to provide more mechanical stimulations and place the foot in a more neutral position, while softer insoles tend to accommodate the foot posture (Iglesias, et al., 2012). Special attention should be paid that excessive rigid insoles induced discomfort (S. D. Perry, et al., 2008), which may impair balance, as better comfort perception might allow for better postural and balance control in individuals (Nigg, 2010). While textured insoles could improve balance of elderly non-fallers, they may not be helpful for elderly fallers as Hatton et al (2012) found no balance improvement of textured insoles in elderly recurrent fallers. While insoles with medium hardness and appropriate texture patterns generally improve the balance in older adults, an optimal design providing best balance outcomes still remains unclear. Evidence related to the long-term effect of textured insoles was not enough, only one study investigated and supported the long-term effect of textured insoles in older adults (S. D. Perry, et al., 2008).

All studies of vibrating insoles providing sub-threshold vibrations reported positive results of improved postural balance. The intensity of vibrations is rather important in affecting balance performance. This review identifies that while sub-threshold vibration consistently enhanced balance, one study which used supra-threshold vibration did not produce any positive outcome in balance (Simeonov, et al., 2011).

The possible reason could be that sub-threshold vibration could enhance plantar sensory input through SR without notice of users, while continuously providing supra-threshold vibrations may negatively affect balance by interfering with individual's detection of mechanical input signals produced from the stepping on the floor. Continuous supra-threshold vibration may also cause discomfort or increase subject's consciousness by interfering the automaticity of balance control (Wulf, et al., 2001). Attention needs to be paid to the fact that none of the studies about vibrating insoles involved a subject control group or investigated the long-term effect.

Previous studies reported that custom-made orthopaedic insoles (Gross, et al., 2012) enhanced static and dynamic balance in older adults upon treating the foot deformity. Another reasons could be that such design could increase the contact area between foot and ground, providing supplemented information about the relative position of foot to ground for users during walking (S. D. Perry, et al., 2008). These strategies would be helpful for improving the balance of older adults. However, the effect of orthopaedic insoles on balance in people without foot pain or deformity still remains unclear.

2.7.4.2 Future directions

Though stronger evidence is still needed, it can be seen that the effectiveness of insoles on balance improvement largely depended on the user's condition, as various insoles improved the balance based on different mechanisms. All three insoles are suitable for users with deficits of plantar pressure sensation. In particular, vibrating insoles need to be powered by battery, they might not be a good option for users who have sweaty foot which may arise safety concerns. Textured insoles are appropriate for most users, however, special attention should be paid when it comes to the patients with diabetic neuropathy. The rigid texture patterns might damage skin without the notice of these patients, which may lead to some severe medical conditions, such as pressure sore or even amputation. Textured insoles fabricated by rigid materials might also lead to discomfort and pain in users after long-term usage. In these conditions, the orthopaedic insoles might be a good option since they are conventionally used to treat foot pain (Gross, et al., 2002) and correct foot deformity (Conceição, et al., 2014). Arch supports, metatarsal pads, and heel cups are key components of orthopaedic insoles. Arch supports relieve plantar fasciitis by supporting the longitudinal arch and relieving soft tissue stretch (Conceição, et al., 2014). Metatarsal pads relieve pain over the metatarsal heads by redistributing loadings to the metatarsal shafts (P. Y. Lee, et al., 2014). Heel cups help to grasp the heel in a more neutral position (T.-h. Chen, et al., 2014). The orthopaedic insoles are suitable for users with foot pain, foot deformity, instable ankle-foot joints, and diabetic foot. However, only one previous study investigated the effect of custom-made orthopaedic insoles on balance by employing some subjective non-instrumented clinical tests (Gross, et al., 2012). It found positive effects of custom-made insoles on balance, and suggested that such positive effects might be brought by compensating and treating the foot deformity in subjects. It still remains unclear whether people without foot deformity or foot pain could benefit from the orthopaedic insoles. Future studies are needed to clarify this issue.

Insoles could be optimized for long-term use. Most insoles were found to be effective in enhancing balance in short-term time period, however, they may lead to some discomfort and side effects after long-term use. Textured insoles with rigid small nubs tended to cause discomfort or even pain after long-term use (S. D. Perry, et al., 2008), which may limit its application in daily life. The vibrator was made of rigid metal, and users complained of pain and discomfort when using the vibrating insoles (de Morais Barbosa, et al., 2013). Most vibrating insoles were not designed for in-shoe use, which limited its spreading in clinical practice (A. A. Priplata, et al., 2006) and potential daily use. Additional limitations of using vibrating insoles as a daily balance improvement tool include high price and requiring external power supply to activate the vibration. It has been suggested that the economic and practicality problems associated with wearing vibrating insoles may outweigh their beneficial effects on balance control (Anna L Hatton, et al., 2013). Thus, the vibrating insoles may not be an appropriate and feasible solution for balance improvement in daily living. On the other hand, the orthopaedic insoles appeared to have great potential and limited attention has been paid on their balance improving effect. Further investigations are required to answer the questions of whether orthopaedic insoles could improve the balance of people without any foot pain or deformity.

2.7.5 Summary

A synthesis of research examining the effect of vibrating insoles, textured insoles, and orthopaedic insoles on static and dynamic balance performance suggests that most of these insoles are effective. Insoles with rigid hardness and appropriately designed texture patterns on upper insole surface could enhance both static and dynamic balance; vibrating insoles are effective in enhancing standing balance, and also show some positive effects on walking balance; custom-made orthopaedic insoles are effective in enhancing balance after treating the foot deformity of subjects. More specifically, orthopaedic insoles have a good potential to be used as balance aids in daily life, while more comprehensive investigations and further optimization of them are still required.

2.8 Potential of plantar pressure sensory augmentation on

balance improvement

Plantar pressure sensation

Tactile sensory input from the plantar foot is one crucial element for balance (Oliveira, et al., 2011), as it provides information for necessary adjustments of body posture and motion for maintaining balance (Eils, et al., 2004). There were a number of studies which supported the important contribution of cutaneous sensation from the plantar foot surface in balance control (Cruz-Almeida, et al., 2014; Manor, et al., 2009; Meyer, et al., 2004; T.-Y. Wang & Lin, 2008).

Plantar pressure sensation could be reduced by soft foot support materials (S. D. Perry, et al., 2000), aging (Bretan, et al., 2010), rheumatoid arthritis, and neuropathy (Jaiswal, et al., 2013), which could also adversely affect balance. Poor balance and difficulty in walking could be caused by declines in cutaneous plantar surface sensitivity and proprioception that can be commonly found among older people (Bretan, et al., 2010). Declined plantar pressure sensation could lead to difficulty in maintaining postural stability (Höhne, et al., 2011). The evaluation of plantar pressure sensation can be achieved by a monofilament test (Slater, et al., 2014).

Potential of improving balance by augmenting plantar pressure sensation

Changing the contact mechanics between foot and support surface may be able to alter the plantar sensitivity to mechanical stimulations, which might potentially be helpful for improving balance performance.

Insole is an important design element of footwear, which could modify the foot-floor contact mechanics and plantar sensitivity. Vibrating insoles provided sub-sensory vibratory noise to the plantar surface of the feet, enhancing plantar sensory input based on the stochastic resonance theory (Hijmans, et al., 2008b). However, vibrating insoles produced pain and discomfort, since the vibrators having to be made of rigid steel produced excessive pressure to the metatarsal heads and heels (Anna L Hatton, et al., 2013). Patients complained of pain and uncomfortable when using the vibrating insoles (de Morais Barbosa, et al., 2013). This may prevent their long-term use. Most vibrating insoles were not designed for in-shoe use, which limited its spreading in clinical practice (A. A. Priplata, et al., 2006). It has been suggested that the economic and practicality problems associated with wearing vibrating insoles may outweigh their beneficial efforts on balance control (Anna L Hatton, et al., 2013). Textured insoles could also bring some positive effects on balance. However, the rigid textured patterns may induce discomfort and pain (S. D. Perry, et al., 2008), and even excessive loading at plantar foot which may induce soft tissue damage after prolonged usage in people with declined plantar pressure sensation (Wu, et al., 2007).

Orthopaedic insoles consist of arch supports, metatarsal pads and heel cups. Besides pain relief, these design features increased the contact area between the foot and support surface (Committee, 2008). The increased contact area enlarged the base-of-support and provided a larger surface area for plantar sensory input that enhanced balance (Gross, et al., 2012). Arch support and heel cup can also facilitate stabilization on the ankle-subtalar complex (Anna L Hatton, et al., 2013). However, few investigations have comprehensively investigated these traditional design elements of insoles, especially their combined effects on balance. There was one previous study investigated the effect of custom-made orthopaedic insoles on balance using some subjective non-instrumented clinical tests (Gross, et al., 2012). It found the positive effect of custom-made insoles on balance, and suggested this positive effect might be brought by compensating and treating the foot deformity in the elderly. It still remains unclear whether people without foot deformity or foot pain could benefit from the orthopaedic insoles.

Orthopaedic insoles may also have some positive effects on balance for people without foot pain or deformity. Previous studies measuring the plantar pressure distribution indicated that orthopaedic insoles increased the contact area between the foot and the support surface (T.-h. Chen, et al., 2014; Gross, et al., 2012). In addition, orthopaedic insoles redistributed the plantar pressure by increasing the pressure over the metatarsal shafts, and reducing the pressure over the heel and the metatarsal heads which are the common painful sites (Bus, et al., 2004). It just happens that the midfoot metatarsal shaft region has been shown to have higher tactile sensitivity than the heel and the metatarsal heads (Hennig & Sterzing, 2009). The increased contact area and the elevated pressure over some more tactile sensitive regions could enhance plantar tactile input, which gives the traditional orthopaedic insoles the potential to improve balance of people with deficits of plantar tactile sensation. Scientific methods have not yet confirmed about this.

In addition to the insoles directly enhanced plantar sensory input at foot, providing corresponding biofeedback information based on body motion has also achieved some success regarding balance improvement. However, many biofeedback systems can only be used in indoor balance training because the visual and auditory feedbacks used in these systems interfere with daily tasks of speaking, seeing and hearing in daily life (Wall, et al., 2009). It is not known if the balance improving effects that are observed in indoor training can be remained when the device is not used, some other feedback strategies are needed (Zijlstra, et al., 2010). Some biofeedback systems mounted insertional motion sensors on subject’s body. The added weights to the trunk increased the energy cost of the users when they move (Tzu-wei & Kuo, 2014). In addition, most of the previous devices need to connect to computers for analysing signals and sending feedback (Goebel, et al., 2009; Sienko, et al., 2008;

Sienko, et al., 2013; Wall & Weinberg, 2003; Wall, et al., 2009), making these devices only appropriate for indoor balance training.

Meanwhile, the plantar force distribution at the feet can also provide important information regarding the degree of body sway (Hass, et al., 2004; Ruhe, et al., 2010). Compared to the trunk or head mounted inertial motion sensors, thin-film plantar force sensors can be concealed at insoles and the associated electronic components can be easily attached to the shoes, this potentially reduced the weight at upper trunk. The increased shoe weight added by thin-film sensors and the associated electronic components will not affect the walking patterns much as previous study revealed that the altered shoe weight did not influence the swing phase kinematics statistically (W. C. Lee, et al., 2006). Such advantages could allow the biofeedback system to be made wearable and be used in both indoor and outdoor environment in daily activities. While there were a lot of studies investigating plantar pressure distribution as reviewed in (Abdul Razak, et al., 2012), to date very little attempt has been made to investigate the possibility of using the information of plantar forces to feedback the postural sway. An attempt was made to use a floor-mounted force plate to sense body sway and gave electro−tactile stimulations to tongue to feedback the degree of body sway (Nicolas Vuillerme, et al., 2007), which was unfortunately confined to laboratory setting. Some other simple attempts were made to feedback the onset of foot contact and weight bearing at the prosthetic/paretic side during walking (M.-Y. Lee, et al., 2007; Sungkarat, et al., 2011). With current wireless technology, considerations can be made to position the vibrators at other body regions while connecting the sensors and the vibrators wirelessly. This could make good use of the plantar force data for balance and gait assessment, and reduce the added weight at the trunk.

2.9 Summary of literature review

Improving balance could potentially reduce the risks of falls. This chapter started by reviewing the background information of balance and gait disorders, and evaluation methods to assess balance. This justifies the choice of balance outcome measures adopted in this project.

This chapter then reviewed the previous efforts of improving balance using insoles and biofeedback system. Previous studies shown that vibrating insoles and textured insoles could improve balance, but have the limitations of causing discomfort which limited their long-term applications. Meanwhile, this study identified that orthopaedic insoles with arch supports, metatarsal pads, and heel cups, which were traditionally used for relieving foot pain and correct foot deformity, might be an effective alternative approach. Future studies are needed to verify this hypothesis.

Biofeedback systems integrated with force plate, motion capture systems, and inertial motion sensors could improve balance. However, integrating the force plates and motion capture systems limited the previous biofeedback systems be applied in in-door environment only. Integrating inertial motion sensors at head and trunk could make the whole system more portable, however, the added electronics at trunk tends to increase the weight mounted at trunk which may interfere with body motions. On the other hand, integrating force sensors at plantar surface of foot could ease problem as the weight adding at trunk would be reduced, and plantar pressure measurement has been shown to be an accurate and reliable approach to assess balance and gait performance. While providing visual, auditory, and electro-tactile feedback may interfere with daily tasks of speaking, eating and hearing, providing vibrotactile feedback at skin surface could ease this problem. This will further facilitate the application of biofeedback systems as balance aids in daily life, as well as acting as balance training tools. Previous efforts of applying biofeedback system to improve balance were mainly focused on the static balance, such efforts need to be extended further to improving dynamic balance in the future.

These issues are covered in this project in the following chapters.

CHAPTER 3. RESEARCH METHOD

3.1 Chapter summary

Since both vibrotactile biofeedback system and orthopaedic insoles have the potential to improve balance, this project designed and developed the prototype of these two devices first. Pilot studies were then conducted to optimize the design of these two devices. After the optimization of these two devices, a series of clinical trials were conducted to evaluate the effects of them on balance and gait.

In the following parts, a brief background and introduction of each clinical trial were described first, followed by the detailed description of the experimental protocol of each study.

Ethical approval was granted from the Human Subjects Ethics Sub-committee of The Hong Kong Polytechnic University (HSEARS20140211002). This study was registered on the Chinese Clinical Trial Registry (ChiCTR-IPB-15006530) and the Hong Kong Clinical Trial Registry (HKCTR-1853).

3.2 Improving postural stability by vibrotactile biofeedback system

3.2.1 Subjects

Convenience sampling approach was used to recruit thirty healthy subjects (including fifteen elderly adults aged 65 years or over and fifteen young adults aged between 18 and 35 years) in this study. This sample size produced a statistical power of 0.8, assuming a medium effect size of 0.5 and two-sided significant level of 0.05 on a repeated-measures design. Subjects should be healthy, fully independent, living in a community-based setting, and capable of ambulation without walking assisting devices. Subjects should not have pes planus, pes cavus hallux valgus, hammer toes or foot pain, as assessed by a certified orthotist. In addition, subjects should not have neurological or vestibular disorders, diabetes, severe cardiovascular or pulmonary diseases, or previous history of foot injury. All the subjects should be able to follow the instructions and procedures of the research protocol.

Subjects consented to participate in this study were scheduled for testing. Ethical approval has been granted from the Human Subjects Ethics Sub-committee of the Hong Kong Polytechnic University (HSEARS20140211002). This study was registered on the Chinese Clinical Trial Registry (ChiCTR-IPB-15006530) and the Hong Kong Clinical Trial Registry (HKCTR-1853).

3.2.2 Design and setting of the vibrotactile biofeedback system

The vibrotactile biofeedback system consisted of a pair of flat insoles attached with six force sensors (A301, Tekscan Co., Ltd, USA), a microcontroller unit (ATMEGA328P, Atmel Co., Ltd, USA), a wireless transmitter (HC-05, HC information Tech. Co., Ltd, China) and receiver (HC-05, HC information Tech. Co., Ltd, China) system, four vibrators (XY-B1027-DX, Xiongying electronics Co., Ltd, China), and two rechargeable lithium ion batteries (FLB-18650-3.0, UltraFire Co., Ltd, China) (Figure 3-1). The entire biofeedback system weighed less than 100 grams. The microcontroller (length 11 cm × width 2 cm × height 2.5 cm) processed the plantar force data and delivered appropriate vibrating signals to the vibrators through the wireless Bluetooth communication. Three force sensors (thickness 0.2 mm, length 25.4 mm, width 14 mm, sensing area 9.53 mm diameter, force range 0-445 N) were attached to each foot measuring the forces at the first and fifth metatarsal heads, as well as the heel (Figure 3-2). The forces detected at the first metatarsal heads as well as the heels were averaged across the left and right sides, which were used to indicate the forward and backward postural sway, respectively. The forces measured at the left and right fifth metatarsal heads were used to indicate the left and right postural sway. Four vibrators providing vibrating stimulations were attached to the anterior, posterior, left and right side of upper trunk. The generation of vibration was based on the plantar pressure detected by force sensors. Full magnitude of vibration was provoked once the forces detected by sensors exceeded the thresholds, which are described further in the procedure section. The vibration was generated to remind the subjects of their body sway (Figure 3-3).

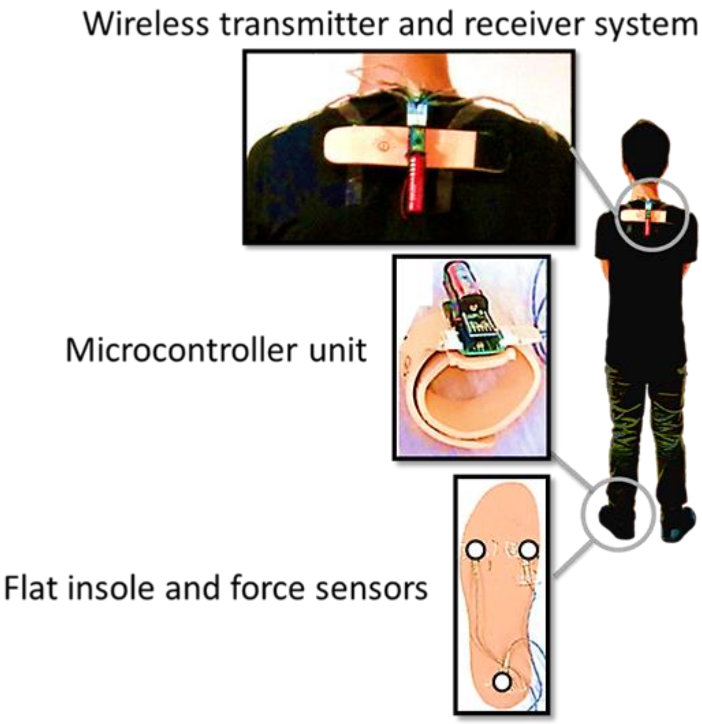


Figure 3-1 The biofeedback system, consisted of four vibrators at upper trunk, a wireless transmitter and receiver system, a microcontroller unit, a pair of flat insoles and six force sensors

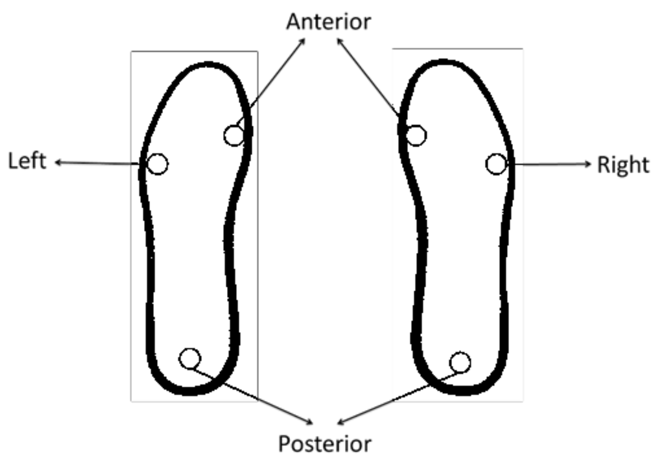


Figure 3-2 Locations of the force sensors at the plantar surface of foot

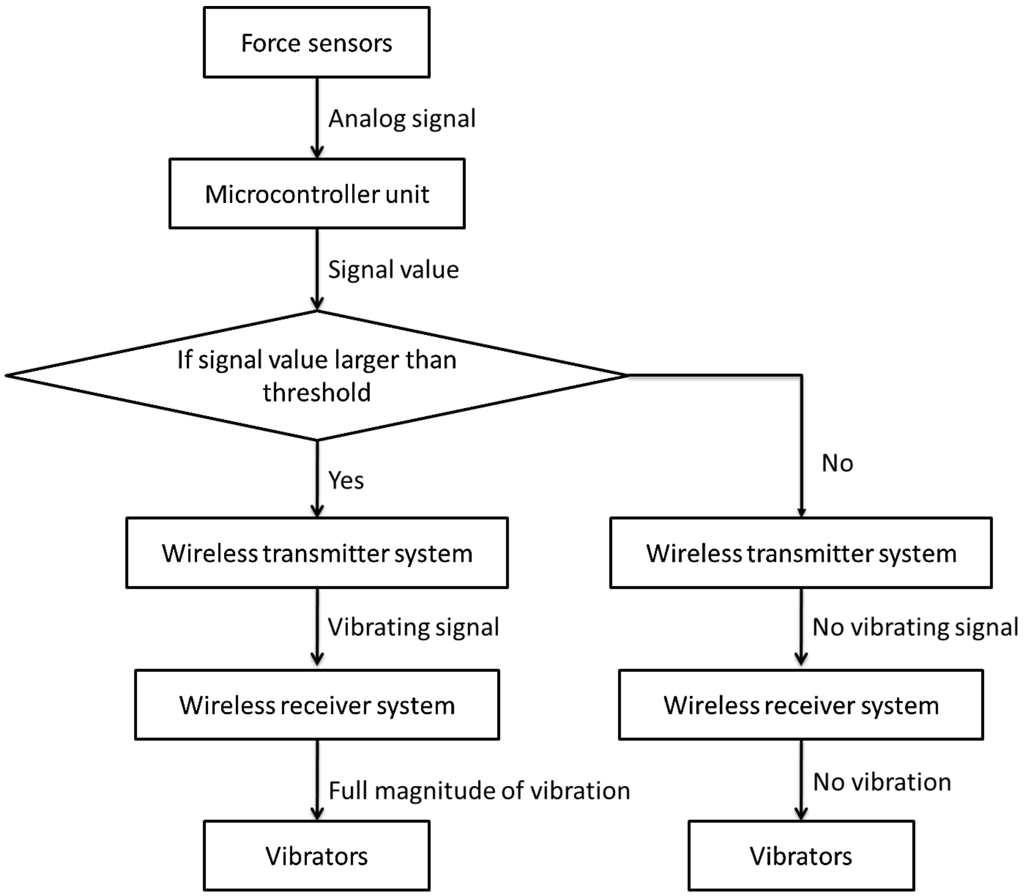


Figure 3-3 Flow chart of the vibrotactile biofeedback system setting

3.2.3 Experimental procedure

Before the experiment, all subjects were explained and instructed about how the biofeedback system should be used to provide additional information of their static balance status. They were informed that each vibrator corresponded to body movement in one particular direction, i.e. forward, backward, left, and right. Subjects were instructed to lean forward, backward, to the left and right sides to experience the vibrations in four different directions. This was conducted to ensure that each subject was capable of using the vibration signals as a balance aid. Each subject was given 10 minutes to get familiar with the new biofeedback system. At the end of the practicing period, subjects were required to perform quiet standing with the biofeedback system turned-on for 90s, and for 3 repeated trials. The force recorded at each force sensor over the 3 trials was averaged and then multiplied by 110%, which was set as the threshold for each sensor. The biofeedback system worked by delivering vibrations through the vibrators as long as the measured corresponding forces exceeded the calculated threshold.

During the experiment, a Romberg test was used to evaluate the balance control. Subjects were instructed to stand quietly on a force platform, with their arms crossed resting on the opposite shoulders, and eyes closed. Subjects were asked to stand as still as possible, with their heads erect in all three experimental conditions: 1) without socks and the biofeedback system turned-off (condition 1), 2) with socks and the biofeedback system turned-off (condition 2), and 3) with socks and the biofeedback system turned-on (condition 3). The sequence of three experimental conditions was randomized for each subject, with each experimental condition been coded. The wearing socks and eye-closed intervention was used to reduce the somatosensory input in subjects. When performing the Romberg test, all subjects were instructed to stand for 90 seconds in each trial to ensure the reliability of this test (Ruhe, et al., 2010).

3.2.4 Equipment and outcome measures

3.2.4.1 Force platform

A force platform (OR6, Advanced Mechanical Technology, Inc. MA, USA) sampling at 1000Hz was used to measure the COP signals. The COP signals were processed with a data capture software: Nexus 2 (Vicon Motion Systems Ltd. Oxford, UK). Based on the computed changes of locations of COP and the time of occurrence, the COP-based parameters: (1) mean distance (MDIST, mm); (2) root mean square distance (RDIST, mm); (3) mean velocity (MVELO, mm/s); (4) the 95% confidence circle area (AREA-CC, mm^2); (5) the 95% confidence ellipse area (AREA-CE, mm^2); (6) sway area (AREA-SW, mm^2); (7) planar diameter of the 95% confidence circle area (PD-CC, mm); (8) planar diameter of the 95% confidence ellipse area (PD-CE, mm); and (9) range of COP in anteroposterior (AP) and mediolateral (ML) directions (mm) were calculated using the Microsoft Excel (Prieto, et al., 1996).

3.2.4.2 5.07/10-g Semmes-Weinstein Monofilament

The 5.07/10-g Semmes-Weinstein monofilament (Connecticut Bio-instruments Inc. NY, USA) was used to assess the planter touch-pressure sensation of subjects' feet with and without the sock intervention (Figure 3-4), following the standard testing procedures as specified in (Slater, et al., 2014). Three sites at the plantar surface of foot were assessed, including the hallux, and the first and fifth metatarsal heads (Figure 3-4). At each site, the monofilament was pressed to the skin at 90 degrees with sufficient force to produce bowing for at least 1s. Two applications and a sham application were performed at each site. The site and sequence of the actual and sham application was randomized for each subject. Subjects were instructed to keep their eyes closed and respond “yes/no” after each application. Scores were graded from 0 to 3 based on the number of correct answers (Slater, et al., 2014). The higher score of the monofilament test represented the better plantar pressure sensation. All monofilament tests were performed in all subjects by the same examiner.

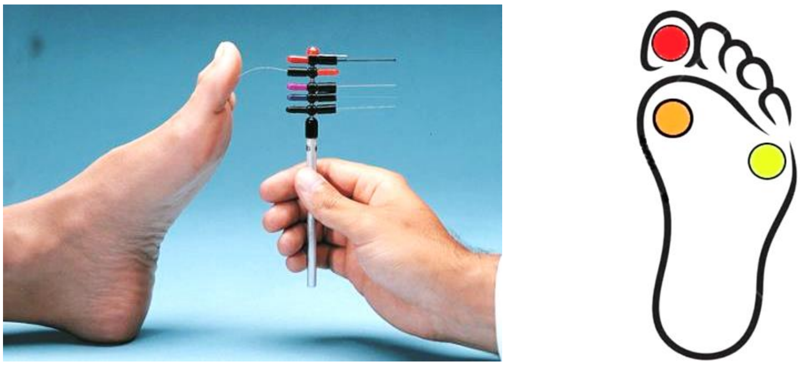


Figure 3-4 The Semmes-Weinstein monofilament and the three testing sites at the plantar surface of foot (for the vibrotactile biofeedback system experiment)

3.2.5 Statistical analysis

Statistical analysis was performed using the Statistical Package for Social Sciences (SPSS, version 21.0, IBM Corporation, Armonk, NY, USA). Wilcoxon Signed-Ranks Test was used to compare the monofilament score with and without the socks intervention. Two-way mixed ANOVA were performed priory to evaluate the main effects of three experimental conditions (condition 1, condition 2, and condition 3), the main effect of two subject groups (young vs elderly subjects), as well as the interaction effect between conditions and groups in all measured COP parameters in all subjects. The level of significance was set as 0.05. If significant interaction effect was found, the simple main effect was then analyzed to determine the difference between the groups at each level of each factor (condition and group). If significant interaction effect was not found and significant main effect of condition was found, post hoc pairwise comparisons with Bonferroni corrections were conducted to understand where the differences between the conditions within each subject group lie.

3.3 Improving postural balance while subjects under balance perturbation using vibrotactile biofeedback system

3.3.1 Subjects

Convenience sampling approach was used to recruit 10 healthy young adults in this pilot study. Subjects shall be 18 to 35 years old and be able to understand and follow the experimental instructions. Subjects were excluded if they had any medical conditions that affected the balance ability, such as vestibular disorders, rheumatic disorders, foot deformity, as well as the use of antidepressants, tranquilizers or antipsychotic drugs. All subjects were university students and were recruited from the The Hong Kong Polytechnic University.

3.3.2 Design and setting of the vibrotactile biofeedback system

3.3.2.1 Vibrotactile biofeedback system integrated with plantar force measurement

The system comprised a plantar force acquisition and analysis unit (secured at the distal leg) as well as a vibration unit. The plantar force acquisition and analysis unit consisted of four thin-film force sensors (A301, Tekscan Co., Ltd, USA), a microprocessor (ATMEGA328P, Atmel Co., Ltd, USA), a rechargeable lithium ion battery (FLB-16340-880-PTD, UltraFire Co., Ltd, China) and a wireless transmitter module (HC-05, HC information Tech. Co., Ltd, China). The vibration unit consisted of four vibrators (XY-B1027-DX, Xiongying electronics Co., Ltd, China), a rechargeable lithium ion battery (FLB-16340-880-PTD, UltraFire Co., Ltd, China) and a wireless receiver module (HC-05, HC information Tech. Co., Ltd, China). The vibration frequency of the vibrators was 220Hz with a full strength of 1G that was greatly identifiable by human (Kyung, et al., 2005). The microcontroller converted the analog force data received from force sensors into digital data, analysed the measured plantar force data, and then sent a wireless control signal to the vibration unit if the measured forces exceeded certain thresholds. The sampling rate of the force sensors and signal transmission time was 10Hz and 0.67ms, respectively.

The four force sensors were adhered to a pair of 2mm-thick ethylene-vinyl acetate (EVA) flat insoles at the positions of the first metatarsal heads and the heels of both feet (Figure 3-5). The force values obtained from the four sensors were used to detect the anteroposterior, left and right body sways (Table 3-1). The vibrators were located at the sternum, the back, left and right arms. They corresponded to the anterior, posterior, left and right body sways, respectively. Each vibrator was activated instantly, only when the measured plantar force exceeded the pre-set force threshold. Identification of the thresholds is detailed in the section of experimental procedure (Table 3-1).

Table 3-1 Locations of the corresponding two force sensors and vibrators for body tilt in forward, backward, left and right directions.

Direction of body tilt	Locations of a pair of force sensors used to detect one of the body tilting directions	Location of the corresponding vibrator
Forward	Left foot's metatarsal head (S0) & Right foot's metatarsal head (S1)	Sternum (V0)
Backward	Left foot's heel (S2) & Right foot's heel (S3)	Back (V2)
Left	Left foot's metatarsal head (S0) & Left foot's heel (S2)	Left arm (V3)
Right	Right foot's metatarsal head (S1) & Right foot's heel (S3)	Right arm (V1)

Notes:

- A vibration threshold was determined by multiplying 120% to the summation of force values measured by the pair of sensors

-The corresponding vibrator vibrated only when the summation of instantaneous forces measured by the sensor pair exceeded the vibration threshold.

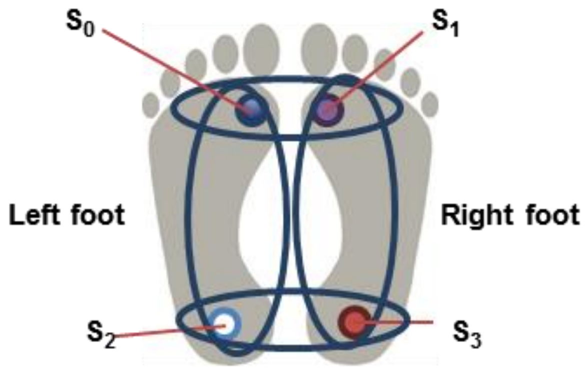


Figure 3-5 Location of the force sensors and corresponding vibrators.

3.3.2.2 Perturbation floor

The perturbation floor was made of a wood board (50cm×50cm), covered by a 12mm-thick soft Polyvinyl chloride (PVC) foam (ON1117, density 45kg/m^3, stiffness 7292N/m, AORTHA, Co., Ltd, Hong Kong). The foam resembled shoes with soft soles, which could reduce subject's sensation over the floor reaction force (S. D. Perry, et al., 2000). Translational movement of the wood board was brought by an actuator (MAR40×500-S, SHHAGO, Co., Ltd, China), which elongated at a constant velocity of 50mm/s. The velocity of 50mm/s was reached from a static condition in 0.05 seconds.

3.3.3 Experimental procedure

The vibration threshold of the biofeedback system was first determined for each subject. This was done by 1) measuring forces under the feet using the system during static standing, with eyes opened, looking forward, feet together, and hands alongside bodies for 30 seconds, and repeating the measurements three times; 2) averaging the plantar forces measured over the measurement period in three trials for each sensor; and 3) adding the averaged force values of the two sensors that corresponded to each of the body tilting directions (see Table 3-1), and then multiplying by 120% to determine the threshold values. The vibrators were set to activate when the added instantaneous force values of two corresponding force sensors exceeded the pre-determined threshold. Previous pilot studies had found that a multiplier of 120% was effective in reducing body sway. The threshold force values were acquired for each subject due to different plantar pressure distribution patterns among people (Machado, et al., 2016).

Subjects were then given a 10-minute practicing period to get familiar with the biofeedback system (Boonsinsukh, et al., 2011). They stood on the perturbation floor with feet together, hands alongside bodies, and eyes opened and looking forward. The floor moved in each of the four possible directions (forward, backward, left, and right side), with and without the biofeedback system turned-on. When the biofeedback system was used, subjects were instructed that the vibration of a vibrator indicated excessive body sway of a particular direction that required self-correction.

During the testing stage, subjects stood on the perturbation floor with the same posture as in the practice section. Each subject was tested with 40 successful trials (4 directions of perturbation × 2 conditions of the system (turned- on and off) × 5 successful trials for each direction and condition). The trial order was randomized. A trial was considered to be unsuccessful if the subjects stepped out of base of foot support in response to the perturbation (Hsu, et al., 2013). At each condition, the platform moved for a duration of 10 seconds without prior notice to the subjects. There was a helper standing next to the subjects for protection if necessary. The 40 trials lasted for less than 10 minutes.

3.3.4 Equipment and outcome measures

An eight-camera 3D motion analysis system (ViconNexus 1.7.5, Oxford Metrics, UK) was used to track the COM movements. The position of COM relative to the ground was determined by calculating the centroid of three reflective markers attached to the left and right anterior superior iliac spines, and the mid-point of left and right posterior superior iliac spines (Eames, et al., 1999). The maximum displacements of COM opposite to the direction of perturbation(S_{max1}), time to reach S_{max1} since the onset of perturbation (T_{peak}), displacements of COM when reaching a new equilibrium position (S_{max2}), and duration between S_{max1} and S_{max2} (T_{rec}) were calculated (Figure 4-3). S_{max2} was identified at a point in the displacement-time curve at which the velocity of the COM movement approached the velocity of the perturbation floor and became steady thereafter. Due to the continued movement of the perturbation floor, the COM relative to the ground continued to move at a speed of 50mm/s after reaching S_{max2}.

3.3.5 Statistical analysis

Statistical analysis was conducted using the Statistical Package for Social Science (SPSS, version 22.0, IBM Corporation, Armonk, NY, USA) to analyze the effects of the two factors (system and perturbation direction) on each COM parameter. There were two levels in system factor (turned on and off) and four levels in perturbation direction factor (forward, backward, left and right). Two-way repeated measures ANOVA were performed to examine the main and interaction effects of the two factors on S_{max1}, S_{max2}, T_{peak} and T_{rec}. If significant interaction effect was found, the simple effect of system (turned-on and turned-off) at each four directions of perturbations, and the simple effect of perturbation direction (forward, backward, left and right) at each condition of system would be further analyzed. If significant interaction effect was not found but significant main effect of either system or perturbation direction was found, post hoc pairwise comparisons with Bonferroni corrections would be conducted to further understand where the significant differences among the levels of the factor laid, while collapsing over levels of the other factor. The level of significance was set as 0.05.

3.4 Improving gait and plantar foot loading using vibrotactile biofeedback system

3.4.1 Subjects

Convenience sampling approach was used to recruit eight hemiplegic patients in this study. All subjects were referred by a local Physiotherapy Clinic where they received trainings for treating dynamic balance disorder. They were unilateral hemiplegia caused by cerebral hemisphere stroke, living in a community-based setting, able to walk independently without walking assisting devices for more than 10 meters, and with good cooperation and compliance in gait analysis. All subjects were able to understand and follow the experimental instructions. They did not have fixed deformities over the ankle joint complex, but had rearfoot varus deformity at the affected side which could be corrected by external corrective forces, as evaluated by a Certified Orthotist following standard procedures specified in (Magee, 2014). Subjects who had other peripheral or central nervous system dysfunctions, active inflammatory or pathologic changes in the joints of lower extremities in the previous 6 months, and active medical problems were not included in this study.

All subjects have signed written-informed consents before participating in the study. Ethical approval was granted from the Human Subjects Ethics Sub-committee of The Hong Kong Polytechnic University (HSEARS20140211002). This study was registered on the Chinese Clinical Trial Registry (ChiCTR-IPB-15006530) and the Hong Kong Clinical Trial Registry (HKCTR-1853).

3.4.2 Design and setting of the vibrotactile biofeedback system

The vibrotactile biofeedback system consisted of two separate components of 1) a plantar force acquisition unit (5.5cm×2.5cm×1.7cm) and 2) a vibration feedback unit (4.5cm×2.2cm×1.5cm) that were both attached to the subjects' affected side (Figure 3-6). The plantar force acquisition unit consisted of two thin-film force sensors (A301, Tekscan Co., Ltd, USA), a microprocessor unit (ATMEGA328P, Atmel Co., Ltd, USA), a wireless transmitter module (HC-05, HC information Tech. Co., Ltd, China), and a rechargeable lithium-ion battery (FLB-16340-880-PTD, UltraFire Co., Ltd, China). The vibration feedback unit consisted of one vibrator (XY-B1027-DX, Xiongying electronics Co., Ltd, China), a wireless receiver module (HC-05, HC information Tech. Co., Ltd, China), and a rechargeable lithium-ion battery (FLB-16340-880-PTD, UltraFire Co., Ltd, China).

The two thin-film force sensors (25.4mm×14mm×0.203mm, sensing area 9.53mm diameter each) were attached by adhesive tapes to the bottom of a piece of 2mm-thick flat insole, which was made of a medium firm (30-35 Shore A Hardness) ethylene-vinyl acetate (EVA, Foot Specialist Footcare & Products Co. Ltd, HK). The same 2mm-thick flat insole was also put underneath the unaffected foot. The sensors were located at the first and fifth metatarsal heads of the affected side, verified by a certified orthotist, to evaluate the medial and lateral plantar force. One vibrator (10mm diameter×2.7mm height) was fastened by an elastic strap at the subject's wrist of the affected side. The vibrator was set to produce full magnitude of vibration when the real-time averaged forces measured at the first metatarsal head was less than 50% of that measured at the fifth metatarsal head at the same walking step. The vibrator was not activated in other conditions. Pilot studies showed that other ratios (25% and 100%) did not appear to provide appropriate reminder on foot inversion to subjects.

The plantar force acquisition unit analysed the force data at foot soles and delivered control signals to the vibration feedback unit via Bluetooth communication. The vibration frequency and strength of the vibrator were 220 Hz and 1 G, respectively, which were found to be highly recognizable by humans (Kyung, et al., 2005). All subjects were assessed before the experiment to ensure that they could perceive the vibration of the vibrators. Both sampling frequency and transmission rate of the device were 10 Hz. The rechargeable batteries enabled the entire system to function for 24 hours continuously. The entire biofeedback system weighed less than 70 grams.

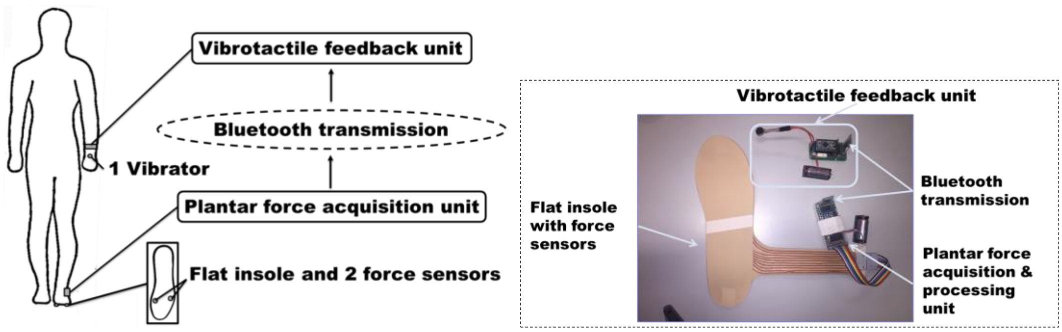


Figure 3-6 The vibrotactile system, consisted of a plantar force acquisition unit, a vibrotactile feedback unit and two force sensors attached to a flat insole

3.4.3 Experimental procedure

This study was conducted in a university locomotion laboratory. All subjects were explained how the biofeedback system functioned prior to the experiment. They were informed that the vibration of the vibrator corresponded to the excessive foot inversion at the affected lower limb. They were instructed to put more loading at the medial forefoot for the following step when the vibrator was activated. During the practicing period, the subjects were instructed to shift weight between the medial and lateral foot and experience the vibrations, to ensure that they understood the function of this system and were capable of using the feedback vibrations as a training aid. Subjects were given 10 minutes to get familiar with the new biofeedback system (Boonsinsukh, et al., 2011).

Gait analysis was then conducted over-ground on all subjects. Each subject was instructed to walk along a smooth, horizontal 7m-long walkway at a comfortable speed. The sequence of two testing conditions was randomly assigned to each subject: 1) with the biofeedback system turned-off; and 2) with the biofeedback system turned-on. Subjects were blinded from the experimental condition during the experiment. Same instructions were given to the subjects as to the actions they should take when there was a vibration feedback. Each testing condition was repeated 5 times consecutively for each subject. Between two conditions, each subject was given a 10-minute rest to eliminate the possible effect of fatigue. If subjects verbally reported any kinds of discomfort during the experiment, the experiment would be stopped with the situation being recorded. Two complete gait cycles in the middle of each walking trial (containing a total of 7-9 walking steps) were extracted to avoid the variable steps associated with initiation and termination of gait (C. Chen, et al., 2007). This strategy also enabled to collect data of one full gait cycle for both affected and unaffected sides, as well as the sufficient number of strides that are required to achieve high reliability when analyzing gait parameters (Hollman, et al., 2010). During the experiment, all subjects wore the same shoe model (TFGF81722/TFGF82722, TOREAD®, TOREAD Co., Ltd, China) provided by the researchers.

3.4.4 Equipment and outcome measures

An in-shoe plantar pressure measurement system (novel pedar-x system, Pedar™, novel GmbH, Munich, DE), which was shown to have high repeatability (Putti, et al., 2007) and validity (Price, et al., 2016), was sampling at 50 Hz and used to measure the plantar pressure distribution during walking in 2 experimental conditions. Before and after data collection of each subject, the insoles were checked using the Trublu® calibrating system to ascertain that all sensors produced accurate and reproducible absolute values (Ramanathan, et al., 2010). The plantar foot was divided into six regions: medial forefoot, lateral forefoot, medial midfoot, lateral midfoot, medial rearfoot, and lateral rearfoot (Figure 3-). For all subjects, the forefoot, midfoot, and rearfoot regions comprised the first 35%, the following 35%, and the remaining 30% of the foot length, respectively.

An eight-camera three-dimensional (3D) motion capture system (Vicon Nexus 1.8.1, Vicon Nexus^{TM}, Vicon Motion Systems Ltd., UK), sampling at 100 Hz, was used to measure the 3D kinetic data in subjects during over-ground walking in 2 experimental conditions. A built-in lower limb marker set (Plug-in Gait Model) was adopted, in which 15 infra-red reflective markers were affixed to both sides at the heels, foot dorsum, lateral malleolus, lateral femoral condyles, middle of thighs/shanks, anterior superior iliac spines, and iliac crest. Spatial-temporal and kinematic data were measured and analyzed using the Plug-in Gait Model in Vicon system. The gait data were low-pass filtered using a 4th order Butterworth filter with a 6 Hz cut-off frequency.

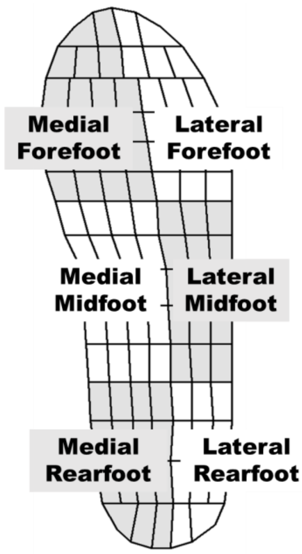


Figure 3-7 Foot regions: medial forefoot, lateral forefoot, medial midfoot, lateral midfoot, medial rearfoot, and lateral rearfoot

3.4.5 Statistical analysis

The parameters included for analysis were the average and peak plantar pressure parameters at each of the six plantar foot regions, total foot-floor contact area, stance time, swing time, stride time, walking speed, and peak lower limb joint angles during both stance and swing phases. Statistical analysis was performed using Statistical Package for Social Sciences (SPSS, version 22.0, IBM Corporation, Armonk, NY, USA). Two-way repeated measures ANOVA was performed prior to examine the main effect of “interventions” (with vs. without biofeedback), the main effect of “limbs” (affected vs. unaffected side), and the interaction effect between two variables (interventions × limbs) in all measured parameters among all subjects. If significant interaction effect was found in ANOVA, pair-wise comparisons of “interventions” (with vs. without biofeedback) and “limbs” (affected vs. unaffected limb) were performed by using paired t-test with Bonferroni corrections. The level of significance was set at 0.05.

3.5 Improving postural stability by orthopaedic insoles

3.5.1 Subjects

Convenience sampling approach was used to recruit fourteen healthy elderly subjects aged 65 years or over in this study. Subjects should be healthy, fully independent, living in a community-based setting, and capable of ambulation without walking assisting devices. Subjects should not have pes planus, pes cavus, hallux valgus, hammer toes and foot pain, as assessed by a certified orthotist. In addition, subjects should not have neurological or vestibular disorders, diabetes, severe cardiovascular or pulmonary diseases, or previous history of foot injury. All subjects should be able to follow the instructions and procedures of the research protocol.

Subjects who consented to participate in the study were scheduled for the testing and orthotic fitting. Ethical approval was granted from the Human Subjects Ethics Sub-committee of The Hong Kong Polytechnic University (HSEARS20140211002). This study was registered on the Chinese Clinical Trial Registry (ChiCTR-IPB-15006530) and the Hong Kong Clinical Trial Registry (HKCTR-1853).

3.5.2 Design of the orthopaedic insole

The insoles were commercially available full-length insoles with medial arch supports and heel cups (Foot Specialist Footcare & Products Co. Ltd, HK) (Figure 3-8), which were originally targeted to treat flat foot, plantar fasciitis and metatarsalgia. There were 3 different medial arch supports (10, 15 and 20 mm), which corresponded to the length of the insoles. A metatarsal pad (Foot Specialist Footcare & Products Co. Ltd, HK), made of medium firm (30-35 Shore A Hardness) ethylene-vinyl acetate (EVA), was added to the prefabricated insoles just proximal to the 2nd and 3rd metatarsal heads. Three different heights of metatarsal pads (4, 6 and 8 mm) were used. The highest possible metatarsal pad without giving discomfort was selected for each subject. The insoles and metatarsal pads were selected and adjusted by a certified orthotist.

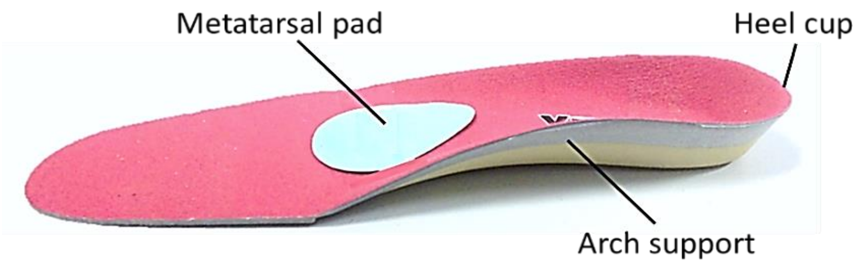


Figure 3-8 Design of the orthopedic insole, consisted of a metatarsal pad, an arch support, and a heel cup

3.5.3 Experimental procedure

A Romberg test was conducted to assess the static balance of all subjects following the standard procedures (Agrawal, et al., 2011). During the experiment, each subject was instructed to stand quietly on a force platform, with arms crossed resting on the opposite shoulders and eye-closed. Subjects were instructed to stand in the center of the force platform with the medial sides of the foot touching each other, following the protocols of Romberg test. The insoles were fixed in the same position on the force platform by adhesive tape for the insole condition. Balance performance was assessed under three experimental conditions: 1) bare feet, without socks or insoles (condition 1), 2) with thick socks but without insoles (condition 2); and 3) with both thick socks and insoles (condition 3). The socks were used to simulate the reduced plantar sensory inputs (Y.-J. Tsai & Lin, 2013). In each testing trial, subjects were instructed to stand as still as possible for 90 seconds. Such testing methods and duration were shown to have high test-retest reliability (Ruhe, et al., 2010). Each test condition was repeated 3 times consecutively for each subject. Between each condition, each subject was given a 10-minute rest to eliminate the possible effects of fatigue. During the experiment, the testing sequence of the three different experimental conditions was randomized, with each experimental condition been coded.

3.5.4 Equipment and outcome measures

3.5.4.1 Force platform

A force platform (OR6, Advanced Mechanical Technology, Inc., Watertown, MA, USA) sampling at 1000Hz was used to measure the relative location of COP signals to the coordinate origin of force platform. More details can be found in research method of Study 1, i.e. section 3.2.4.

3.5.4.2 5.07/10-g Semmes-Weinstein Monofilament

The 5.07/10-g Semmes-Weinstein monofilament (Connecticut Bio-instruments Inc. NY, USA) was used to assess the planter touch-pressure sensation of subjects' feet with and without the sock intervention (Figure 3-4), following the standard testing procedures as specified in (Slater, et al., 2014). More details can be found in research method of Study 1, i.e. section 3.2.4.

3.5.5 Statistical analysis

Statistical analysis was performed using the Statistical Package for Social Sciences (SPSS, version 21.0, IBM Corporation, Armonk, NY, USA). Wilcoxon Signed-Ranks Test was used to compare the monofilament score with and without the sock intervention. One-way repeated ANOVA with Bonferroni corrections was performed to study if significant differences existed in all measured COP parameters among the three conditions in all fourteen subjects. The level of significance was set as 0.05.

CHAPTER 4. RESULTS

4.1 Chapter summary

After introducing the research methods of each study in the previous chapter, this chapter summarizes and reports the results of each study, including studies on effects of biofeedback systems on static postural balance during standing (Study 1), effects of biofeedback systems on postural balance while subjects standing on a perturbation floor (Study 2), effects of biofeedback systems on plantar foot loading and lower-limb motor control during walking (Study 3), and effects of orthopaedic insoles on static postural balance (Study 4). The interpretation and discussion of the results are provided in the next chapter.

4.2 Effects of vibrotactile biofeedback system on postural stability

4.2.1 Subject information

Fifteen older subjects (six females and nine males) and fifteen young subjects (seven females and eight males) participated in the study. Table 4-1 describes the subject characteristics, including age, gender, height and weight.

Table 4-1 Subject information (effects of vibrotactile biofeedback system)

Mean ± SD	Older subjects (n=15)	Young subjects (n=15)
Age (years)	70.1 ± 3.7	26.7 ± 2.9
Gender	6F + 9M	7F + 8M
Height (cm)	160.6 ± 7.6	167.6 ± 5.8
Weight (kg)	61.7 ± 11.4	61.4 ± 11.2

4.2.2 Monofilament score

As shown in Table 4-2, the average monofilament score decreased significantly from 2.9 to 1.1 in elderly subjects (P<0.001), and decreased significantly from 3.0 to 1.0 in young subjects while wearing socks (P<0.001).

Table 4-2 Comparison of monofilament score without and with the sock-wearing intervention (effects of vibrotactile biofeedback system)

Monofilament score (Mean ± SD)							
Elderly subjects (n=15)				Young subjects (n=15)			
Position	Without	With	P-value	Position	Without	With	P-value
Hallux	3.0 ± 0.0	1.1 ± 0.4	<0.001	Hallux	3.0 ± 0.0	1.0 ± 0.0	<0.001
1st metatarsal head	2.9 ± 0.3	1.0 ± 0.0	<0.001	1st metatarsal head	3.0 ± 0.0	1.0 ± 0.0	<0.001
5th metatarsal head	2.7 ± 0.8	1.0 ± 0.0	<0.001	5th metatarsal head	3.0 ± 0.0	1.0 ± 0.0	<0.001
Average	2.9 ± 0.4	1.1 ± 0.1	<0.001	Average	3.0 ± 0.0	1.0 ± 0.0	<0.001

Higher monofilament score indicates better plantar pressure sensation

4.2.3 COP displacement

The numerical results of COP displacement in older and young subjects during quite standing are summarized in Table 4-3, Table 4-4, and Table 4-5. All the COP parameters, including mean distance, resultant distance, mean velocity, sway area and planar diameter, increased significantly in young and elder subjects while wearing socks (P<0.017). For the young subjects, the vibrotactile biofeedback system reduced the mean distance, and range of the COP in ML and AP directions significantly by 14.7%, 12.5% and 11.5%, respectively (P<0.017), with eyes closed and socks. For the older adult, the biofeedback system decreased the mean distance, range of the COP in ML and AP directions significantly by 10.7%, 23.6% and 15.9%, respectively (P<0.017). No significant difference was found between the baseline and the condition of using biofeedback system under experimentally reduced tactile sensitivity (condition 1 vs. 3).

The typical examples of the COP trajectory in all three conditions in one elderly subject and one young subject are shown in Figure 4-1 and Figure 4-2, respectively. When comparing the area of COP excursion without and with wearing socks, as shown in Figure 4-1 A and B, and Figure 4-2 A and B, the socks intervention obviously increased the excursions of postural sway, while the excursions of COP was reduced when adding the biofeedback as shown in Figure 4-1 C and Figure 4-2 C.

Table 4-3 Comparison of COP parameters in 3 different conditions in young and elderly subjects (effects of vibrotactile biofeedback system, two-way mixed ANOVA)

Measurements of COP (mean ± SD)	Young and elderly subjects (n=30)			Two-way mixed ANOVA (p-value)		
	No socks, biofeedback system turned-off (condition 1)	With socks, biofeedback system turned-off (condition 2)	With socks, biofeedback system turned-on (condition 3)	Main effect		Interaction Effect
				Conditions	Groups	
MDIST (mm)	6.68±1.89	8.30±1.94	7.24 ± 2.11	<0.001	1.000	0.122
RDIST (mm)	7.67±2.18	9.57±2.29	8.26±2.48	<0.001	0.965	0.121
MVELO (mm/s)	0.074±0.021	0.093±0.022	0.086±0.034	<0.001	1.000	0.043
AREA-CC (mm^2)	568.12±383.74	876.52±516.33	660.86±516.28	0.010	0.851	0.209
AREA-CE (mm^2)	550.47±392.19	861.38±490.55	668.10±500.98	0.002	0.761	0.117
PD-CC (mm)	25.69±7.38	32.19±7.93	27.50±8.53	<0.001	0.930	0.090
PD-CE(mm)	25.20±7.58	31.99±7.85	27.73±8.37	<0.001	0.822	0.036
ML Range of COP(mm)	34.44±11.60	46.91±11.41	38.32±9.38	<0.001	0.741	0.005
AP Range of COP(mm)	38.40±10.00	45.84±9.96	39.60±12.09	<0.001	0.732	0.919

RD: resultant distance, which is the vector distance from the mean COP to each pair of points;
MDIST: mean distance, represents the average distance from the mean COP;
RDIST: RMS distance from the mean COP;
MVELO: mean velocity, which is the rate of mean distance of COP;
AREA-CC: the 95% confidence circle area, which is the area of a circle with a radius equal to the one-sided 95% confidence limit of the RD time series;
AREA-CE: the 95% confidence ellipse area, which is the area of the 95% bivariate confidence ellipse and is expected to enclose approximately 95% of the points on the COP path;
PD-CC: Planar Diameter of the 95% confidence circle area, the maximum distance between any two points of the circle that includes almost 95% of the points on the COP path;
PD-CE: Planar Diameter of the 95% confidence ellipse area, the maximum distance between any two points of the 95% confidence ellipse area.

Table 4-4 Post-hoc comparison of COP parameters in 3 different conditions in elderly subjects (effects of vibrotactile biofeedback system)

	Elderly subjects (n=15)			Condition 2 minus condition 1		Condition 3 minus Condition 2	
Measurements of COP (mean ± SD)	No socks, biofeedback system turned-off (condition 1)	With socks, biofeedback system turned-off (condition 2)	With socks, biofeedback system turned-on (condition 3)	Difference	p-value	Difference	p-value
MDIST (mm)	6.26 ± 0.96	8.15 ± 1.39	7.28 ± 1.28	+30.1%	<0.001	-10.7%	0.004
RDIST (mm)	7.19 ± 1.08	9.40 ± 1.54	8.21 ± 1.37	+30.7%	<0.001	-12.7%	<0.001
MVELO (mm/s)	0.07 ± 0.01	0.09 ± 0.02	0.08 ± 0.01	+30.1%	<0.001	-10.7%	0.004
AREA-CC (mm^2)	472.54 ± 131.86	819.24 ± 271.56	598.77 ± 183.17	+73.4%	<0.001	-26.9%	<0.001
AREA-CE (mm^2)	435.67 ± 143.28	809.72 ± 299.01	621.28 ± 213.02	+85.9%	<0.001	-23.3%	0.002
PD-CC (mm)	24.11 ± 3.62	31.65 ± 5.05	27.02 ± 4.24	+31.2%	<0.001	-14.6%	<0.001
PD-CE(mm)	23.11 ± 3.97	31.48 ± 5.60	27.48 ± 4.79	+36.2%	<0.001	-12.7%	0.001
ML Range of COP(mm)	30.57 ± 8.51	49.27 ± 8.88	37.63 ± 5.56	+61.2%	<0.001	-23.6%	<0.001
AP Range of COP(mm)	37.27 ± 8.39	45.09 ± 7.20	37.93 ± 5.93	+21.0%	0.001	-15.9%	0.002

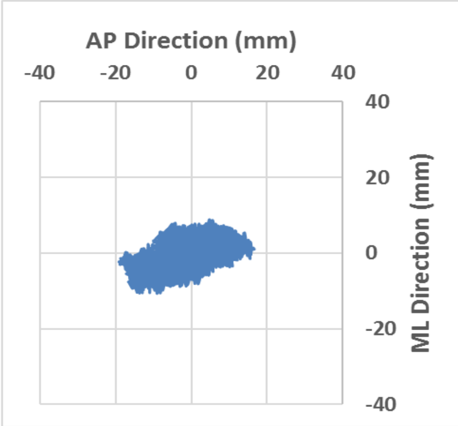
RD: resultant distance, which is the vector distance from the mean COP to each pair of points;
MDIST: mean distance, represents the average distance from the mean COP;
RDIST: RMS distance from the mean COP;
MVELO: mean velocity, which is the rate of mean distance of COP;
AREA-CC: the 95% confidence circle area, which is the area of a circle with a radius equal to the one-sided 95% confidence limit of the RD time series;
AREA-CE: the 95% confidence ellipse area, which is the area of the 95% bivariate confidence ellipse and is expected to enclose approximately 95% of the points on the COP path;
PD-CC: Planar Diameter of the 95% confidence circle area, the maximum distance between any two points of the circle that includes almost 95% of the points on the COP path;
PD-CE: Planar Diameter of the 95% confidence ellipse area, the maximum distance between any two points of the 95% confidence ellipse area.

Table 4-5 Post-hoc comparison of COP parameters in 3 different conditions in young subjects (effects of vibrotactile biofeedback system)

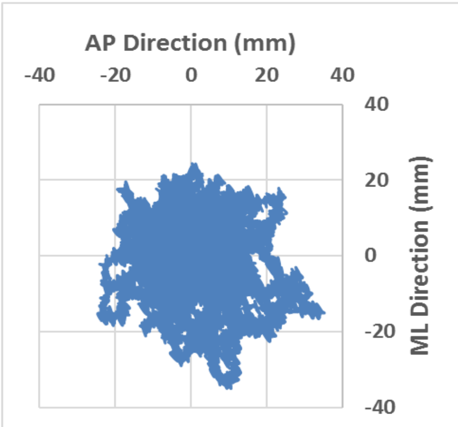
	Young subjects (n=15)			Condition 2 minus condition 1		Condition 3 minus Condition 2	
Measurements of COP (mean ± SD)	No socks, biofeedback system turned-off (condition 1)	With socks, biofeedback system turned-off (condition 2)	With socks, biofeedback system turned-on (condition 3)	Difference	p-value	Difference	p-value
MDIST (mm)	7.10 ± 2.47	8.45 ± 2.41	6.46 ± 1.89	+19.1%	<0.001	-14.7%	0.002
RDIST (mm)	8.14 ± 2.87	9.74 ± 2.91	7.43 ± 2.29	+19.6%	<0.001	-14.6%	0.002
MVELO (mm/s)	0.08 ± 0.03	0.09 ± 0.03	0.07 ± 0.02	+19.1%	<0.001	-14.7%	0.002
AREA-CC (mm^2)	663.69 ± 517.75	933.80 ± 686.62	546.85 ± 453.68	+40.7%	0.001	-22.6%	0.005
AREA-CE (mm^2)	665.27 ± 519.47	913.04 ± 635.09	536.93 ± 435.10	+37.2%	0.001	-21.7%	0.007
PD-CC (mm)	27.27 ± 9.71	32.74 ± 10.20	24.92 ± 8.08	+20.1%	<0.001	-14.5%	<0.001
PD-CE(mm)	27.30 ± 9.69	32.50 ± 9.78	24.77 ± 7.84	+19.0%	<0.001	-13.9%	0.003
ML Range of COP(mm)	38.31 ± 13.20	44.55 ± 13.38	34.86 ± 12.93	+16.3%	0.001	-12.5%	0.001
AP Range of COP(mm)	39.52 ± 11.57	46.60 ± 12.34	37.39 ± 11.11	+17.9%	<0.001	-11.5%	0.086

RD: resultant distance, which is the vector distance from the mean COP to each pair of points;
MDIST: mean distance, represents the average distance from the mean COP;
RDIST: RMS distance from the mean COP;
MVELO: mean velocity, which is the rate of mean distance of COP;
AREA-CC: the 95% confidence circle area, which is the area of a circle with a radius equal to the one-sided 95% confidence limit of the RD time series;
AREA-CE: the 95% confidence ellipse area, which is the area of the 95% bivariate confidence ellipse and is expected to enclose approximately 95% of the points on the COP path;
PD-CC: Planar Diameter of the 95% confidence circle area, the maximum distance between any two points of the circle that includes almost 95% of the points on the COP path;
PD-CE: Planar Diameter of the 95% confidence ellipse area, the maximum distance between any two points of the 95% confidence ellipse area.

A. COP trajectory-no socks, biofeedback system turned-off



B. COP trajectory-with socks, biofeedback system turned-off



C. COP trajectory-with socks, biofeedback system turned-on

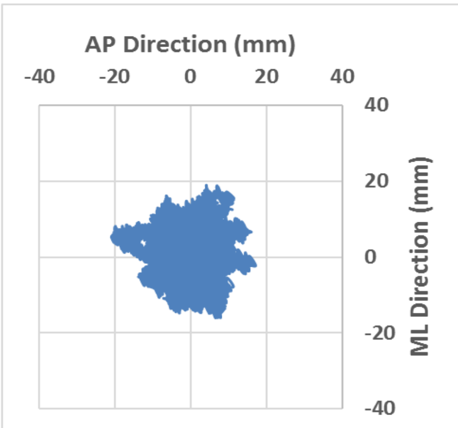
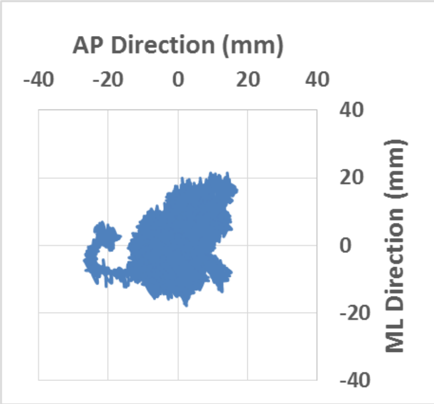
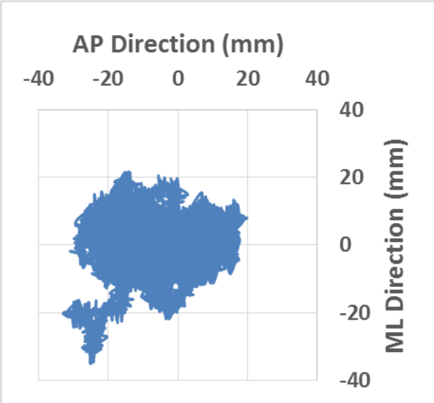


Figure 4-1 COP displacements in 3 different conditions in one elderly subject (effects of vibrotactile biofeedback system)

A. COP trajectory-no socks, biofeedback system turned-off



B. COP trajectory-with socks, biofeedback system turned-off



C. COP trajectory-with socks, biofeedback system turned-on

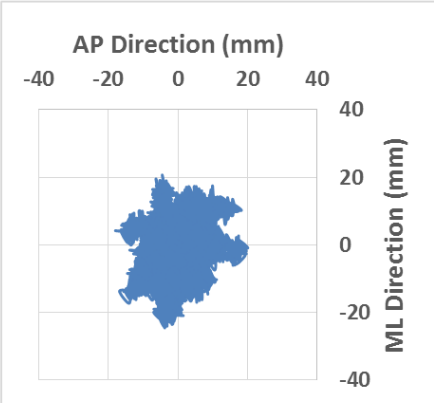


Figure 4-2 COP displacements in 3 different conditions in one young subject (effects of vibrotactile biofeedback system)

4.3 Effects of vibrotactile biofeedback system on postural balance while subjects under balance perturbation

4.3.1 Subject information

Ten healthy young adults (5 males & 5 females, aged 21.2 ± 1.0 years, height 166.9 ± 7.39cm, weight 55.3 ± 8.0kg), without medical conditions affecting balance ability, participated in the study. The foot condition and location of force sensors was checked and determined by a certified orthotist. All subjects have signed written-informed consents before participating in the study.

4.3.2 Center of mass displacement and reaction time for balance recovery

Figure 4-3 shows the typical COM displacement-time patterns in each testing condition. As the perturbation floor moved, the COM shifted to the opposite direction of the perturbation and reached S_{max1}. The COM then moved towards the direction of floor movement, reaching a new equilibrium position S_{max2}. None of the subjects stepped out of base of foot support in response to the perturbation.

No interaction effects between system and perturbation direction was found in each of the four COM parameters. Significant main effect of system was found in S_{max1} (p=0.010) and T_{peak} (p=0.015), with the S_{max1} and T_{peak} significantly reduced upon receiving the biofeedback cues. Specifically, the reductions of S_{max1} upon using the system in forward, backward, left and right perturbation were 12.6%, 11.8%, 12.4%, and 12.5%, respectively. Large average reductions of S_{max2} upon using the system were noted in forward, backward, left and right perturbation with 43.0%, 29.9%, 13.0%, and 27.5% drops, respectively, although significant differences were not reached (Table 4-6).

Significant main effect of perturbation direction was found in T_{peak} ($p<0.001$) and T_{rec} ($p=0.003$). Post hoc pairwise comparisons further found that the T_{peak} during backward perturbation was significantly longer than that of the forward ($p=0.036$), left ($p<0.001$) and right ($p=0.002$) perturbation, and the T_{rec} during left perturbation was significantly shorter than that of the forward ($p=0.021$) and backward ($p=0.025$) perturbation (Table 4-6).

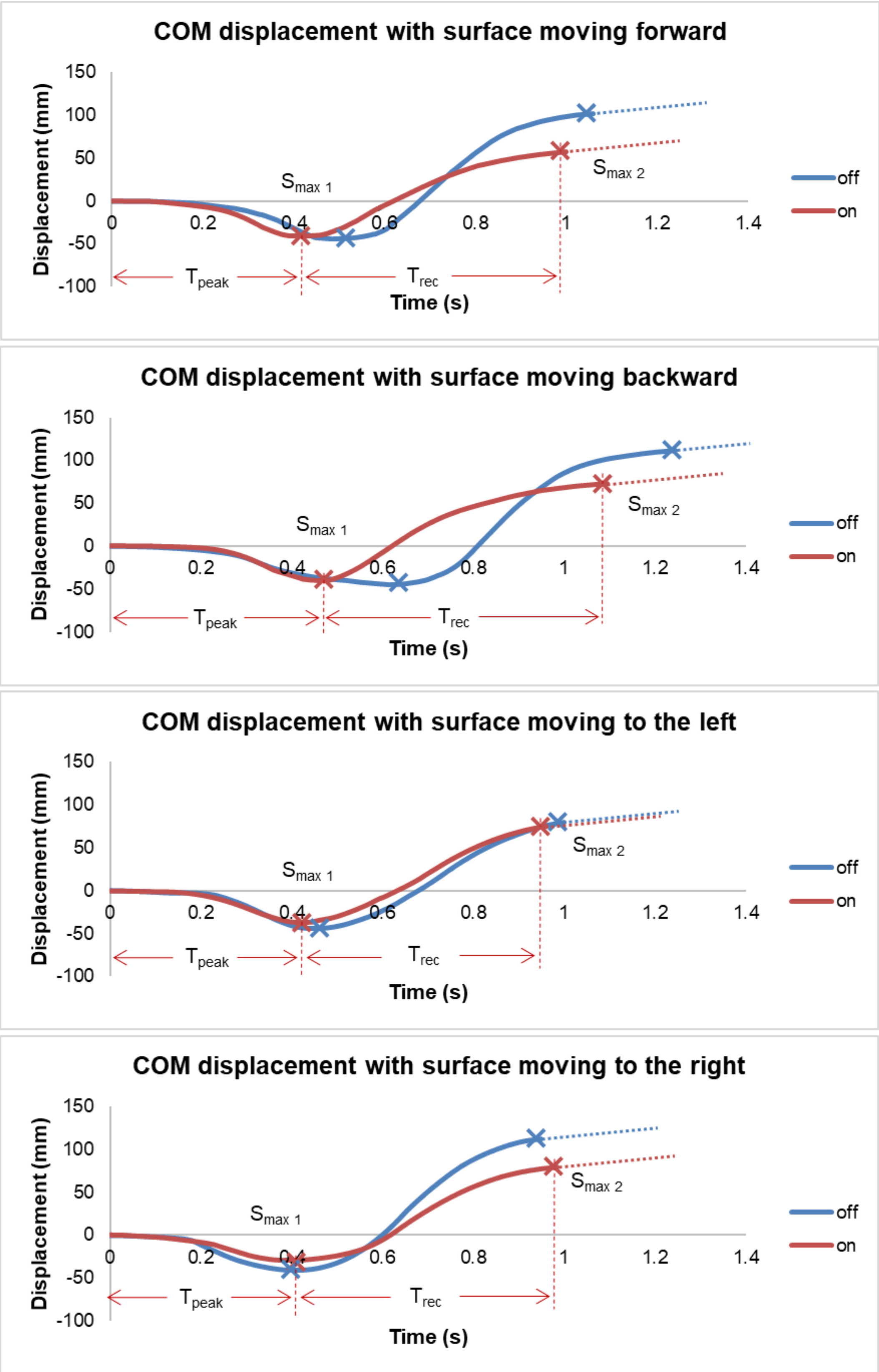


Figure 4-3 Example of COM displacements in 8 experimental conditions in one subject

Table 4-6 Comparison of COM parameters with and without the biofeedback provided (n=10)

Perturbation Direction	Parameters	Mean ± SD	
		Biofeedback Turned-on	Biofeedback Turned-off
Forward	S_{max1} (mm) *	36.5 ± 11.3	41.7 ± 12.8
	S_{max2} (mm)	54.2 ± 21.7	95.0 ± 41.1
	T_{peak} (ms) *, #	442.0 ± 95.7	522.0 ± 90.3
	T_{rec} (ms) #	641.0 ± 80.1	660.0 ± 90.3
Backward	S_{max1} (mm) *	40.0 ± 10.0	45.3 ± 7.9
	S_{max2} (mm)	66.0 ± 29.6	94.2 ± 44.3
	T_{peak} (ms) *, #	571.0 ± 101.4	608.0 ± 86.9
	T_{rec} (ms) #	685.0 ± 101.9	679.0 ± 92.2
Left	S_{max1} (mm) *	36.5 ± 11.7	41.7 ± 12.8
	S_{max2} (mm)	85.5 ± 30.6	98.3 ± 39.3
	T_{peak} (ms) *, #	411.0 ± 130.3	421.0 ± 77.1
	T_{rec} (ms) #	514.0 ± 130.0	538.0 ± 119.8
Right	S_{max1} (mm) *	34.2 ± 14.4	39.1 ± 15.3
	S_{max2} (mm)	78.1 ± 31.3	107.8 ± 40.7
	T_{peak} (ms) *, #	412.0 ± 110.1	405.0 ± 114.0
	T_{rec} (ms) #	558.0 ± 128.0	551.0 ± 137.3

Notes:

*: Significant main effect of device found.

#: Significant main effect of perturbation direction found.

4.4 Effects of vibrotactile biofeedback system on gait and plantar foot loading

4.4.1 Subject information

A total of eight patients (seven males and one female), with an average age of 53.5 years, participated in the study (Table 4-7). The causes of the stroke in these patients were ischemic in six and haemorrhage in two patients. The average duration since the onset of stroke was 3.8 years. Two subjects were hemiplegic at the left sides and the remaining six were at the right sides. The foot plantar-flexion during swing phase was observed in seven patients. None of the subjects verbally reported any discomfort related to the use of the biofeedback during the experiment. The following shows the significant changes in gait variables and plantar pressure distribution upon using the biofeedback.

Table 4-7 Subject information

S	Age (years)	Gender	Weight (kg)	Height (m)	Pathology of stroke	Duration after stroke (years)	Hemiplegic side	MAS score
1	68	F	54.5	1.63	Ischemic	3	L	1+
2	50	M	73.5	1.78	Ischemic	14	R	1+
3	50	M	61.5	1.81	Ischemic	1	R	1+
4	58	M	70.0	1.80	Hemorrhage	3	R	1+
5	47	M	74.0	1.75	Ischemic	1	L	1+
6	67	M	87.0	1.78	Ischemic	2	R	1+
7	41	M	85.0	1.75	Hemorrhage	4	R	1
8	47	M	73.5	1.71	Ischemic	2	R	1+

MAS: Results of Modified Arshworth Scale for grading the spasticity of ankle plantar-flexor

4.4.2 Plantar pressure distribution and gait parameters

4.4.2.1 Changes in kinematic variables

Without the biofeedback, the peak foot inversion of the affected side during swing phase (angle 25.1 degrees) was 39.1%-significantly more than the unaffected side ($p=0.047$). Turning on the biofeedback system led to a significant 17.2% reduction of peak foot inversion (angle 20.8 degrees) at the affected limb during swing phase ($p=0.012$) (Figure 4-4).

When the biofeedback system was turned off, the unaffected side had significantly more peak knee flexion ($p=0.047$) during swing phase and more peak hip abduction during both stance ($p=0.024$) and swing ($p=0.075$) phases than the affected side. Turning on the biofeedback system significantly reduced the unaffected-side peak knee flexion during swing phase ($p=0.009$) and peak hip abduction during stance phase ($p=0.017$). There was no longer significant difference in peak hip abductions between the 2 legs after turning on the device (Figure 4-4).

4.4.2.2 Changes in plantar-pressure distribution

With the biofeedback system turned off, the total foot-floor contact area in mid-stance phase ($p=0.040$) and the peak plantar pressure at the medial midfoot ($p=0.034$) of the affected limb were significantly lower than those of the unaffected limb. When it was turned on, such contact area ($p=0.001$) and plantar pressure ($p=0.001$) at the affected limb were then significantly increased. There was no longer significant difference in total foot-floor contact area or peak plantar pressure at the medial midfoot between the 2 legs after turning on the device (Figure 4-5 and Figure 4-6).

4.4.2.3 Changes in kinematic variables and plantar-pressure distribution that happened at both the affected and unaffected sides

While turning on the biofeedback system did not significantly change the walking speeds, it significantly increased the stance ($p=0.003$) and stride ($p=0.001$) time, average plantar pressure at medial forefoot ($p=0.001$), peak ($p=0.001$) and average ($p=0.020$) plantar pressure at medial midfoot of both limbs (Figure 4-5 and Figure 4-6).

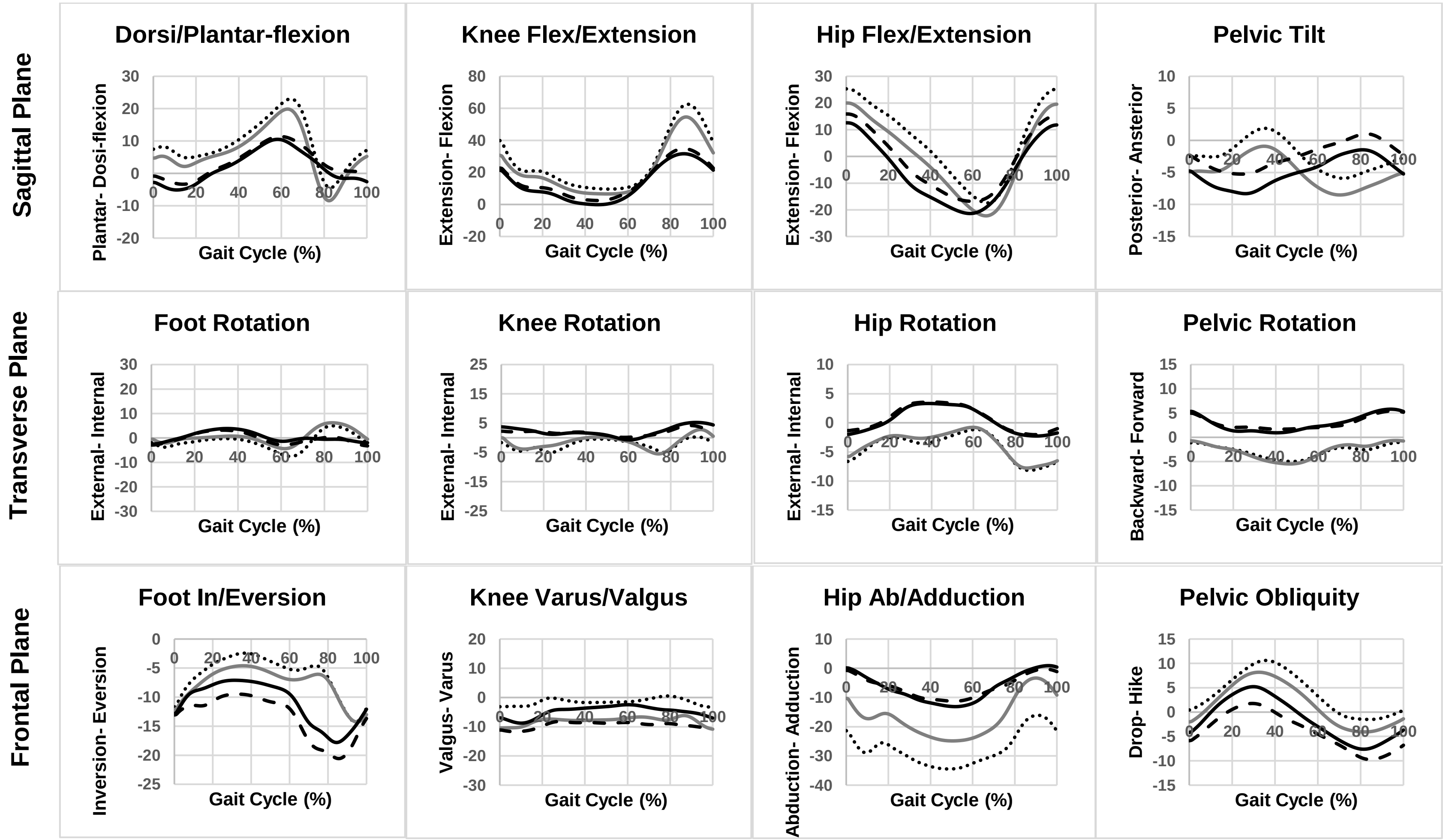


Figure 4-4 Three-dimensional kinematic data during walking with and without biofeedback system turned-on

Affected side-Without biofeedback Affected side-With biofeedback Unaffected side-Without biofeedback Unaffected side-With biofeedback

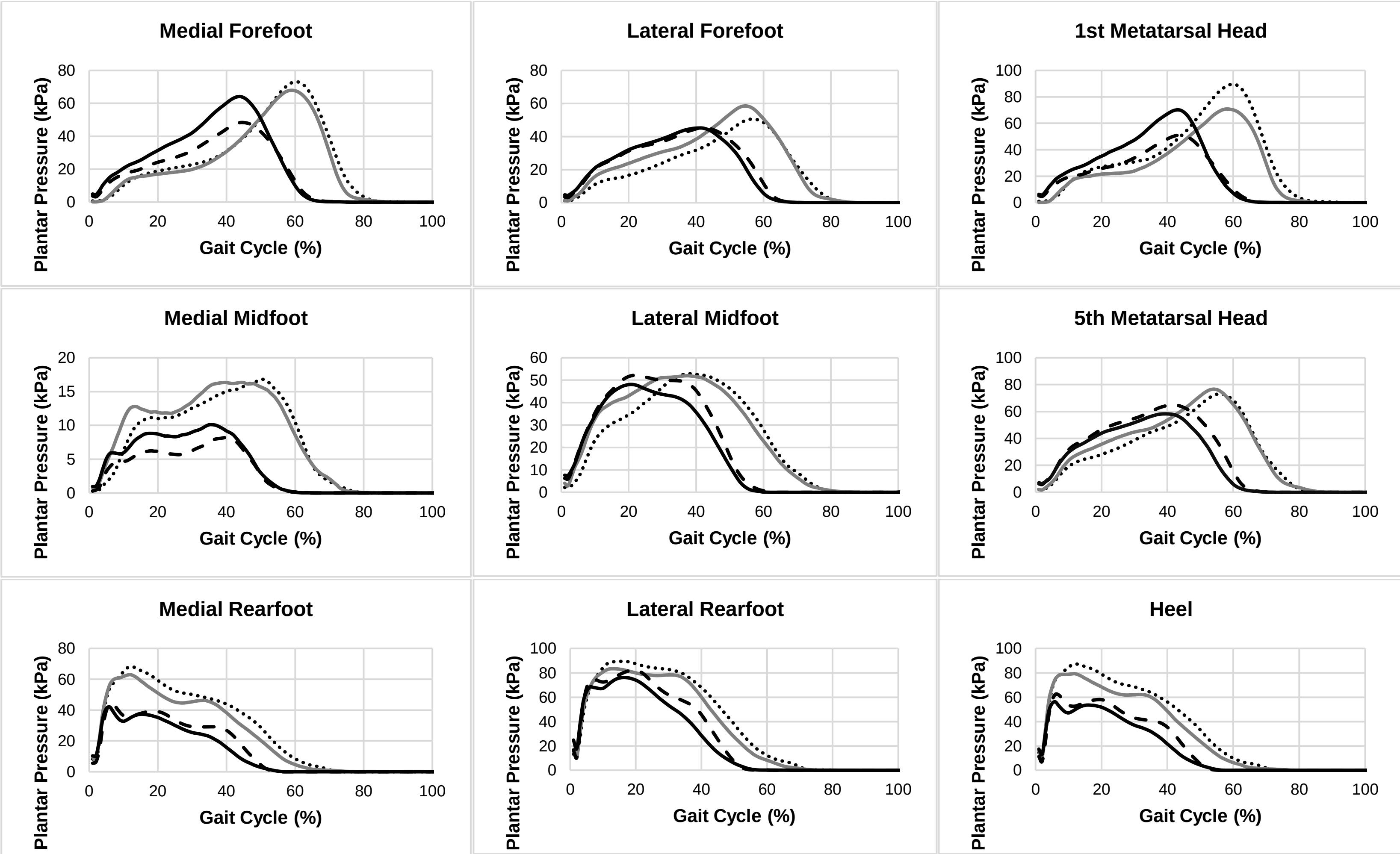


Figure 4-5 Regional plantar pressure pattern in patients with and without biofeedback system turned-on

Affected side-Without biofeedback   Affected side-With biofeedback   Unaffected side-Without biofeedback   Unaffected side-With biofeedback

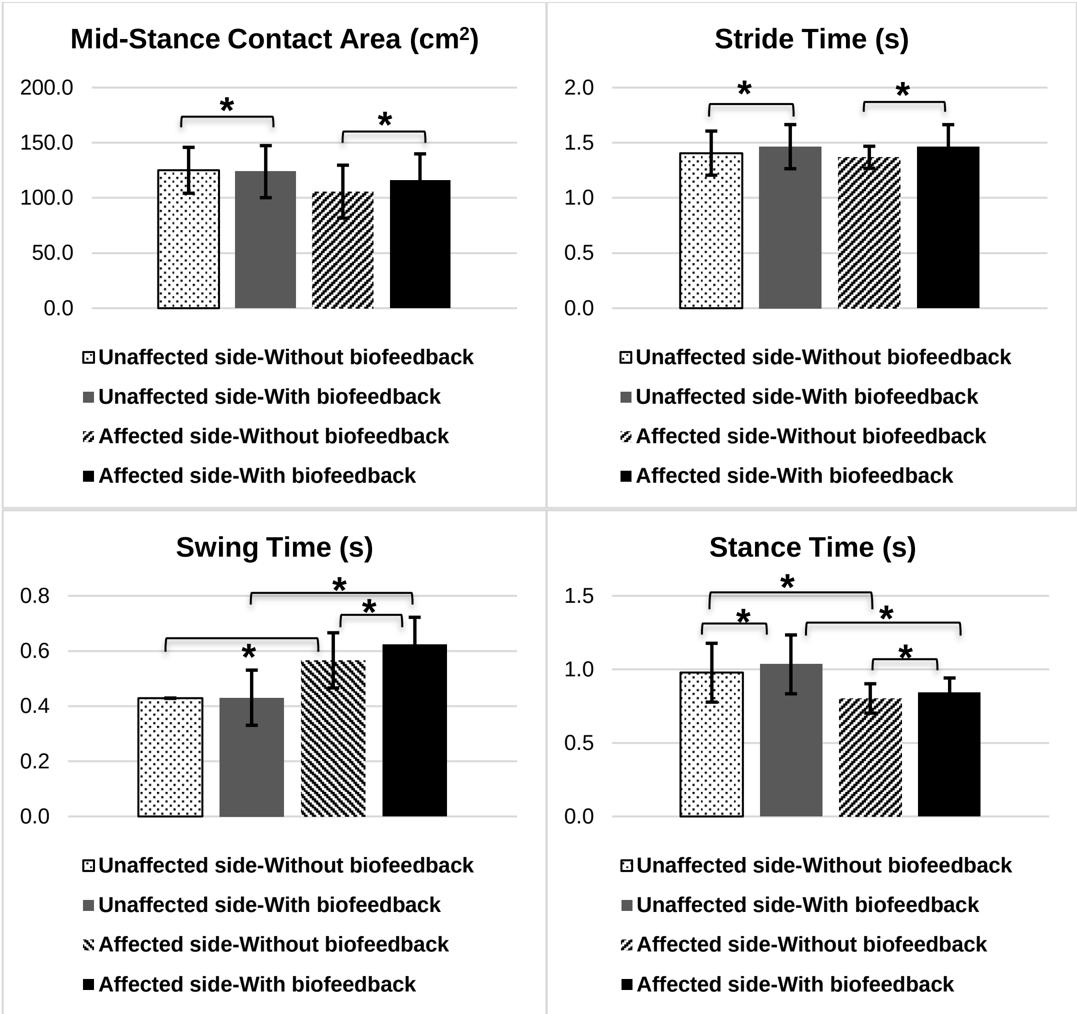


Figure 4-6 Contact area and temporal gait parameters in patients with and without biofeedback system turned-on

*：Significant difference existed.

4.5 Effects of orthopaedic insole on postural stability

4.5.1 Subject information

Fourteen elderly subjects (four females and ten males, aged 70.2±3.4 years, height 162.8±7.9cm, and weight 63.6±10.0kg) participated in the study.

4.5.2 Monofilament score

Table 4-8 shows that the average monofilament score significantly decreased from 2.8 to 1.1 after using the socks ($p<0.001$). The percentage decreases of monofilament score at hallux, 1st metatarsal head, and 5th metatarsal head were 61.9% ($p<0.001$), 63.4% ($p<0.001$), and 61.1% ($p<0.001$), respectively.

Table 4-8 Comparison of monofilament score without and with the sock-wearing intervention (effects of insole)

Monofilament score (Mean ± SD)			
Elderly subjects (n=14)			
Position	Without	With	P-value
Hallux	3.0 ± 0.0	1.1 ± 0.3	<0.001
1st metatarsal head	2.9 ± 0.2	1.1 ± 0.2	<0.001
5th metatarsal head	2.6 ± 0.6	1.0 ± 0.0	<0.001
Average	2.8 ± 0.3	1.1 ± 0.1	<0.001

Higher monofilament score indicates better plantar pressure sensation

4.5.3 COP displacement

The typical examples of the COP trajectory in three conditions of one elderly subject are shown in Figure 4-7. Comparing the COP displacement of without and with the sock intervention, as shown in Figure 4-7 A and B, the socks intervention increased the range of COP obviously. The sway area of COP was then reduced when adding the intervention of wearing orthopedic insoles as shown in Figure 4-7 C.

The numerical results of COP parameters of older adults are demonstrated in Table 4-11. All COP parameters increased significantly while wearing the socks as compared to without socks, and decreased significantly while wearing both socks and insoles among elderly subjects, including mean distance, resultant distance, mean velocity, sway area and planar diameter ($P<0.017$). No significant difference was found between the condition of barefoot and the condition of wearing both socks and insoles.

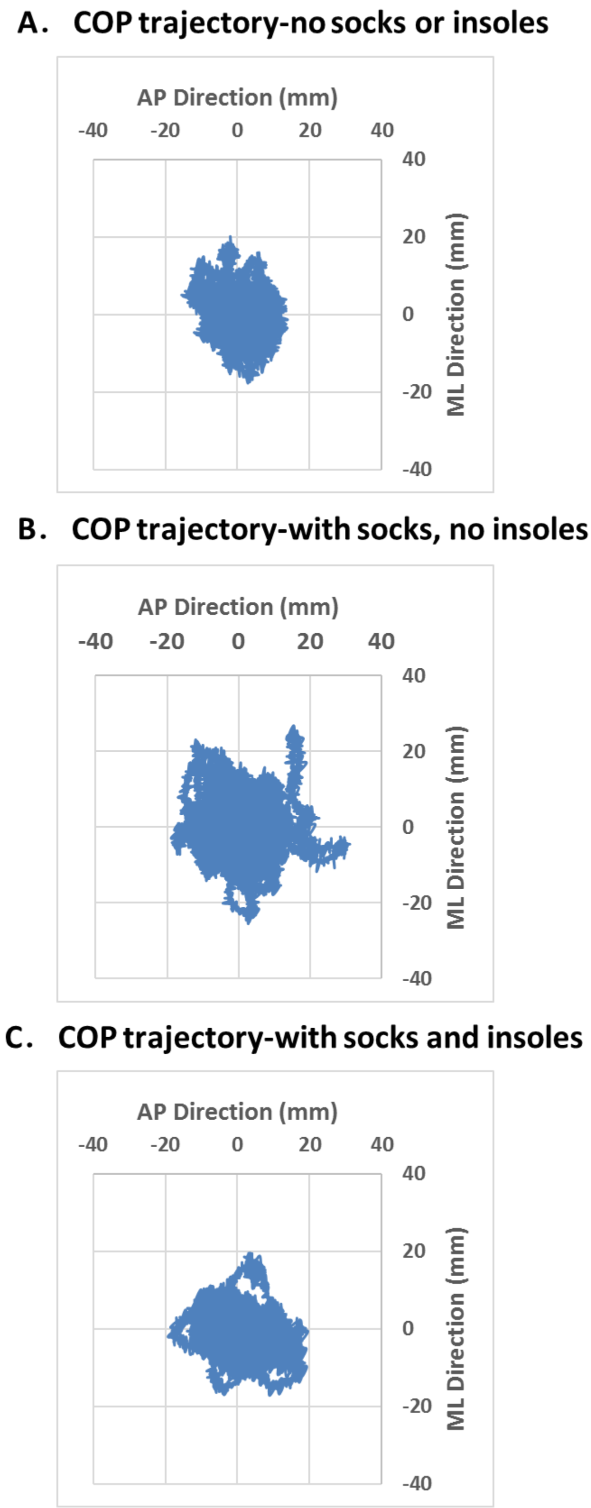


Figure 4-7 The COP trajectory in three different conditions in one elderly subject (effects of insole).

Table 4-9 Post-hoc comparison of COP parameters in 3 different conditions in elderly subjects (effects of insole)

	Elderly subjects (n=14)			Condition 2 minus condition 1		Condition 3 minus Condition 2	
Measurements of COP (mean ± SD)	No socks or insoles (Condition 1)	With socks, no insoles (Condition 2)	With socks and insoles (Condition 3)	Difference	p-value	Difference	p-value
Mean Distance (mm)	6.21 ± 0.98	8.27 ± 1.59	7.02 ± 1.65	+33.2%	<0.001	-15.0%	<0.001
Root Mean Square Distance (mm)	7.11 ± 1.09	9.54 ± 1.76	8.02 ± 1.87	+34.2%	<0.001	-16.0%	<0.001
Mean Velocity (mm/s)	0.07 ± 0.01	0.09 ± 0.02	0.08 ± 0.02	+33.2%	<0.001	-15.0%	<0.001
Sway Area (mm^2)	2.27.71 ± 466.65	2569.98 ± 614.71	2209.13 ± 580.26	+26.7%	<0.001	-14.0%	0.002
95% Confidence Circle Area (mm^2)	460.02 ± 132.39	847.81 ± 305.92	596.92 ± 305.09	+84.3%	<0.001	-29.6%	<0.001
95% Confidence Ellipse Area (mm^2)	421.44 ± 147.36	847.95 ± 338.92	609.91 ± 313.82	+101.2%	0.001	-28.1%	<0.001
Anterior-Posterior Range (mm)	37.34 ± 8.63	45.67 ± 7.83	39.68 ± 8.38	+22.3%	0.002	-13.1%	0.004
Medial-Lateral Range (mm)	30.67 ± 9.09	51.75 ± 9.07	38.47 ± 7.64	+68.7%	<0.001	-25.7%	<0.001

CHAPTER 5. DISCUSSION AND SUGGESTIONS FOR FUTURE RESEARCH

5.1 Chapter summary

Balance and gait disorders can lead to falls and fall-related injuries (Zijlstra, et al., 2010). This project aimed to improve balance and gait by augmenting plantar pressure sensation via biomechanical and electronic approaches, in an attempt to reduce the risk of falls. A series of clinical trials have been conducted to investigate the effect of the proposed approaches on balance and gait. This chapter starts with separate discussion of each study, including the effects of vibrotactile biofeedback systems on static postural balance during standing (Study 1), the effects of vibrotactile biofeedback systems on postural balance while subjects standing on a perturbation floor (Study 2), the effects of vibrotactile biofeedback systems on plantar foot loading and lower-limb motor control during walking (Study 3), and the effects of orthopaedic insoles on static postural balance (Study 4). After that, an overall discussion of the whole project is presented in this chapter.

Generally, this project demonstrated the positive effects of the wearable vibrotactile biofeedback systems integrating with plantar force sensors on improving static and dynamic postural balance, gait and plantar foot loading during walking in healthy young and older adults, and patients with hemiplegic stroke; as well as the positive effects of orthopaedic insoles with medial arch supports, metatarsal pads and heel cups on improving static postural balance in healthy older adults.

5.2 Effects of vibrotactile biofeedback system on postural stability

The underlying principle of this vibrotactile biofeedback system was to supplement the user with additional information of his/her body sway based on the measured plantar pressure distribution, through vibrotactile stimulation at their upper trunks.

The results of 5.07/10-g monofilament score is described as the best diagnostic criteria of loss of protective sensation, and subjects who scored no more than 1 at any single site would be defined as having this problem (Slater, et al., 2014). The significantly decreased monofilament score while using only socks indicated reduced plantar pressure sensation of subjects. Along with the significantly increased postural sway while using socks, it reinforces the important contribution of plantar tactile sensation in postural control. This corroborates previous studies reporting reduced postural control after experimentally simulating the impaired plantar cutaneous sensation through localized anesthesia (Höhne, et al., 2012) and reducing the temperature of subjects' feet (Nurse & Nigg, 2001).

Considering the importance of the plantar tactile sensation to postural control, this system provides augmented sensory reminder based on the plantar pressure information. The mean distance and ML range of COP reduced significantly while using the biofeedback system and socks with eye closed, suggesting that subjects were able to take advantage of this vibrotactile biofeedback system to improve postural control, even when their sensory inputs were reduced. The positive finding regarding the effects of portable vibrotactile system in postural control in this study corroborates previous studies reporting availability of different kinds of biofeedback systems, including vibrotactile (Janssen, et al., 2010; Wall III, 2010), electro-tactile (Tyler, et al., 2003; Nicolas Vuillerme, et al., 2007), visual (Nitz, et al., 2010), and auditory (Dozza, et al., 2005), in improving postural control. Furthermore, no significant difference was found between the baseline and the condition of using biofeedback system under experimentally reduced tactile sensitivity (condition 1 vs. 3). This might provide some insights that this system could help regain the normal postural control in subjects, even with reduced sensory input.

Postural control during standing and walking is achieved by proper functioning of vestibular, proprioceptive and visual systems, which are important in balance control. Dysfunctions of vestibular, proprioceptive and visual systems could interfere with postural control and lead to balance disorders (Day, et al., 2002), which could resulted from series of pathologies, such as diabetes, vestibular deficits, stroke, multiple sclerosis, amputation and Parkinson's disease. The positive results of this vibrotactile biofeedback system in improving postural control under reduced sensory input suggests that apart from patients with deficits in plantar tactile sensation, this device may also benefit other patients with balance disorders as mentioned above.

The biofeedback system provides vibrotactile sensory augmentation, which would not interfere with daily tasks. It is portable, light weight, easy to operate and adapts to the in-shoe use. Previous studies have also indicated that the positive effects of biofeedback on balance still persisted when the users were in high cognitive load (dual-task) situations (Haggerty, et al., 2012). All these advantages make it more acceptable and feasible to apply this system in hospitals and rehabilitation centers as a balance training device. Furthermore, with its wearable design, this system might also be suitable and feasible to be used as a real-time balance aids for tasks in daily life in the future, as good static postural control facilitates better dynamic functional balance (Forte, et al., 2014) and reduces risk of falls (Maeda, et al., 1998). Both elderly individuals and others who are prone to falls could benefit from this system.

To make the daily use of this device more feasible, some refinements could be made in the future. The setting of this system, e.g. 110% threshold, might need to be modified in advance to adapt to different pathological conditions and different daily tasks. In addition to COP information obtained in a clinical or laboratory setting, some wearable sensors might be added to record subjects' reactions and evaluate the balance performance under real-life daily activity. The trunk-mounted microcontroller unit and vibrators could be optimized and mounted on the wrist like a watch, or the proximal ankle joint.

While more efforts are still needed, the vibrotactile biofeedback system still has great potential and deserves more efforts. Future studies should determine the effectiveness of vibrotactile biofeedback system in enhancing dynamic postural control, such as locomotion and other activities in daily living. The investigation focusing on the long-term effect of biofeedback system is also needed.

Only healthy young and older adults with experimentally reduced plantar sensory input induced by socks were recruited in this study, further studies investigating its effects in patients with other sensory deficits causing postural instability are required. Further evidence is required to show if the devices are beneficial to the balance of older adults with various health problems, such as peripheral neural disorders and cognitive problems that impose large impact on balance and risk of falls (Hennig & Sterzing, 2009). In addition, future investigations can look into the long-term stabilizing effect when users had more time to get used to the devices in the future.

5.3 Effects of vibrotactile biofeedback system on postural balance while subjects under balance perturbation

This study developed a new wearable feedback system which provided immediate vibrotactile clues to users based on plantar force measurement. Results suggested that the vibrotactile feedback system significantly improved balance control during translational perturbations. Its positive findings show its great potential in future fall prevention in real life conditions, such as standing on a bus or a train that suddenly decelerate or accelerate.

When a sudden surface perturbation is provided, the human body naturally tilts towards the opposite side of translation to a maximum displacement of S_{max1} due to inertia (Pai, et al., 2000; Santos, et al., 2010; Scholz, et al., 2007). The body then senses the movement and starts making a correction at T_{peak} (Pai, et al., 2000; Santos, et al., 2010; Scholz, et al., 2007), reversing to tilt towards the same direction of perturbation and reaches a new equilibrium position (S_{max2}) after T_{rec} (Pai, et al., 2000; Santos, et al., 2010). Thereafter, the body keeps the new postural equilibrium with little further COM displacement (Santos, et al., 2010; Scholz, et al., 2007).

Large S_{max1} and T_{peak} in response to a floor perturbation have been suggested to be linked to poorer balance recovery and higher risk of falls (Owings, et al., 2001). This study found statistically significant reductions of both S_{max1} and T_{peak} upon using the biofeedback system during surface perturbations. One possible explanation was that the vibration clues enabled users to sense the perturbation earlier, reducing the reaction time to the perturbation. This might then trigger the cognitive processing of postural movement and the upcoming anticipatory postural adjustments earlier, resulting in better control over the movement of COM. This is supported by a previous study which found significantly larger maximum COM displacement in healthy young subjects under an unpredictable surface perturbation condition, as compared to a predictable perturbation (Santos, et al., 2010).

The finding of this study was contradictory to one previous study which found no reduction of S_{max1} or T_{peak}, but reduction of T_{rec}, when using a vibrotactile biofeedback system with gyroscopes and accelerometers measuring directly the body tilt (Sienko, et al., 2012). The use of different sensing methods and thresholds for biofeedback could be the reason. The results from the current study and the study conducted by Sienko and her colleagues (2012) suggested that postural recovery time improved with inertial sensors on the trunk, while initial reaction improved with force sensors at the foot plantar surface in response to transitional perturbations. Future studies could explore for different postural recovery situations with different methods and placement of sensing apparatus. Attempts could be also made to combine both trunk-mounted inertial sensors and foot-placed force sensors, and investigate if this could result in an even better balance improvement effects.

The T_{peak} in backward perturbation was found to be longer than the other three directions, and the T_{rec} in forward perturbation was longer than the left perturbation. This could be explained by a previous study which indicated that during fixed-support standing, a mediolateral perturbation induced activation of proximal leg muscles earlier than forward-backward translational perturbation (Torres-Oviedo & Ting, 2007). This could lead to earlier onset of peak leg and trunk torque integrals during the mediolateral perturbation (Jones, et al., 2008), which might help achieve the postural equilibrium quicker.

No statistically significant reduction of S_{max2} or T_{rec} upon using the system was noted. Different threshold values were attempted in pilot studies, but they did not induce a consistent change in S_{max2} and T_{rec}. These results imply that while the biofeedback system could help the subjects to initiate the cognitive processing of postural movement and the upcoming anticipatory postural adjustments earlier significantly reducing S_{max1} and T_{peak}, it might not lead to consistent changes in re-establishing a state of postural equilibrium. Large standard deviations in S_{max2} and T_{rec} were found, suggesting that subjects used different approaches in attaining a new equilibrium position during floor perturbation. The relationships between the S_{max2} and T_{rec} and the risk of falls are not well known, which warrants further investigations. Future attempts could also adjust the sensor configurations and algorithm, and investigate the effects on S_{max2} and T_{rec}.

Comparing various physiological strategies that respond to a translational surface perturbation, a fixed-support strategy (no movements at the feet) predominately uses an ankle strategy in response to perturbation (Maki & McIlroy, 2006), while a change-in-support strategy where taking a step or reaching to an object for support is allowed predominately uses a hip strategy (Maki & McIlroy, 2006). This study instructed the subjects to use the fixed-support strategy only to standardize subject's response to the translational surface perturbation. The fixed-support strategy is important in providing early defence against loss of balance (Maki & McIlroy, 1997). This strategy is also useful in a real-life situation of standing in a limited space, for example, being crowded in a train. However, a change-in-support strategy has the potential of providing greater degree of stabilization (Maki & Mcilroy, 1999). The effects of the biofeedback system on reaction time and COM displacement could be different between the two strategies. Future studies could investigate the effects of biofeedback on balance control when subjects employ different strategies to recover balance and prevent falls in various real-life conditions. This could further facilitate the potential application of the system in fall prevention in daily life in the future.

All subjects in this study were healthy young adults, which limited the generalization of the findings of this study. Future studies should investigate the effects of plantar force measurement-based biofeedback system on balance in other populations, such as the elderly and patients with balance disorders, who are more prone to fall. Future studies could also compare the differences between the use of plantar force and inertia sensors in changing balance control and investigate an optimum configuration of the sensing and feedback methods.

The measured COM displacement was relative to the ground in this study. This truly reflected the COM movement caused by both the perturbation floor and the regulation of body posture. While comparisons among different conditions were allowed as the perturbation floor moved at the same speed among repeated measurements of each subject, the data reported in this study might not be comparable to other studies which adopted different speeds of floor translation.

5.4 Effects of vibrotactile biofeedback system on gait and plantar foot loading

This study developed a plantar-force based vibrotactile biofeedback and investigated the effects of its use on plantar foot loading and gait in hemiplegic stroke patients with flexible foot varus deformity. With no biofeedback, the foot inversion angle at the affected side was significantly higher than the unaffected side. The biofeedback device attempted to relieve foot varus by giving vibration clues when the medial side of the affected foot did not exert high enough forces during walking. This significantly reduced the maximum foot inversion of the affected side during swing phase. Significant increase in the plantar force at the medial forefoot during stance phase and total foot-floor contact area were then observed. This potentially improves postural balance (Hertel, et al., 2002), reduces chances of developing foot pain (Kaplan, et al., 2003), and soft tissue injury (Burns, et al., 2005).

It is interesting to note that while the device provided feedback on the weight bearing characteristics of the foot at the affected side, significant changes were observed at the unaffected side. Without turning-on the biofeedback device, subjects walked with significantly more peak hip abduction and knee flexion during swing phase at the unaffected side than the affected side, and these angles were higher than people without stroke (J. Perry & Burnfield, 2010). Increasing hip abduction widened the base of support, which might compensate for the reduced walking balance caused by the abnormal orientation and loading of the feet at the affected side (J. Perry & Burnfield, 2010; Reinbolt, et al., 2008). Meanwhile, excessive knee flexion provides more foot clearance during swing phase at which the entire body weight is put against the opposite limb (Mills, et al., 2008; J. Perry & Burnfield, 2010; Woolley, 2015). Turning on the device significantly reduced the unaffected-side knee flexion during swing phase and hip abduction during stance phases. Such reductions decreased the asymmetry between affected and unaffected legs. The improved symmetry of hip and knee joints during walking could improve the walking efficiency of patients of stroke (Brouwer, et al., 2009).

The stance time of both limbs increased while walking speed did not have significant changes upon using the biofeedback device. The significantly increased stance time could reflect that subjects were more confident of bearing weight on their feet (Mâaref, et al., 2010), indicating better walking capacity (Jonkers, et al., 2009). The biofeedback device did not compromise walking speed. This suggested that subjects did not need to walk more carefully and slowly when paying attention to the reminder signals from the device, which is consistent with a previous study identified retained beneficial effects of vibrotactile biofeedback when subjects performed dual cognitive tasks while receiving vibrotactile stimulations (Haggerty, et al., 2012). This also indicates that the changes in plantar pressure were not due to variations in walking speed.

In this study, the threshold ratio of provoking vibrotactile feedback was set at a level at which the plantar force at the medial forefoot reached 50% of that at the lateral forefoot. The threshold was chosen from a series of threshold ratios in pilot study, including 25%, 50% and 100%. It appeared that the ratio of 25% was too easy for the subjects to achieve, which lowered the value of using the device for gait training; while the ratio of 100% was too difficult for subjects to achieve in a limited training time period, leading to unstopped vibrations during walking. Subjects cannot benefit from the unstopped vibration, as no useful differentiated reminders were provided. It is worthwhile to involve more threshold ratios and further explore the best setting of the device in the future.

The clinical implication of this study is that a device measuring plantar forces and providing instant biofeedback has great potentials of improving gait in people with stroke. Subjects did not verbally report any discomfort upon using the biofeedback device in this study. Embedding thin-film force sensors into shoes/insoles and using appropriate feedback devices facilitate realization of home-based rehabilitation programs, which have high level of continuity, adherence, and compliance rates of training in patients (Davis, et al., 2009; Madureira, et al., 2007). The nature of low interference with daily tasks of vibrotactile biofeedback (Wall III, 2010) also allows the device to be used as a walking aid, which is capable of continuously monitoring the foot posture and walking ability, in both indoor and outdoor daily activities in the future.

This study investigated the immediate effect of this wearable vibrotactile biofeedback device on plantar loading and gait pattern in patients with chronic stroke. Future study shall investigate if such positive effects retained after long-term use, and in home-based settings. The evaluation of the applicability and repeatability of the device could be conducted in the future. The sample size of this study was rather small, while there are also some other published papers with small sample size demonstrated an effect of biofeedback devices (M. R. Afzal, et al., 2015; Alahakone, et al., 2010; Crea, et al., 2015; M.-Y. Lee, et al., 2007; Wall III, et al., 2001). Future studies shall investigate the effect of such plantar force-based biofeedback device in larger samples who have poor walking ability.

5.5 Effects of orthopaedic insole on postural stability

Falls and fall-induced injuries are major public health problems, and continuous efforts have been made to improve balance. This study demonstrated the positive effects of an economical approach, i.e. orthopaedic insoles with medial arch supports, metatarsal pads and heel cups that were conventionally used to treat foot pain and deformity, on static balance of persons with experimentally reduced plantar sensitivity. The possible underlying mechanism is that orthopaedic insoles can increase the plantar tactile sensory input by distributing plantar pressure to the relatively more sensitive areas of the foot, increase the contact area between the foot and the support surface, as well as put the heel in a more stable position.

The ability to detect the touch of 5.07/10-g monofilament is described as the best indicator to determine the loss of protective sensation at plantar foot. According to the protocol of the International Consensus on the Diabetic Foot (ICDF), any scores of ≤1 at any single sites defined an individual as having loss of protective sensation (Slater, et al., 2014). The bowing of monofilament during the test ensured that the magnitude of the applied force (i.e. 10 g/0.1 N) kept consistent in conditions of with and without wearing socks (Bell-Krotoski, et al., 1995). With the sock intervention, both young and older subjects were unable to sense the 5.07/10-g monofilament (scored ≤1 in this study) at plantar foot. This suggested that the socks reduced the ability of plantar foot to sense the mechanical stimulations. Possible reasons could be that the deformation of socks may distribute the forces and reduce the mechanical pressure acting against the foot, which restricted the plantar foot to detecting less mechanical stimulations. The increase in postural sway while wearing the socks indicated the important role of plantar pressure sensation in the maintenance of balance (Y.-J. Tsai & Lin, 2013). The findings were in accordance with previous studies which reported reduced static balance performance after the experimentally induced reduction of plantar sensitivity, such as exposing subjects' feet on ice for a few minutes (Manor, et al., 2009), injecting anesthetic solution at foot (Höhne, et al., 2012), and asking the subjects to stand on a soft foam surface (Patel, et al., 2008b). This study observed that socks only could decrease postural stability. Clinicians need to be aware of this when making clinical decisions.

Following the significant increase in all COP parameters by the effect of socks, all COP parameters significantly reduced while using the orthopaedic insoles with socks. In fact, no significant difference was found between the condition of barefoot and the condition of wearing both socks and insoles. This indicated that the negative balance effects of socks were dampened by the use of orthopaedic insoles. A previous study revealed that non-fallers tended to have smaller COP range (16.5% and 14.2% smaller in ML and AP directions, respectively) and mean velocity (15.0% slower) compared with fallers (Melzer, et al., 2010). Coincidently, this current study showed that the insoles reduced these parameters to similar percentages in older (reduction of approximate 15%) adults. It is also interesting to note that the degree of improvement in postural stability upon using orthopaedic insoles is similar to the condition of using higher-cost vibrating insoles (A. A. Priplata, et al., 2006). The reduced COP parameters while wearing orthopaedic insoles might reduce the chance of falls. Future studies should investigate the potential effects of orthopaedic insole in balance improvement under more diverse medical and physical conditions. The effects of orthopaedic insoles on postural balance of people with impairments in plantar tactile sensation caused by aged degeneration, diabetic neuropathy, and rheumatoid arthritis under various characteristics of shoes soles and supporting surfaces can be investigated. Future studies should also look into the potential relationships among plantar tactile sensation, plantar forces, and balance; which are largely unexplored.

Orthopaedic insoles can enhance plantar pressure sensory input by producing greater plantar pressure at the metatarsal shafts and the longitudinal arch, which have higher sensitivity (Hennig & Sterzing, 2009); and can also increase the contact area between the plantar feet surface and support space as compared to flat insoles (T.-h. Chen, et al., 2014; Gross, et al., 2012), which helps increase the area for sensory input. The insoles can also put ankle-foot complex in a more stable position (T.-h. Chen, et al., 2014). These mechanisms compensate the simulated effects of deficits in plantar tactile sensation. Existing insole designs (e.g. vibrating insoles and textured insoles) may cause discomfort and even pain, which limited their applications among users (Anna L Hatton, et al., 2013; S. D. Perry, et al., 2008). In this study, participants had no complaints of discomfort while wearing the orthopaedic insoles, because orthopaedic insoles could confine with the anatomical shape of the foot and avoid high localized pressure. They are also more affordable for users, as no electronic components were contained.

This study did not involve a shoes condition. In addition to orthopaedic insoles, some shoes with similar designs of heel cups and arch supports could have a similar balance improving effect, which merits further investigation. Future studies could consider investigating the effect of socks and orthopaedic insoles on postural balance when subjects are wearing standardized shoes.

Only the healthy older subjects with reduced plantar pressure sensory input that induced by socks were recruited in this study, further studies investigating the effects in patients with other somatosensory, vestibular and visual deficits causing postural instability are required. Elderly with co-morbidity were excluded in this study. Further evidence is required to show if the orthopaedic insoles are beneficial to the balance of older adults with various health problems. Some common health problems, for example, peripheral nervous disorders, cognitive problems also impose large impact on the balance and risk of falls (Hennig & Sterzing, 2009). In addition, future investigation can look into the long-term stabilizing effect when users had time to get used to the orthopaedic insoles in the future. In this study, only the effect of orthopaedic insoles on postural balance was investigated. The dynamic balance tasks are more common and more challenging in daily life, further investigations and explorations shall be conducted to address these problems.

5.6 Implications and perspectives

This project set out to investigate if augmenting plantar pressure sensation could improve balance and gait, in an attempt to reduce the risk of falls. The positive results of the several systematic studies supported the hypothesis that augmenting plantar pressure sensation could improve balance and gait performance.

5.6.1 Balance and gait improvement

Generally, this project demonstrate the improvement of postural stability during quite standing in healthy young and older adults with vibrotactile biofeedback system integrated with plantar force sensors (Study 1), the improvement of postural balance under balance perturbation during standing in healthy young adults with vibrotactile biofeedback system integrated with plantar force sensors (Study 2), the improvement of plantar foot loading and gait during walking in patients with stroke with the use of vibrotactile biofeedback system integrated with plantar force sensors (Study 3), as well as the improvement of postural stability during quite standing in healthy older adults with orthopaedic insoles (Study 4).

This is the first study, to my knowledge, to systematically examine the effect of plantar force measurement-based biofeedback systems on balance and gait control during quite standing, during standing following a balance perturbation, and during walking. The results describe for the first time that augmenting plantar pressure sensation via electronic approaches could improve balance and gait in healthy young and older adults, and patients with stroke. This study also offers an alternative cost-effective option of improving static postural balance by the biomechanical approach of orthopaedic insoles with arch supports, metatarsal pads, and heel cups. The positive results upon applying orthopaedic insoles and vibrotactile biofeedback system suggest that both biomechanical and electronic approaches could augment the plantar pressure sensory input, and improve postural stability in static and dynamic situations. This may potentially reduce the risk of falls in users.

This study reinforces the importance of sensory systems to balance control. These findings can contribute considerably to the development and evaluation of smart wearable devices for balance and gait improvements. The results are of direct practical relevance to improving balance and gait. Although this study was only conducted in healthy young and older adults, and patients with hemiplegic stroke, the results should be generalizable to other populations. This study was mainly conducted in a lab-setting condition. With the characteristics of wearable and easy to operate with, the novel approaches of augmenting plantar pressure sensation investigated in this study would also be beneficial in other indoor and outdoor environmental settings, examples are during home-based balance trainings and daily activities.

5.6.2 Future directions

This project also highlights several issues that merit further exploration and research.

Experimental design

Randomized controlled trials (RCTs) with double blindness of both subjects and experimenters should be conducted. Clinical trials with larger sample size should be conducted in the future. This helps enhance the trial's methodological quality and evidence level. Further studies about the long-term effect of the orthopaedic insole and biofeedback device intervention shall also be conducted.

Combined effect

It is estimated that combining two components together, e.g. embeding force sensors into orthopaedic insoles and providing real-time vibrotactile biofeedback at other body parts, could facilitate the long-term use and further enhance the balance. Future studies could consider investigating the effect of the combined system on more completed tasks, such as ascending/descending stairs and running, in more diverse and representative populations.

Orthopaedic insoles

Comparisons of different designs of orthopaedic insoles should be conducted to allow better identification of the balance improvement mechanisms and optimization of the insole designs. Several possible explanations regarding the positive balance improving effects of orthopaedic insoles have been proposed, including enlarging the contact area between foot and support surface (T.-h. Chen, et al., 2014; C. Z.-H. Ma, et al., 2016a) and redistributing force to more force-sensitive areas (C. Z.-H. Ma, et al., 2016a; C. Z. Ma, et al., 2014b, 2015). However, there was a lack of evidence directly supporting these propositions. Investigations into the effects of systematically modified designs of orthopaedic insoles on balance would help confirm the underlying mechanisms, and contribute to knowledge for even better insole designs and prescriptions. Considerations could be putting the pads at different plantar sites, and producing customized stimulation intensity through different specific characteristics of each insole component, including size, hardness and distribution density. In addition, the relationship among individual sensory threshold, the intensity of provided sensory stimulations (magnitude and duration), and outcome balance performance could and shall be carefully examined in the future.

The effects of orthopaedic insoles on balance in populations with different characteristics shall be studied. It is generally suggested that orthopaedic insoles could improve the balance of older adults with experimentally reduced plantar pressure sensory input, further efforts are still needed to investigate the effect of orthopaedic insoles in elderly with various aging degenerations and medical conditions. Future studies shall evaluate the participant’s condition more comprehensively and recruit subjects with more specific characteristics. This could help further determine and identify if orthopaedic insoles are not beneficial for some specific populations, and facilitate the evidence-based clinical application in the future. Efforts could also be put on optimizing the design of insoles to compromise different medical conditions.

The orthopaedic insoles could be optimized to achieve better balance improvement and for long-term use. The diameter, height, hardness, and distribution of arch support, metatarsal pads and heel cups shall be more carefully chosen and determined to avoid possible discomfort and pain in users upon long-term usage. Comparisons among different insole designs in the same subjects could facilitate the identification of the optimal design features of orthopaedic insoles that offer the best positive outcomes in balance and gait control.

Vibrotactile biofeedback system

The vibrotactile biofeedback systems could be developed more wearable and more appropriate for outdoor usage in the future. Previous biofeedback systems for improving balance were connected physically to computers for analyzing signals and sending feedback (Goebel, et al., 2009; Sienko, et al., 2008; Sienko, et al., 2013; Wall & Weinberg, 2003; Wall, et al., 2009). These devices acted as indoor/laboratory-based balance training devices only. With current state-of-the-art smartphone and other smart product applications, advancement of wearable sensors and Bluetooth connections, the devices could be developed more lightweight, with more powerful calculation capacity and smaller size in different wearable products (shoes, apparels or accessories) in the future. The thin-film force sensors could be inserted into insoles and the relevant electronics be put at shoe soles to develop some kinds of smart shoes. The force sensors could be connected with a smartphone via Bluetooth and/or Wi-Fi connection. The force sensors and software in a smartphone could also be utilized and be developed as potential mobile balance aids for daily uses. With larger number of force sensors been used, it would be more feasible to measure the movement trajectory of center of pressure during standing and walking (Putti, et al., 2007; Ramanathan, et al., 2010), which is an important indicator of balance performance and falling risk (Hernandez, et al., 2012; Moghadam, et al., 2011).

Future studies could consider to integrating both force sensors and inertial motion sensors to capture the body motion. Previous devices have attempted to detect COM position only using inertial motion sensors, but the XcoM appears to be more related to dynamic balance performance (A. Hof, et al., 2005; A. L. Hof, 2008). Considerations could be given to measure the displacement of XcoM by using inertial motion sensors and force sensors together in the future, as they could measure the movements of both COM and COP, which could be used to calculate the movements of XcoM.

Visual, auditory, and tactile biofeedback information could be used as reminder during laboratory-based as well as home-based rehabilitation training sessions.

When considering the requirements of outdoor training and daily balance aid, the choice of tactile biofeedback might be more appropriate, as it does not hinder daily tasks of speaking, eating, seeing and hearing (Janssen, et al., 2010; Wall III, 2010). The tactile biofeedback information could be delivered to human body wirelessly.

The effect of biofeedback systems on home-based balance training should be investigated in the future. Conducting balance training at home (or the so-called home-based balance training) contributed to high continuity and adherence of training (Madureira, et al., 2007). Good compliance rates of home-based balance training programs have been achieved (Davis, et al., 2009; Liu-Ambrose, et al., 2008). All the above-mentioned possible design characteristics provide the vibrotactactile biofeedback devices developed in this project the potential to act as balance aids in daily life, as well as the home-based rehabilitation training devices that could be used anytime and at anywhere, especially when some of the wearable balance improving devices have been suggested to be as effective as therapist's verbal instructions (Byl, et al., 2015).

5.6.3 Clinical decision-making

Orthopaedic insoles

While some textured insoles (S. D. Perry, et al., 2008) and vibrating insoles (de Morais Barbosa, et al., 2013) may cause pain and discomfort after long-term use, orthopaedic insoles could be a good option for elderly people with foot deformities and pain, and expertise in orthotics is required in dealing with such cases. In addition to the potential effects of balance improvement, the arch supports of an orthopaedic insole relieve pain associated with plantar fasciitis by supporting the longitudinal arch and relieving soft tissue stretch (Conceição, et al., 2014). Metatarsal pads of orthopaedic insoles can also relieve pain over the metatarsal heads by redistributing loadings to the metatarsal shafts (P. Y. Lee, et al., 2014). Heel cups help to grasp the heel in a more neutral position (T.-h. Chen, et al., 2014).

Orthopaedic insoles may not be effective in improving balance of individuals in some conditions. Slippery floor and poor lighting can contribute to the occurrence of falls (Aizen, et al., 2007; Eriksson, et al., 2009). These environmental factors cannot be addressed by the use of insoles. Some medical problems, such as hypotension and complications from medication, can impose balance problems (Y.-C. Chen, et al., 2009; Rubenstein & Josephson, 2002; von Heideken Wågert, et al., 2009). There is a lack of evidence supporting whether orthopaedic insoles can improve postural balance of people with such medical conditions. In addition, some neuromuscular disease, such as stroke, may require physiotherapy and more extensive orthotic treatments to achieve better postural balance.

Vibrotactile biofeedback system

The decision-making of choosing appropriate sensors could be made after thorough evaluations and be further utilized based on the user's condition in the future. Combined inertial motion and force sensors should be superior for the development of new wearable device, as they could compensate each other's function (C. Z.-H. Ma, et al., 2016b). There are various tailor-made options for patients with different types of sensory deficiency. The inertial motion sensors were shown to be able to detect the movement of the whole body and the body segments accurately in healthy older adults and patients with balance and gait disorders (Crea, et al., 2015; Giggins, et al., 2014; Leardini, et al., 2014; O'Donovan, et al., 2007). However, the inertial motion sensors could not measure the foot-floor contact surface information, which could be eased by force sensors put at the plantar surface of the foot. Plantar tactile sensation plays an important role in balance control (Cruz-Almeida, et al., 2014; Maurer, et al., 2005; Meyer, et al., 2004), as it provides instantaneous and continuous information about support surface characteristics (Witana, et al., 2009) and the body's relative movement to the foot (Kavounoudias, et al., 1998) to the central nervous systems. Declined plantar tactile sensitivity can induce poor balance and predispose risk of falls (T.-Y. Wang & Lin, 2008). Aging, diabetic neuropathy, Parkinson's disease, and rheumatoid arthritis can lead to impairments in plantar tactile sensation (Hennig & Sterzing, 2009). The force sensors could be helpful in those people by providing them additional foot-floor contact information, which compensates the pathological plantar pressure sensory deficits. Furthermore, the force sensors put at the left and right foot could also help distinguish the plantar force distribution of the affected and sound sides. This makes the plantar force sensors a suitable option for patients with stroke, as well as amputees, who commonly have different conditions regarding the sound and affected sides.

5.7 Limitations of study

The project has several possible limitations. The following parts discusses the limitation of each study involved in this project and suggests some potential solutions to ease them in the future investigations.

Study 1: Effects of vibrotactile biofeedback system on postural stability

Only healthy young and older subjects with experimentally reduced plantar pressure sensory input induced by socks were recruited in this study, further studies investigating its effects in patients with other somatosensory, vestibular or visual deficits causing postural instability are required. Further evidence is required to show if the devices are beneficial to the balance of older adults with various health problems, such as peripheral neural disorders and cognitive problems that impose large impact on the balance and risk of falls (Hennig & Sterzing, 2009). In addition, future investigations can look into the long-term stabilizing effect when users had longer time to get used to the devices in the future.

Study 2: Effects of vibrotactile biofeedback system on postural balance while subjects under balance perturbation

All subjects in this study were healthy young adults, which limited the generalization of the findings of this study. Future studies should investigate the effects of plantar force measurement-based biofeedback system on balance in other populations, such as the elderly and patients with balance disorders, who are more prone to fall. Future studies could also compare the differences between the use of plantar force and inertia sensors in changing balance control and investigate an optimum configuration of the sensing and feedback methods.

The measured COM displacement was relative to the ground in this study. This truly reflected the COM movement caused by both the perturbation floor and the regulation of body posture. While comparisons among different conditions were allowed as the perturbation floor moved at the same speed among repeated measurements of each subject, the data reported in this study might not be comparable to other studies which adopted different speeds of floor translation.

Study 3: Effects of vibrotactile biofeedback system on gait and plantar foot loading

This study investigated the immediate effect of this wearable vibrotactile biofeedback system on plantar loading and gait pattern in patients. Future study shall investigate if such positive effects retained after long-term use. The sample size of this study was rather small, while there are also some other published papers with small sample size demonstrated an effect of biofeedback devices (M. R. Afzal, et al., 2015; Alahakone, et al., 2010; Crea, et al., 2015; M.-Y. Lee, et al., 2007; Wall III, et al., 2001). Future studies shall investigate the effect of such plantar force-based biofeedback system in larger samples who have poor walking ability.

Study 4: Effects of orthopaedic insole on postural stability

Only healthy older subjects with reduced plantar pressure sensory input that induced by wearing socks were recruited in this study, further studies investigating the effects in patients with other somatosensory, vestibular or visual deficits causing postural instability are required. Elderly with co-morbidity were excluded in this study. Further evidence is required to show if the orthopaedic insoles are beneficial to the balance of older adults with various health problems. Some common health problems, for example, peripheral neural disorders and cognitive problems also impose large impact on the balance and risk of falls (Hennig & Sterzing, 2009). In addition, future investigation can look into the long-term stabilizing effect when users had more time to get used to the orthopaedic insoles in the future. In this study, only the effect of orthopaedic insoles on postural balance was investigated. The dynamic balance tasks are more common and more complicated in daily life, further investigations and explorations should be conducted to address these problems.

In this project, the subjects participating in Study 1 were unfortunately different from those of Study 4. Future studies shall recruit the same subjects and comprehensively compare if the effects of vibrotactile biofeedback system and orthopaedic insoles are different on postural stability. This will enable the comparisons between the two approaches and further allow the identification of a better approach between the biomechanical and electronic approaches.

While more work is needed, both orthopaedic insoles and vibrotactile biofeedback system have great potential and deserve more efforts. Future studies should determine the effectiveness of optimized insole and vibrotactile biofeedback system design in enhancing dynamic postural stability, such as routine locomotion, ascending and descending stairs, and other activities in daily living. The investigation focusing on long-term effect of the insoles and biofeedback system is also needed. The current investigation does not enable us to determine the combining effect of orthopaedic insoles and vibrotactile biofeedback system.

Randomized controlled trials with double blindness of both subjects and experimenters should be conducted. This helps enhance the evidence level of clinical trials. The effect of orthopaedic insoles and vibrotactile biofeedback system on balance shall also be investigated in more representative samples with larger sample sizes in the future.

CHAPTER 6. CONCLUSIONS

This project adopted a step-by-step approach, started from improving postural balance during quite standing, and ended with the attempts of improving dynamic balance and gait. All of them are linked together by the theme of improving balance through augmenting plantar pressure sensation.

6.1 Effects of vibrotactile biofeedback system on postural stability

The immediate effect of a novel wearable vibrotactile biofeedback system on postural stability improvement was studied. This device provided the corresponding directional information of body sway to the upper trunk based on the changes of plantar pressure distribution detected by in-shoe force sensors at plantar surface of the feet. This study reveals that application of vibrotactile biofeedback is effective in reducing postural sway which represents enhanced postural stability, and could potentially reduce the risks of falls in young and elderly subjects with reduced sensory input. To avoid interfering with tasks of speaking, eating and hearing, this system provides vibrotactile stimulations, instead of visual or auditory biofeedback. This system attached thin force sensors at the plantar surface of feet to detect changes of plantar pressure distribution, effectively solving the problem of mounting bulky inertial measurement units at trunk. Although initial success was achieved, more work is needed to realize the concept of developing wearable biofeedback system based on plantar force information for improving balance in daily use.

6.2 Effects of vibrotactile biofeedback system on postural

balance while subjects under balance perturbation

This preliminary study introduced a newly developed wearable vibrotactile biofeedback system, based on plantar force measurements, which was found to have significantly reduced the reaction time and maximum COM displacement in translational support surface perturbations. The positive results implied better reaction and improved balance control in such perturbations. Thin-film plantar-force sensors offer an advantage that they can be embedded into the shoes, removing the need of mounting any sensors to the trunk. Further optimization of the system design and capability is suggested, facilitating its application in fall prevention in real life conditions, such as standing in buses or trains that suddenly decelerate or accelerate.

6.3 Effects of vibrotactile biofeedback system on gait and plantar foot loading

Subjects in this study showed significant improvements in foot loading and gait upon using instant vibrotactile biofeedback regarding medical and lateral forefoot loadings. Instant vibrotactile biofeedback of plantar force at the medial and lateral forefoot significantly reduced the abnormally excessive foot inversion angle by more than 15%. This significantly increased foot-floor contact area and weight bearing over the medial aspect of the foot of the affected limb, which might help improve balance and walking capability. Improvements in gait patterns were also noted as the biofeedback significantly reduced the excessive hip abduction and knee flexion of the unaffected limb.

6.4 Effects of orthopaedic insole on postural stability

This study investigated the immediate effect of orthopaedic insoles on postural balance of healthy older adults, whose balance was adversely affected by the use of socks. After using the socks, the subjects' static postural sway increased. This raises concern for people who are prone to falls about wearing thick socks. Upon using insoles, this study showed the subjects then exhibited significantly less static postural sway. Orthopaedic insoles with an arch support, a metatarsal pad, and a heel cup were traditionally used to treat foot pain and deformity. This study indicated their potential of an additional benefit of balance improvement. This sheds new light on the application of a low-cost and practical solution for improving balance, which appears not to have caught much attention.

6.5 Generalization of the findings

The findings of this research project generally supported the hypothesis that vibrotactile biofeedback systems and orthopaedic insoles could augment plantar pressure sensation and improve balance and gait performance in healthy young and older adults, and patients with stroke. The augmentation of plantar pressure sensation could be achieved not only by measuring the plantar forces using force sensors at plantar foot and providing corresponding biofeedback at other body segments, but also by directly altering the mechanical stimulations at plantar surface of foot using insoles.

Generally, this study demonstrates the positive effects of the wearable vibrotactile biofeedback systems integrating with plantar force measurement in improving static postural stability, dynamic postural balance, gait and plantar foot loading during walking; as well as the positive effects of orthopaedic insoles with medial arch supports, metatarsal pads and heel cups in improving static postural stability. This inspires future research in this field. The wearable characteristic of orthopaedic insoles and vibrotactile biofeedback systems also allows them to be used in both indoor and outdoor settings, which further makes them appropriate to be applied as both balance training devices and balance aids in daily life in the future.

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