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EFFECT OF THE SMARTSTEP^{TM} STABILIZATION SYSTEM ON BALANCE IN OLDER ADULTS IN AN INDEPENDENT LIVING RESIDENCE

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ABSTRACT OF DISSERTATION

Ann L. Livengood

The Graduate School

University of Kentucky

2008

EFFECT OF THE SMARTSTEP™ STABILIZATION SYSTEM ON BALANCE IN OLDER ADULTS IN AN INDEPENDENT LIVING RESIDENCE

ABSTRACT OF DISSERTATION

A dissertation submitted in partial fulfillment
of the requirement for the degree of Doctor of Philosophy
in the Graduate School at the University of Kentucky

By
Ann L. Livengood
Lexington, Kentucky

Co-Directors: Dr. Carl G. Mattacola, Associate Professor of Rehabilitation Sciences, and
Dr. Robert Shapiro, Professor of Exercise Science
Lexington, Kentucky

ABSTRACT OF DISSERTATION

EFFECT OF THE SMARTSTEP™ STABILIZATION SYSTEM ON BALANCE IN OLDER ADULTS IN AN INDEPENDENT LIVING RESIDENCE

An increase in postural sway is one of the risk factors that have been linked to an increased incidence of falls in the older adult population. Researchers have shown that peripheral sensation is crucial in maintaining a static posture for adults of all ages. It has been reported that older adults have decreased tactile sensation of the plantar surface of their feet. and when the sensory feedback was increased older adults had improved postural control. It was hypothesized that facilitation of the sole of the foot with the use of a semi-rigid foot orthotic would result in improved postural stability in older adults.

Twenty-seven volunteers (19 females, 8 males, mean age: 87 ± 5 yrs) were recruited as subjects from a retirement community. All subjects were supplied with the SmartStep™ Stabilization System. There were a total of 5 Test Days for each subject. The first 2 Test Days were performed while the subjects wore their own shoes, while the last 3 Test Days were performed while the subjects wore the SmartStep™. Test Days 1 and 2 were performed 48 hours apart. Test Day 3 occurred 2 to 4 weeks after Test 2. Test Days 4 and 5 occurred 4-weeks after the prior Test Day. During the 8-weeks between Test Days 3 and 5, subjects were asked to wear the SmartStep™ as their daily shoe.

Clinical measures of balance, force plate measurements, sensation testing, and confidence and activity scales were collected on all subjects throughout the eight week test period. Statistical significance was found for 3 of the clinical measures. The Timed “Up & Go” improved from 17.25 to 15.47 sec. The Functional Reach and Lateral Reach Tests demonstrated a decline in scores during the eight weeks. There was only 1 statistically significant finding for the force plate measures. The center of pressure displacement in the anterior-posterior direction was increased from 4.6 to 5.3 cm. No significant differences where reported for any other dependent variable. The results did not indicate statistically that the in-shoe orthotic enhanced postural stability in this group of subjects. However, there were indications that there was a subset of the current population that benefited from the intervention and this needs to be investigated further.

KEYWORDS: postural control, postural stability, in-shoe orthotic, elderly, plantar sensation

Ann L. Livengood

December 17, 2008

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DISSERTATION

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Table of Contents

List of Tables

List of Figures

Chapter One

Introduction

Background

Falling is the third leading cause of injury-related deaths among all ages and first among adults aged 65 and older.[1] Approximately 30% of older adults and 40% of adults over 80 years old fall once a year and 20% to 30% of these victims will suffer from injuries that are moderate to severe.[1-4] Injuries received from falling accounted for approximately 25% of all nonfatal injuries that were seen in American Emergency Departments for the year 2000.[1] Studies performed in 1989[4] and 1994[1]reported that 5.3% of all hospitalization charges for adults over the age of 65 were due to falls and the total direct cost of fall injuries was $20.2 billion.

The incidence of falls has been found to increase with age,[4, 5] as well as the severity of injuries caused by these falls.[4] As America prepares for the 76 million American “Baby Boomers” to become active older adults in the next decades, it is imperative that interventions are improved to decrease the falling incidence as well as injury severity. The majority of the serious falling injuries in older adults occurred while individuals were performing outdoor activities[6] and 37% of injuries occurred during activities of daily living.[7] These results indicate that healthy, active, community-dwelling individuals are being affected by falling injuries. An injury not only causes a physical affliction, but financial and emotional consequences can ensue as well. The active, independent lifestyle of many older adults is severely affected by an injurious fall. It has been reported that 42% of older adults who had been injured in a fall, and had been admitted to the hospital from self care, were discharged to a nursing facility.[4] The number of patients discharged to nursing care after a fall injury is almost two times greater than the rate of persons who were hospitalized for non-fall related trauma and three times greater for non-trauma hospitalizations.[4]

Many risk factors have been suggested to contribute to an increased incidence of falling in older adults. Some of the commonly cited factors are prescription medications, muscle weaknesses, decreased joint range of motion, decreased visual acuity, and increased postural sway indicating balance impairments.[2, 8-12] Previous studies have revealed that older adults have increased postural sway when compared to young adults, especially when assessed with the eyes closed.[13-18] This increase in postural sway has been linked to an increase in the incidence of falls in the older adult population.[19, 20] Postural stability begins to decline for women when they are in their 40s, and continues to decline significantly with each subsequent decade.[17]

Postural control is dependent on the integration of vestibular, visual, and somatosensory information.[21] The afferent information from the vestibular system is utilized to measure the accelerations (gravitational, linear, and angular) of the head.[21, 22] Vision is utilized in integrating the relationship of the body to surrounding objects.[22] The somatosensory system provides input about the orientation of body parts to each other and to the support surface.[21-23] The afferent information from all three of these systems is processed in the central nervous system (CNS) to determine the timing, direction, and magnitude of the corrective adjustments needed to sustain a vertical position. Although there are multiple sensory inputs available, in most cases, the CNS relies on one sense at a time. This allows the CNS to be more flexible during those times when one of the inputs may be unavailable.[24] When one sense is unavailable, the remaining two systems are usually able to compensate for the lack of sensory information contributing to the postural control system.[21] Lack of sensory input could be due to an injury, temporary impairment, or a permanent decrease in function of the one or more of the systems due to normal aging.[22, 25, 26]

Somatosensory input is critical to postural control and includes both joint proprioception and tactile sensory information.[21, 22] Both proprioceptive and tactile sensory receptors deliver information to the CNS about postural sway. Research has confirmed the critical role of proprioceptive and tactile sensory receptors in maintaining postural stability.[21] Most studies indicate that the somatosensory system is the dominant sensory input in maintaining balance for both older and young adults.[27, 28] Additionally, cutaneous receptors have been demonstrated to result in an increased response to the stretch reflex when stimulated, suggesting that direct communication is occurring between this system and the muscle spindle gamma system in influencing alpha motoneuron activity.[21] It is thought that both proprioceptive and tactile sensory receptors converge on the alpha motoneuron and on facilitory and inhibitory spinal cord interneurons influencing the gamma motoneuron, resulting in reflexive influences on muscle activation during functions such as walking.[29, 30]

Researchers have shown that peripheral sensation is crucial in maintaining a static posture for adults of all ages.[26, 31] It has been reported that older adults have decreased tactile sensation of the plantar surface of their feet,[32, 33] and have decreased proprioceptor activity. Maki et al.[32] reported that when the sensory feedback was increased to the plantar surface of the foot, older adults had improved reactions to postural perturbations.

Because there is an increased incidence of falls in older adults and the financial burden that can be caused by the falling injuries is great, intervention programs which reduce the risks associated with falling (such as balance deficits) are needed. To date, the literature contains interventions that rely on everything from strength training to nutritional changes, and many combinations of these different interventions.[11, 34-36] Another area of intervention that has been researched is augmentation of the foot's plantar surface sensations.[32, 37, 38]

One type of intervention that would address the plantar tactile sensory deficits in the older adult population is the use of an in-shoe orthotic device. Foot orthotics are typically prescribed for the biomechanical affects of stabilizing the foot. In the clinical setting, orthotics are commonly prescribed for many reasons: altering the rearfoot motion in the gait cycle, assistance in shock attenuation, and proprioceptive inputs. Orthotics are constructed to adapt the foot to the external environment and to place the foot into a position so joint articulations are congruent.[39]

Although traditional research has focused on the use of orthotics to alter the gait cycle,[40] recent literature has begun to focus on the use of orthotics as an aid for proprioception and postural stability.[41-50] Several studies have been performed to evaluate the utilization of orthotics in subjects who have a foot or ankle injury[41, 44-46] and in healthy subjects.[47] All of these studies reported an improvement in postural stability with the aid of an orthotic. Hornyik[41] reported a positive somatosensory effect of foot orthotics on the postural stability system as demonstrated with improvement in dynamic directional control and modified static control after short and long-term use. The efficacy for this orthotic intervention to increase somatosensory inputs has been limited to the subjects' immediate reaction to tactile stimulation at the foot. Nigg et al.[39] have suggested that orthotics act as a filter to the forces acting on the sole of the foot. These "filtered' forces are then transmitted to the CNS to initiate an appropriate dynamic response. It is hypothesized that facilitation of the sole of the foot with the use of a semi-rigid foot orthotic will result in improved postural stability in older adults.

Maintenance of balance is dependent, in part, on the tactile sensory information provided by the feet. Postural control has been shown to be decreased with cooling, anesthesia or ischemic induced sensory loss to the plantar surface of the foot.[27, 28, 51-53] There are various mechanoreceptors of the foot, and their distribution and density vary throughout the plantar surface.[54] Mechanical pressure is transferred to the CNS and is continually processed during stance. Kavounoudias et al.[54] investigated the role of plantar cutaneous information in controlling human balance and demonstrated that cutaneous afferents contribute to human balance control.

Researchers have supported the hypothesis that there are decreases in the number of plantar mechanoreceptors[55] and sensation detection due to aging.[56-61] The processing of cutaneous messages from the plantar surface of the foot along with the other sensory messages allows the CNS to continually monitor body position and make adjustments based on the stimulation from the ground. Therefore, the effect of orthotics to act as a filter to provide constant and improved sensory feedback may be an important component of rehabilitation to improve balance.

Statement of the Problem

It has been demonstrated that older adults have balance deficits that lead to falls and subsequent injury. Decreased somatosensory input may be one of the causes of these balance deficits. Utilizing an intervention that increases somatosensory input would be beneficial in this population. It is not known if increasing the plantar cutaneous sensory input with an in-shoe orthotic would decrease balance deficits seen in older adults.

Purpose

The purpose of this study was to investigate both the initial and time dependent effects of an in-shoe orthotic system on postural responses while performing both clinical and force plate measurements of postural stability in an older adult population. The effects of the in-shoe orthotic were investigated at day 1 and then 4 weeks and 8 weeks after initial usage. This assessment was based on clinical measures that included the Berg Balance Scale, Timed “Up and Go”, Four Square Step Test, Functional Reach Test, and Lateral Reach Test. The force plate measurements that were utilized were Quiet Standing with Eyes Open, Eyes Closed, and Feet Together. One of the subpurposes of this study was to investigate the effects of the in-shoe orthotic system on activity levels and balance confidence. This was assessed with survey measurements that included the Activities-specific Balance Confidence Scale and the Activity Questionnaire. Another subpurpose was to investigate whether peripheral sensation was changed over the 8 week period and this was assessed utilizing a Semmes-Weinstein Monofilament test and Quantitative Vibration Perception Threshold testing.

Research Hypotheses

To evaluate the effect of the in-shoe orthotic system on postural responses in an older adult population, several research hypotheses have been formulated. If the in-shoe system is able to enhance postural stability through increased filtering of sensation information to the sole of the foot, the following research hypotheses will be supported:

1. There will be significant improvements at the initial in-shoe orthotic system data collection when compared to the non-orthotic results for all Clinical Measurements and Force Plate Measurements.
2. There will be significant improvements in Clinical Measurements and Force Plate Measurements at the 4 week collection compared to the initial and non-orthotic data collection data.

3. There will be no significant subsequent improvements in the Clinical Measurements and Force Plate Measurements at the 8 week collection compared to the 4 week data collection period.
4. There will be a significant increase in the Activities-specific Balance Confidence scale and the Activity Questionnaire at both the 4 and 8 week data collection period compared to the first data collection.
5. There will be no significant difference in the Semmes-Weinstein Monofilament and Quantitative Vibration Perception Threshold when comparing week 8 data to the initial data.

Significance of the Study

There is a need for research that investigates strategies to decrease falls, and thus fall injuries, in older adults. By studying interventions that can improve postural control in this population, older adults may benefit from these strategies. If there is a simple, adjunct intervention, like the in-shoe orthotic system, older adults will be more likely to comply. It is generally agreed that interventions to prevent falls need to be approached with a multidisciplinary solution. If this study supports the hypothesis that in-shoe orthotics improve postural control in the older adult population, then their usage as part of an integrated intervention program for fall prevention may be warranted.

Limitations

1. The number of days between Test Days 2 and 3 were not the same for each subject due to delays in the delivery of the shoes.
2. Due to the space available for data collection, the force plate had to be placed on a low-pile carpet. All efforts were taken to make sure that it was level at all times and did not move during use.

Delimitations

1. Subjects wore their own shoes for the first 2 days of data collection and the type of shoe was not controlled. Subjects were told to wear the shoes that they would wear to "walk around" the most.
2. Due to the number of available subjects, there was not a control group.
3. All subjects had intact somatosensory systems so that the in-shoe orthotic did not cause disturbances to the skin on the plantar surface of the foot.
4. Vision correction was utilized when necessary, and participants with known vestibular problems were excluded.

Definitions

Community-dwelling: Individuals who are living independently in the community as opposed to in an institutional setting.

Postural Control: The ability to adjust the body's position in space for the two purposes of orientation and stability.[22]

Postural Orientation: Being able to sustain the correct relationship between body segments and between the body and the environment to perform a certain task.[22]

Postural Stability: Also referred to as balance, it is the ability to maintain equilibrium for the whole body. This can be at rest, static equilibrium, or during steady-state motion, dynamic equilibrium. Postural stability can also be defined as maintaining the Center of Gravity (COG) line of projection within the base of support(BOS).[22]

Older Adult: Individuals who are aged 65 years and older.[62]

Young-old Adult: Individuals who are aged over 65 years and less than 79[63] or 84 years.[64, 65]

Oldest-old Adults: Individuals who are aged 80[63] or 85 years and older.[64, 65]

Chapter Two

Review of the Literature

Introduction

The purpose of this study was to evaluate the utilization of an in-shoe orthotic system on the postural stability of older adults over an eight week period. This chapter examines the scientific literature referenced in Chapter One in greater detail. The topic of postural control and balance is a complex topic that includes multiple peripheral sensory systems, the Central Nervous System, and motor control systems. For the purposes of this review, the main focus will include the peripheral sensory systems and the somatosensory system in particular. This chapter is comprised of three major sections:

1. Normal Adult Postural Control
2. Aging and Postural Control
3. Interventions for Enhancing Postural Control of Older Adults

Normal Adult Postural Control

To independently perform most, if not all, of the activities of daily living, a person needs to be able to recover from instability as well as be able to anticipate and react to avoid instability. Controlling posture and balance to perform these tasks requires a complex system that encompasses several control mechanisms in the body.[26, 66] Postural control is defined as controlling the body's position in space for both stability and orientation.[22] To be balanced, or stable, is defined as the ability to maintain the body's center of gravity (COG) vertically above the base of support (BOS).[22, 67] Most of the tasks that humans perform require a vertical orientation to be maintained.[22, 68] In order to maintain this vertical position, postural control is dependent on the integration of vestibular, visual, and somatosensory information. Postural control also requires the generation and coordination of forces that produce the movements that control the body's position in space. [21, 22, 68, 69]

Sensory Systems Related to Postural Control

The afferent information from the vestibular system is utilized to measure the accelerations (gravitational, linear, and angular) of the head.[21, 22] There are two types of receptors within the vestibular system, the semicircular canals and the otoliths.[22, 70] The semicircular canals are utilized to sense the angular accelerations of the head[70] and are particularly sensitive to fast head movements.[22] Otoliths sense head position relative to gravity and linear acceleration and are sensitive to slow head movements.[22, 70] However, the vestibular system is not able to provide the Central Nervous System (CNS) the complete representation of how the body is moving because it can not provide orientation information.[22, 23] The CNS needs input from the visual and somatosensory systems to enhance the information that it receives from the vestibular system.

The afferent information from the visual system is utilized in integrating the relationship of the body to surrounding objects.[22, 71, 72] The visual inputs assist in providing a reference that allows the CNS to know what is vertical. The visual system also provides information about the motion of the head by how surrounding objects move.[22] Even though the information gathered by the visual system is important to postural control, it is not absolutely necessary in the healthy adult. It is well known that healthy adults are able to maintain stability in the absence of vision, e.g., eyes closed or in a dark room. However, experimental evidence also indicates that the visual sensory system provides important information about low frequency body motions as in static posture.[73] Although stability can still be maintained with the loss of visual information, many researchers have reported that postural sway is significantly increased when the eyes are closed when compared to eyes open conditions in healthy adults.[17, 71, 74] In addition, Berensci et al.[75] performed a series of experiments that indicated that peripheral vision, compared to central vision, is more important in maintaining stability. Thus, altering visual input may increase postural sway, but the absence of visual feedback does not result in complete loss of stability, indicating the importance of other input mechanisms at work.

The afferent somatosensory input provides information related to the orientation of the body parts to one another and to the support surface.[21-23] Somatosensory receptors are numerous and can be classified into three general types: 1) mechanoreceptors; 2) thermoreceptors (that measure temperature change); and 3) nociceptors (that measure painful stimuli).[76] The mechanoreceptors are the category that relates to postural control. The mechanoreceptors can be further divided into two categories: 1) cutaneous and 2) musculoskeletal (Table 2.1).[21, 22, 76, 77] The cutaneous mechanoreceptors include Pacinian corpuscles, Meissner's corpuscles, Merkel's discs, and Ruffini endings.[21, 22, 76] These receptors detect the sensations of vibration, pressure, and skin tension.[76, 77] The musculoskeletal mechanoreceptors include muscle spindles, Golgi tendon organs, and joint receptors. [21, 22, 76] These receptors are associated with proprioception by detecting the position, velocity, and tension that determines the relative position and movement rates of the body parts.[76, 77] Together, the cutaneous and musculoskeletal mechanoreceptors contribute significant information for postural control.

Table 2.1: Summary of Somatosensory Mechanoreceptors

Receptor Name	Stimulus Type	Sensation Detected
Cutaneous		
Pacinian corpuscles	Vibration	High-frequency vibration
Meissner's corpuscles	Vibration	Flutter, contact
Merkel's discs	Skin distortion	Local pressure
Ruffini endings	Skin distortion	Skin stretch
Musculoskeletal		
Muscle spindles	Muscle elongation	Proprioception
Golgi tendon organs	Tendon tension	Proprioception
Joint receptors	Joint movement and tension	Proprioception

Adapted from Fredericks, 1996[76]

There is redundancy in the three sensory systems (vestibular, vision, and somatosensory) involved in postural control. This allows for more flexibility during those times when one of the inputs may not be available.[24] However, although there are three inputs, researchers have concluded that the proprioceptive and cutaneous inputs are relied on primarily to maintain quiet stance in normal circumstances.[27, 28, 78-80] Several researchers have manipulated the sensation of the foot and ankle to elicit the association between reduced foot sensation and balance difficulties.[27, 51, 81-88] A few of these researchers have investigated the impact that reduction in plantar sensitivity has on postural control by isolating the plantar cutaneous receptors specifically.[87-89] This body of research has supported the association that a decrease in sensation of the plantar aspect of the foot increases postural sway.

Role of the somatosensory system of the foot and ankle

Nashner et al.[81] and Bloem et al.[82] investigated the somatosensory system of the lower extremity by reducing the stimulation of the ankle joint proprioceptors. Nashner et al.[81] utilized ‘sway referencing’, i.e., rotation of the support surface concurrent with body orientation, to achieve this stimulus reduction. By systematically manipulating the vestibular, visual, and somatosensory systems the researchers elicited the most dramatic performance deficits when subjects had inappropriate responses to proprioceptive inputs.[81] The other method to investigate the ankle joint proprioceptors was termed ‘nulled ankle input’ and was achieved by simultaneously translating and rotating the support surface.[82] Using this method, Bloem et al.[82] were able to determine that the joint proprioceptors of the ankle have an important role in postural control. Even though both of these studies where able to reduce the somatosensory input of the ankle joint, these methods allow the plantar sensitivity to remain intact and provide information regarding the orientation of the support.

There have been several methods employed to reduce the plantar sensation to try to isolate the influence of these receptors. Utilization of hypothermia as an anesthetic has produced increased body sway in both the anterior-posterior[90] and medial-lateral planes.[51, 83] Hypoxic anesthesia is another method that has been utilized to reduce foot somatosensory input.[27, 88] Results from Horak et al.[27] supported the hypothesis that cutaneous and joint somatosensory information from the feet and ankles may play an important role in guaranteeing that the postural movements are appropriate for the current biomechanical constraints of the surface and/or foot. The method of ischemia utilized by Wang et al.[88] differs from others by attempting to differentiate between plantar sensation loss and total somatosensory loss. Greater postural sway was observed when the plantar cutaneous sensitivity was reduced and the only differences between partial loss and total loss occurred when vision was altered as well.[88]

One more method of reducing the somatosensory input that can be found in the literature is the usage of pharmaceutical anesthesia.[84, 87, 89] Konradsen et al.[84] did not find a change in postural sway during static balance with a lidocaine block of the ankle and foot, but did conclude that the ankle ligaments had an important role in foot placement while walking. Meyer et al.[87, 89] utilized a different lidocaine blocking protocol that tried to isolate specific plantar cutaneous receptors located on different sites of the foot. These studies reported that the loss of plantar sensation had a deleterious impact on the postural control system and even more so when other sensory deficits are present.[87, 89]

One last method of manipulating the plantar sensation is the usage of high and low frequency vibration.[86, 91-93] Maurer et al.[93] utilized low frequency vibration and concluded that stimulation of the plantar cutaneous mechanoreceptors led to postural responses, but it did not significantly change reactions for normal subjects. In several studies, Kavounoudias and colleagues stimulated the plantar surface of the foot and the ankle dorsiflexor muscles with high frequency vibration and concluded that the plantar surface of the foot contributes to the spatial representation of the body's tilt and that the tactile and proprioceptive information may utilize vector addition in maintaining upright stance.[86, 91, 92]

In summary, the postural control of normal, healthy adults is controlled by the three sensory systems: vestibular, vision, and somatosensory. Even though the afferent information from all three of these systems is utilized by the CNS to achieve appropriate responses, the somatosensory system has been found to have the greatest input. The complexity of the somatosensory system and the high number of receptors in this system make it difficult to isolate individual mechanisms. By systematically reducing input from different receptors in the foot and ankle, researchers have attempted to discern whether the plantar cutaneous receptors are responsible for a large degree of input to the postural control system. Current literature seems to support this hypothesis.

Aging and Postural Control

Older adults have increased postural sway compared to young adults. Researchers have tried to correlate this increased sway with deterioration in the nervous system.[13, 94, 95] It has been reported that deficits in sensation, muscle strength, reaction time, vestibular function, and vision occur with aging and can contribute to increased balance difficulties in older adults.[22, 25, 26, 31, 96-99] In this section of the review, the effects that aging has on the vestibular, visual, and somatosensory systems will be explored individually and then how the integration of these three systems is effected will be discussed at the end.

Effect of age on vestibular system

Research published about the vestibular system has reported degeneration of the sensory cells found within the inner ear. [99, 100] Rosenhall[99] reported a 40% reduction in hair cells in the semicircular canals in subjects over the age of 70 years old. Deficits in vestibular function in older adults may have a greater effect on stability than just being a loss of redundancy of the sensory input. Diminished capacity of higher integrative processes within the CNS present an additional challange.[81] Woollacott et al.[95] reported that 50% of their older adult subjects displayed vestibular function impairment when both vision and useful somatosensory inputs where removed. The authors concluded that this response may be indicative of impaired vestibular function or central integrative processes in the older adult population that was tested. Teasdale et al.[101] had similar findings with a group of healthy older adults who had significant increases in sway compared to young adults while using vestibular inputs alone during a static stance task.

Effect of aging on visual system

There are several age related changes that occur to the visual system. These changes include a decrease in the amount of light allowed to reach the retina, an increase in glare, a decrease in visual acuity, a reduction in depth perception, and a decrease of 30 degrees in field of view.[102-106] Sekuler and colleagues reported that older adults have a significant reduction in spatial visual sensitivity compared to young adults.[105, 106] The acuity insensitivity was found most frequently to low spatial frequencies and slow moving targets and may adversely affect postural control which relies on low frequency visual information.[106, 107] It has been reported that there are age related increases in sway during quiet stance when input from vision is removed.[13, 108] Therefore, it can be surmised that deficits in the visual system would have a greater affect on postural control in older adults than if young adults had the same decreases in vision. The decrease in visual acuity for close objects has a detrimental effect on postural control as well, however this can usually be corrected through the use of eyeglasses.[102] Peripheral vision was also found to be most beneficial in postural control for young adults as opposed to central vision.[75] So it stands to reason that the loss of peripheral vision due to aging will have a detrimental effect on postural control in this population.[98, 104] Researchers must be aware of these changes and corrections when studying an aging population.

Effect of aging on somatosensory system

Age related changes have been found in both the musculoskeletal and cutaneous components of the somatosensory system.[26, 31-33, 64] As these components become compromised, the postural control system receives less input from these receptors. Since it has been shown that this feedback is important in maintaining postural stability, deficits in the receptors will ultimately lead to deficits in posture as well. The following section summarizes the literature related to deterioration of the somatosensory system due to aging.

Musculoskeletal receptors

Age related changes in the receptors that are in the musculoskeletal category have been investigated in both humans and animals.[109-112] Researchers have investigated changes in the receptors[109-112] as well as clinical measures of proprioception[113-117] in determining the effects of age on the system.

It has been reported that aging results in morphologic changes in muscle spindles.[109, 110, 112] Changes that were observed included increased thickness in the spindle capsule and a loss in intrafusal fibers and were attributed to denervation of the receptor.[112] A 2005 study by Liu et al.[110] found similar decrease in the number of intrafusal fibers for older adults. Both of these studies identified these age related changes in upper extremity muscles only. Neither of these research groups investigated muscles in the lower extremity. An animal study published in 1995 examined the afferent response of muscle spindles to differing levels of stretch that were applied to the medial gastrocnemius of rats.[111] Results from this animal model found that the older adult rats had a decline in spindle sensitivity when compared to middle-aged rats.[111] Along with muscle spindles, joint receptors have been investigated to see if there are changes with aging in humans[118] and animals.[119] Again, the human study involved an upper extremity joint, the coracoacromial, and found a decrease in the articular joint receptors in the older subjects compared to young adults.[118] The animal study investigated the anterior cruciate ligament in rabbits and results indicated deterioration of the articular mechanoreceptors in the older rabbits compared to young and adult rabbits.[119]

Along with histological studies, researchers have assessed proprioception using the clinical tests of joint position sense (JPS) and joint kinesthesia. Verschueren et al.[113] examined JPS while passively moving the ankle into plantarflexion at various velocities. Results from this study revealed that the men who where aged 70 years and older had a significantly greater deviation from the target positions when compared with the young adults. The older men who were aged 60-70 years old had an increase in variance with the task, but were not found to be significantly different compared with the young adults. The researchers went on to have a subset of the subjects perform the task again with vibration being applied to the anterior tibialis muscle. This added vibration resulted in a decrease in JPS ability for the older adults only. The authors reported that these results indicated that the age related deterioration in JPS was due to both a reduction in cutaneous and muscle spindle functions.[113]

Madhavan and Shields evaluated ankle JPS in older adults and included measures of balance and muscle function during a single leg standing activity.[114] Results from this study agreed with Verschueren et al.[113] that the older adults had a decrease in ankle JPS, but the addition of the balance component allowed them to demonstrate that there was a strong association with this decline and the ability to stand on one leg with eyes closed. The results of muscle activity revealed an increase in EMG activity in the older adults that was not seen in the young adult group. The finding of co-contraction of the plantarflexors and dorsiflexors allowed the authors to hypothesize that the older adult’s inability to relax could have been a technique to accommodate to a decrease in muscle spindle sensitivity.[114] Other researchers have reported similar findings of cocontraction of the ankle musculature in older adults performing tests of postural control.[120] The investigators concluded that the older adults coped with the deterioration in their sensory input and processing ability by developing a strategy of stiffening their lower legs during upright standing.[120]

Cutaneous receptors

It is known that the plantar cutaneous receptors relay information about the location and magnitude of forces during weight-bearing activities.[121] There has been evidence for over 50 years that humans have a decrease in the number of plantar Pacinian corpuscles with increased age.[122] In 1966, Bolten et al.[55] reported a decrease in the number of Meissner corpuscles on the plantar aspect of the hallucis due to aging. Quantification of the decrease in Meissner's corpuscles was accomplished by analyzing punch skin biopsies from 91 subjects ranging in age from 11-89 years old.[55] Along with these anatomical results of a reduction in the plantar cutaneous receptors, several studies have revealed that there is a decrease with clinical cutaneous testing when performed on older adults.[56-59, 61, 123-125]

There have been three methods of clinical cutaneous testing published in the literature; 1) vibration perception threshold,[61, 123, 125] 2) monofilament testing,[61] and 3) 2-point discrimination testing.[56-60] Perry[61] utilized both vibration perception threshold and monofilament techniques on four sites on the plantar aspect of the foot in an investigation that studied young adults compared to older adults. Results from this study revealed that the older adults had less sensitivity to both the vibration and monofilament stimuli at all sites when compared to the young adults. When the results of just the older adults were analyzed, it was revealed that early in the seventh decade (72-73 years old) participants started to show a doubling of their vibration detection threshold as compared to their younger counterparts (65-71 years old). A difference between the two groups of older adults was not seen with the monofilament data. The stratification between the two groups of older adults allowed Perry to conclude that the vibration perception threshold method of testing could be more sensitive at detecting the beginning of age related plantar insensitivity.[61] The results from Perry are similar to the findings of Verrillo et al.[124] who reported a decrease in vibration detection among older adults when compared to young adults when vibration was applied to the hand. Combined, these two studies describe a loss of vibration sensitivity in older adults.

Two-point discrimination testing is the third method of clinical cutaneous testing that has been researched in an older adult population.[56-60] Utilizing 2-point discrimination measurements on 13 body sites, Stevens and Choo[57] constructed a spatial acuity map that depicted how tactile spatial acuity changes over the lifespan. Their data indicated that older adults had deficits compared with young adults at all 13 locations that were tested, with the hallucis and plantar aspect of the foot having the largest deficits. Compared to the young adults, the older adults averaged a 400% and 250% deficit at the hallucis and plantar aspect, respectively.[57] These findings were more recently reproduced when Stevens et al.[60] reported an averaged 91% decline at the forefoot of older adults compared to young adults. In this recent study the 2-point discrimination was performed on both the dorsal and plantar surfaces of the foot, with no significant differences elicited between the two surfaces. The authors concluded that the lack of difference between the surfaces of the foot provided evidence that refutes the hypothesis that sensory differences are due to wear and tear on the contact surfaces.[60]

Effect of aging on sensory integration

There is a redundancy of sensory inputs that ensures that stability can still be maintained when one or more of the inputs is absent. When redundancy is not available, mechanisms of integration should cause a reweighting of dependency on the remaining inputs.[126] The previous sections have depicted how older adults may have decreases in the sensitivity of the peripheral sensory systems and with these decreases there is a reduction in redundancy of sensory information available. Therefore, older adults are less effective at shifting the relative weighting of the inputs as the need arises because of environmental changes. There have been several research groups who have reported that older adults have more difficulty when compared to young adults in maintaining postural control when sensory information is drastically reduced.[25, 26, 71, 95, 101, 127-129]

To discern the sensory integration of the vestibular, visual, and somatosensory systems, researchers systematically remove or disrupt one or two of the inputs and measure the postural changes that ensue.[25, 71, 95, 98, 101, 128, 129] Discrepancies have been found in the literature regarding the role of vision on postural control. Several researchers have reported that there are age related increases in sway during quiet stance when input from vision is removed.[13, 108] While other investigations have revealed that healthy older adults only slightly increase their postural sway in eyes closed trials and that this increase is not enough to differentiate the older and young adults.[71, 95, 101, 128] The same has been found with investigations that reported disrupting the somatosensory system and comparing older and young adults.[95, 101, 127, 128] There seems to be a continuum of deficits in the older adult populations that may not be as widely dispersed in younger populations.

Researchers have reported that if eyes are open, there is only a mild increase in postural instability when somatosensory input is distorted by either the use of foam or computerized posturagraphy.[95, 101, 127, 128] While Judge et al.[129] used computerized posturography on 110 older adults and found greater deficits when proprioception was reduced as compared to when vision was reduced. This study did not have a comparison to young adult subjects like the previous studies, however they did make a distinction between the older and oldest participants, and reported that the deficits where greater in the oldest subjects. Similarly, Camicioli et al.[63] compared oldest-old and older adults and reported that the former had decreased postural scores when proprioceptive input was the sense that was inaccurate. This discrepancy between the studies that reported proprioception alone did or did not affect postural control significantly may be explained by the age of the subjects. The largest changes were found in the group of subjects that were classified as oldest-old adult.

Despite the discrepancies in the literature as to the outcome when either visual or proprioceptive inputs were reduced, there seems to be no discrepancy among researchers when both of these inputs are removed or distorted. Teasdale et al.[101] utilized a foam surface to distort the somatosensory input in both older and young adults while vision was either available or removed. The results revealed that when healthy older adults were relying on their vestibular inputs alone they had significant increases in postural sway compared to young adults. Researchers have also found similar results when using computerized dynamic posturography to discriminate among the sensory inputs of postural control.[25, 95, 98, 128, 129] This body of literature is in agreement that when both the visual and somatosensory inputs for postural control were removed or distorted there was a significant decrease in the ability to maintain stability in older adults.

Woollacott et al.[95] reported that half of their older adult subjects had a complete loss of balance on the first trial for these trials that manipulated both sensory inputs. The investigators did report that all but one of the subjects who had lost their balance were able to perform trials two and three without exceeding their limits of stability. The authors concluded that this improvement was a sign that the older adults were able to adapt the senses for postural control, but only after practice with the manipulated conditions.[95] Similarly, Judge et al.[129] reported that the older adults were able to substantially adapt to the combination of vision and somatosensory reductions with repeated trials. As stated previously, the current literature reports that healthy older adults do not have significant deficits in postural control compared to young adults when there is manipulation of one peripheral sense. However, they are all in agreement that there are significant decreases in postural control of older adults when two of the senses are not available. There seems to be some evidence to show that the older adults have the ability to adapt to these manipulations of the sensory input with sufficient practice. It is not known how long these adaptations last or the amount of practice needed.

In summary, there are noted age related deficits in the peripheral sensory systems of postural control. Even with these negative changes in the anatomical structures of the sensory receptors related to aging, healthy older adults are able to perform unperturbed balance activities similar to young adults. When the integration of the three sensory systems is challenged there appears to be subsequent deficits in postural control and this is seen more plainly in older adults. When two of the systems, namely visual and proprioceptive inputs, are removed or distorted older adults are often unable to compensate immediately. It has been recommended that since there is strong evidence that there are decreases in the sensitivity of the somatosensory system that there needs to be compensatory strategies for older adults. Such strategies include increasing the sensory input as well as cutaneous and proprioceptive feedback. Orthoses and assistive devices are two of the suggested ways that sensory input could be enhanced during functional activities.[64]

Interventions for Enhancing Postural Control of Older Adults

The scientific and medical communities are interested in interventions that enhance the postural control of older adults because of the link between decreased balance and the increased risk of falling.[130, 131] Many different fall interventions have been reported in the literature including home hazard assessments, changes in medicines, cardiac pacing, muscle strengthening, balance training, functional exercise, augmentation of the plantar cutaneous receptors, and multifactorial programs.[32, 37, 130-136] This review will mainly focus on interventions that attempt to facilitate the somatosensory system.

Interventional studies have implemented varying single intervention strategies as well as multifaceted interventions with older adults in the hopes of reducing falls. Outcome measures utilized in these studies include direct measures of balance (e.g., force platforms), indirect measures of balance (e.g., Functional Reach Test, timed up & go, Berg Balance Scale), fear of falling measures, and reported falls over a period of time after the intervention. Brouwer et al.[137] evaluated an exercise program that included light resistance training and weight shifting, compared to an education program over eight weeks. The researchers reported that even though fear of falling confidence was increased in both groups of older adult women, the group of women who had participated in the exercise had significant improvements in the direct balance measure and therefore it was concluded the postural control system had been enhanced. Similarly, a study using low-impact aerobic dance as the intervention reported that there was an improvement in indirect measures of balance with older women after 12 weeks.[138] When used in conjunction, direct and indirect measures of balance reveal the spectrum of dynamic balance.

Several research groups have utilized Tai Chi as a fall reducing intervention in older adults.[139-144] Tai Chi is a exercise technique that stresses postural control by continuously invoking slow body rotation movements while the base of support is progressively reduced.[139] Wolf et al.[139] reported in 1996 that a 15 week intervention of Tai Chi significantly reduced the fall occurrence in older adults when compared to a group that had undergone balance training and another that had received education only. These researchers did not report any direct or indirect measurements of balance but did report that fear of falling was reduced in the Tai Chi and education groups. Li et al.[142] also reported a reduction of falls in older adults after a six month Tai Chi intervention compared to a group of older adults who had just performed stretching exercises. Compared to Wolf et al.,[139] Li et al.[142] did report significant improvements in multiple indirect measures of balance in the Tai Chi group compared to the stretching control. The researchers reported that the improvements in balance and fall prevention were maintained for at least six months after the intervention period.[142]

Tsang and colleagues reported in two cross sectional studies that older adults who were Tai Chi practitioners[141, 144] and older adults who were golfers[141] performed direct balance measures better than a control group of older adults as well as performing at the same level as young adults. The results revealed that postural sway during single leg stance was significantly better for the older adults who participated in Tai Chi compared to the control group of older adults.[144] When somatosensory measures were investigated by joint reposition sense of the knee joint, it was revealed that the older adult Tai Chi practitioners and the older adult golfers had significant better sensitivity when compared to a control group of older adults.[141] Tsang et al.[143] also reported that after just four weeks of participation in Tai Chi, older adults where able to improve their balance as measured with computerized dynamic posturography. Furthermore, the improved balance performance that was seen at the four week testing was comparable to that of experienced Tai Chi practitioners. This finding allowed the researchers to conclude that four weeks of Tai Chi training were sufficient to improve postural control in older adults.[141]

These studies support the theory that exercise interventions improve postural control in older adults. This adds credence to the hypothesis discussed by Woollacott et al.,[95] that older adults have the ability to adapt their sensory integration if there is adequate practice. Another type of postural control intervention that has been reported in the literature is the augmentation of the somatosensory system of the foot and ankle.[32, 37, 50, 133-136, 145]

A recently published article presented a unique intervention to enhance somatosensory inputs in older adults, therapeutic manipulation.[136] The researchers utilized massage of the feet, and joint mobilization of both the feet and ankles, to target the somatosensory receptors of these sites. The results revealed that the manipulation technique was able to compensate for sensory deficits when the older adult subjects closed their eyes while performing static standing trials. The researchers concluded that the subjects were able to adapt to the reduction in sensory input immediately after the intervention was performed.[136] It is unknown how long these effects last. Bernard-Demanze and colleagues have reported that 10 minutes of massage to the plantar aspect of the foot results in decreased COP sway particularly in the medial-lateral direction for healthy young adults.[146, 147] Improvement in balance control occurred after three bouts of massage and lasted for at least 20 minutes.[147] Therefore, manual sensitization of the feet and ankles was reported to give a minimum of short term benefit in postural control.

Vibration and mechanical noise are types of intervention that attempt to facilitate the somatosensory system. It has been reported that noise can enhance sensory and motor functions of the extremities of older adults by way of a mechanism known as stochastic resonance.[37, 38, 148, 149] Priplata and colleagues hypothesized that the postural sway of both young and older adults would be improved during quiet stance when there was an application of vibration or mechanical noise to the feet.[37, 38] Subsensory “white” noise was applied to the plantar aspects of the feet in both of these studies. In the first study, the subjects stood on a platform and the noise was supplied by nylon indentors that touched the sole of the foot.[38] The second of the studies had the subjects standing on two gel insoles that had three vibrating elements embedded in each insole.[37] The results of both of these studies revealed that the postural sway was decreased with the addition of the noise, which lead the investigators to conclude that the application of noise increased the postural control in these older adults.

According to similar findings, the insertion of a textured insole into the shoes of young adults results in a reduction in ankle plantarflexor and dorsiflexor muscle activity during gait.[145] Nurse et al.[145] reported changes in gait patterns which supported the hypothesis that textured insoles facilitated sensory feedback from the plantar aspect of the feet during gait. Palluel et al.[133] attempted to add to the findings of this previous study by investigating the immediate and temporal effects of textured insoles on postural control of young and older adults. The investigators hypothesized that the spiked sandals would increase the cutaneous sensation similar to the massage affect found by Bernard-Demanze et al.,[146] and thus increase the postural stability in the older adults. The results did not show an immediate effect with the sandals, but after either standing or walking in the sandals for five minutes the results did confirm the hypothesis. The authors concluded that both young and older adults, without discernible sensation deficits, have enhanced postural control when wearing the spiked sandals.[133] This finding differs from Wilson et al.[134] who had middle-aged females wear one of three textured insoles for a four week period. The results of this study found no significant differences in the static balance measurements. The discrepancy between these two studies could be explained by the age of the subjects, middle-aged versus older adults, and the time of insole usage, five minutes versus four weeks.

Another method found in the literature of facilitating sensation of the plantar aspect of the foot is the usage of a raised edge around the border of the feet.[32] The hypothesis was that by increasing the sensation from the boundaries of the base of support there would be a reduction in COP excursions toward the boundary. Subjects were healthy older adults who had measurable loss of sensation as measured by vibration detection threshold. The results revealed that the mechanical facilitation of the foot boundary was able to improve the postural reactions and reduced the COP movement when continuous anterior/posterior perturbations were applied. The authors concluded that the raised border provided the CNS with more information about the base of support as well as the limits of stability in the older adult subjects.[32]

Recently, researchers have reported that in-shoe orthotics can be used as an aid for postural stability. A search of the literature reveals that in-shoe orthotics have been found to be beneficial in improving postural control in a wide range of subjects, from those with foot or ankle injuries[41, 44-46] to those that are considered healthy.[47] All of these studies have been performed on young adult subjects. Stude and Brink[50] reported an increase in proprioceptive symmetry of the lower extremities after experienced golfers wore custom, flexible orthotics for six weeks. However, they did not report the age of their subjects so it is not known if these findings are with an older population. Foot orthotics are usually designed to correct biomechanical and structural abnormalities of the foot and ankle and it is highly likely that there is a resulting effect on the somatosensory system by way of increased receptor stimulation. Since this hypothesis has been upheld in young adults it stands to reason that the older adult population, who is known to have somatosensory deficits, would benefit from orthotics as well. To date, a search of the literature does not elicit research that attempts to add to this body of evidence.

Summary

This chapter reviewed the literature involved in postural control. The first section focused on postural control in normal, healthy adults and the peripheral sensory systems (vestibular, visual, and somatosensory) that contribute to the postural control system. Section two reviewed the current literature regarding the effect of aging on the postural control system. The most deleterious effects of aging have been found to be in the somatosensory system. The final section of this chapter reviewed the interventions that researchers have utilized to improve postural control deficits found in the older adult population, specifically in the somatosensory system. Although there is extensive research on these topics, there are several areas that need to be investigated further. The effectiveness of orthotics on the postural control of the older adult population has not been conclusively determined.

Chapter Three
Methods

Introduction

The purpose of this study was to evaluate the utilization of an in-shoe orthotic system on the postural stability of older adults over an 8 week period. This chapter describes the methodologies that were utilized during the study. The subjects are described first and data collection procedures are discussed second. Data analysis procedures are described third and statistical analyses are discussed last.

Subjects

Twenty-seven volunteers (19 females, 8 males, mean age: 86.93 ± 5.1 years, range: 73-97 years, mean height: 1.66 ± 0.11 m, mean mass: 71.06 ± 15.57 kg) were recruited as subjects from Richmond Place Retirement Community (Lexington, KY). Subjects were excluded for the following: 1) uncontrolled blood glucose levels, 2) any lower extremity or head injury in the past 6 months, 3) any uncontrolled medical conditions, 4) uncorrected visual or vestibular problems, 5) history of foot wounds 6) significant pain that limits daily function, 7) an ear infection within 2 weeks prior to testing, 8) a quantitative vibration perception threshold ≥40 V and detection of ≤2 Semmes Weinstein Monofilament contacts, 9) a score of less than 20 on the Mini Mental State exam. Exclusion criteria 1-7 was obtained with a Health History Questionnaire (Appendix A) and 8-9 were directly collected by the examiner. Prior to testing, all subjects were informed of possible risks and signed an informed consent approved by the University of Kentucky Institutional Review Board (Appendix B).

Instrumentation

Force Plate

Force data were collected at 100 Hz using a Bertec strain gage force plate (Bertec Corporation, Columbus, OH). The force data were collected using Motion Monitor software (Innovative Sports Training Inc., Chicago, IL). The force plate was placed on a low pile, industrial carpet. The force plate was leveled using a standard bubble level and sheets of paper for shims. This was done at the beginning of each day of data collection and was checked periodically during the collection period to make sure the plate was still level. All force data were filtered with a 4th order, zero phase shift Butterworth filter with a cutoff frequency of 10 Hz. A residual analysis was utilized to calculate the 10 Hz cutoff frequency.[150] The force plate output was exported to Excel and utilized to calculate center of pressure (COP) displacement, distance, and the root mean square of velocity (RMS_{vel})[46] for both the anterior-posterior (AP) and medial-lateral (ML) directions (Appendix C).

Sensation Testing

Sensation, both cutaneous and proprioceptive, declines as people age. In addition, sensory deficits in the feet have been identified as an independent risk factor for falls. Semmes-Weinstein Monofilament (SWM) and quantitative vibration perception threshold (QVPT) testing are non-painful, inexpensive, valid, and reliable tests to assess foot sensation.[151-153] The SWM method that was utilized in the current study has been found to have a sensitivity of 72%, a specificity of 71% and an accuracy of 72% when assessing peripheral neuropathy.[152] The QVPT methodology that was utilized has been found to have a sensitivity of 86%, a specificity of 56%, and a positive predictive value of 32% when predicting patients who are at risk for developing diabetic ulcers [153].

The SWM examination was conducted using a 5.07/10-g monofilament. These monofilaments are as thin as a human hair and bend at 10 grams of pressure. A non-callused area on the dorsum of the hallux just proximal to the nail bed served as the test site. The monofilament was applied perpendicular to the test site and held for one second. The subjects had their eyes closed and were instructed to respond “now” when they perceived the monofilament.[151, 152] This was completed four times in an asynchronous manner on the test site. The number of correct responses, out of a maximum of 4, was recorded.

The QVPT testing was performed using a Bio-Thesiometer (Bio-Medical Instrument Company, Newbury, OH) (Figure 3.1). This is a handheld device that has a rubber tip that vibrates at 100 Hz. The handheld unit is connected to a base unit. The base unit has a linear scale that displays the applied voltage that can range from 0 to 50 V. The rubber tip of the instrument was placed on the pulp of the subject’s hallux. The handheld unit was placed so the force was perpendicular to the floor. The voltage was increased slowly until the subject was able to perceive the vibration.[153]

Figure 3.1 Bio-Thesiometer

SmartStep™ Stabilization System

All subjects were supplied with the SmartStep™ Stabilization System (SmartStep, Inc., Kansas City, KS). SmartStep™ consists of the following: 1) a pair of extra depth, diabetic shoes (Aetrex Worldwide, Inc., Teaneck, NJ) 2) a patented in-shoe semi-rigid orthotic (SmartStep, Inc.), 3) a pair of patented SmartKnit Seamless Socks, 4) a pair of Comfort System Lite Socks, 5) a pair of Sleep Socks with non-skid treads. (Figure 3.2)

Figure 3.2: SmartStep™ System

Procedures

Each subject was tested on five days. The first 2 Test Days were performed while the subjects wore their own shoes, while the last 3 Test Days were performed while the subjects wore the SmartStep™. Test Days 1 and 2 occurred at least 48 hours apart. Test Day 3 occurred when the SmartStep™ was initiated and the average time between Test Days 2 and 3 was 22 ± 11 days. Test Days 4 and 5 occurred 4-weeks after the prior Test Day (Table 3.1). During the 8-weeks between Test Days 3 and 5, subjects were asked to wear the SmartStep™. Weekly visits were made to each subject to ensure compliance with wearing the shoes and to check for discomfort or injuries.

The sensation testing was performed on Test Days 1 and 5 and included the SWM and QVPT tests. All 5 Test Days included the same clinical and force plate collection procedures. The clinical measures included the Berg Balance Scale, Timed "Up and Go", Four Square Step Test, Functional Reach Test, and Lateral Reach Test. The force plate measurements were Quiet Standing with Eyes Open, Eyes Closed, and Feet Together. The survey measurements were collected on Test sessions 1, 4 and 5 and included the Activities-specific Balance Confidence Scale and the Activity Questionnaire.

Table 3.1: Data collection schedule

Test Day 1	Test Day 2 (48 hours after Test 1)	Test Day 3 (Initiation of SmartStep™)	Test Day 4 (4 weeks after Test Day 3)	Test Day 5 (4 weeks after Test Day 4)

Clinical Measures

Berg Balance Scale

The Berg Balance Scale (BBS) was developed as a tool to assess performance of functional activities while challenging balance by progressively narrowing the base of support.[154] The BBS consists of 14 movements that are common in activities of daily living. It has been found to be a valid test for predicting falls and to have both inter and intra-rater reliability, 0.98 and 0.99 respectively.[154, 155] The BBS has also be found to have high test-retest reliability in 22 people with hemiparesis (ICC = 0.98).[156] The 14 mobility tests are performed as follows:

1. Change of position: sitting to standing
2. Standing unsupported, eyes-open
3. Sitting unsupported
4. Change of position: standing to sitting
5. Transfers
6. Standing with eyes-closed
7. Standing with feet together
8. Forward Reach
9. Retrieving an object from the floor
10. Turning trunk (feet fixed)
11. Turning 360 degrees
12. Stool Stepping
13. Tandem standing
14. Standing on 1 leg

The scoring for the Balance Scale is out of 56 points (Appendix D). All static balance tests, except Tandem standing, were performed with the subject standing on the force plate so that force data could be collected simultaneously. The BBS was performed once and the score out of 56 points was used as the criterion value. The force data utilized for data analysis included center of pressure (COP) distance, displacement and the root mean square of velocity (RMS_{vel})[46] in both the anterior-posterior (AP) and medial-lateral (ML) directions.

Timed "Up & Go"

The Timed "Up & Go" (TUG) test measures the functional mobility of the subjects. The TUG was found to have inter- and intra-rater reliability of 0.99 and to correlate with log-transformed BBS scores and Gait Speed, -0.81 and -0.61 respectively.[157] The subject started while sitting, with their back against the back of a standard arm chair with a seat height of 46 cm. The subject was asked to stand, walk a distance of 3 meters, turn, walk back to the chair, and sit down again. A standard stopwatch was used to time the subject in seconds and timing began after the word "go" was spoken. Three tests were measured and the average of the 3 was used for data analysis. A rest period of 2 minutes was provided between tests.

Four Square Step Test

The Four Square Step Test (FSST) is a dynamic test of postural stability. This test requires subjects to change directions and step over a one inch obstacle. The FSST has been found to have interrater reliability of 0.98, a specificity of 88% to 100%, a sensitivity of 85% and a positive predictive value of

86% when identifying older, community-dwelling adults with a history of falling.[158] Subjects are required to step over a one inch pipe laying flat on the ground for each of the following directions: 1) forward, 2) sidestep to the right, 3) backwards, and 4) sideways to the left. This is repeated in the opposite direction (sidestep to the right, forward, sidestep left, backwards) and the time is recorded.[158] The FSST was performed 2 times and the best time was utilized as the criterion value.

Functional and Lateral Reach Tests

The Functional Reach Test (FRT) and Lateral Reach Test (LRT) are measures of maximal anterior and lateral distances reached beyond arms length while standing. These tests have been found to have high inter- and intra-rater reliability, 0.91 and 0.92 respectively.[159, 160] Validity has also been demonstrated by correlating these tests to center of pressure excursions.[159, 160] A tape measure and strip of paper were taped to the wall for both of these tests. For the FRT, subjects stood on the force plate so that the tape measure was on the wall to their left. Subjects were placed in a standardized position with their feet 10 cm apart as measured between the medial aspects of the heels. Subjects were instructed to flex both shoulders to 90 degrees and the beginning position was marked on the strip of paper. Subjects were then instructed to lean forward as far as possible without losing their balance or lifting their feet and maintain this position for 3 seconds. The ending position was then marked on the paper. A trial was not accepted if the subject flexed their knees or lifted a foot. Both the beginning and ending positions were marked as the location of the distal end of the third digit. The difference between the beginning and ending position was calculated[159] in centimeters and the average of three trials was used as the criterion value.

A similar procedure was performed for the LRT; however the subjects stood on the force plate with their backs toward the wall. With one arm at the side, and the other arm abducted to 90 degrees, the beginning position was marked on the paper. Subjects were instructed to reach directly sideways as far as possible without lifting either foot, flexing a knee, and rotating or forward flexing the trunk. The maximal reach was maintained for 3 seconds and the ending position was marked by the investigator.[160] The lateral reach was performed in both the right and left directions. The difference between the beginning and ending position was calculated in centimeters and the average of three trials for each direction was used as the criterion value.

Force Plate Measurements

Quiet Standing Eyes Open, Eyes Closed and Feet Together

As part of the BBS, three of the scored items require the subject to stand with their eyes open (EO), with eyes closed (EC) and with their feet together (TOG). The EO and EC conditions were performed with the heels 10 cm apart and the TOG condition was performed with the eyes open. To receive the highest score for these items on the BBS, the subject must be able to stand with EO for 2 minutes, EC for 10 seconds and TOG for 1 minute. All three of these BBS items were collected while the subject was standing on the force plate. The first 50 seconds of the force data collected during the EO and TOG trials were analyzed.

For comparison purposes, the subjects were asked to stand with EC for 50 seconds with the first 10 seconds used to score the BBS and the entire 50 seconds used to analyze the force data. Subjects were instructed to stand quietly with arms hanging down by their sides while looking at a target placed 1 meter in front of them at eye level in the EO trials.[161] The force data utilized for data analysis included center of pressure (COP) distance, displacement and the root mean square of velocity (RMS_{vel})[46] in both the anterior-posterior (AP) and medio-lateral (ML) directions (Appendix C).

Survey Measurements

Activities-specific Balance Confidence Scale

The Activities-specific Balance Confidence (ABC) Scale contains 16 items that allows for objective comparison of subjects' mobility confidence. The ABC Scale has been found to have a test-retest reliability of 0.92 and was reported to be useful in distinguishing higher functioning older adults from lower functioning.[162] The 16 items were scored from 0 to 100 (Appendix E). Subjects marked their answers on a 10 cm line. The ABC Scale was administered prior to the Test Days 1, 4 and 5 data collection sessions only.

Activity Questionnaire (AQ)

An activity questionnaire (Appendix F) was administered on the Test Days 1, 4 and 5. This questionnaire was used to determine if there had been a change in activity level and ability over the 8 week period. The AQ consisted of 10 questions and were scored on a 0 to 4 ordinal scale so the scoring was out of a maximum of 40.

Sensation Measures

Semmes-Weinstein Monofilament (SWM)

The SWM sensation testing was performed on all subjects on Test Day 1 and on Test Day 5. This was used to determine inclusion criteria as well as to determine if there was a change in peripheral sensation in the 8 week period.

Quantitative Vibration Perception Threshold (QVPT)

The QVPT testing was performed on all subjects on Test Day 1 and on Test Day 5. These results were utilized to determine inclusion eligibility as well as to determine if there was a change over the 8 week period. Table 3.2 shows the quintile itemization for all subjects' feet.

Statistical Analysis

Statistical analyses were performed with SPSS 13.0 for Windows (SPSS Inc., Chicago, Illinois). One-way, repeated measures analysis of variance (ANOVA) was performed for each dependent variable. All 6 of the clinical measures, BBS, TUG, FSST, FRT, and LRT Right and Left, were analyzed with a 1x5 repeated measures ANOVA with the 5 Test Days being the within-subjects factor. All 18 of the force plate measures, AP and ML displacement, distance and RMS_{vel} for EO, EC and TOG, were analyzed with a 1x5 repeated measures ANOVA with 5 Test Days being the within-subjects factor. The 2 survey measures, ABC and AQ, were each analyzed with a 1x3 repeated measures ANOVA with Test Days 1, 4 and 5 being the within-subjects factor. The 4 sensation tests, SWM and QVPT on each foot, were analyzed with a 1x2 repeated measures ANOVA with Test Days 1 and 5 being the within-subjects factor. An alpha level of $p < 0.05$ was set *a priori*. If significant main effects were found, a Fisher's LSD post hoc analysis was performed to determine where the differences were located.

Table 3.2: Tally of Quantitative Vibration Perception Threshold (QVPT) Scores for the Right and Left Feet of all 27 subjects for Test Days 1 and 5.

	Test 1		Test 5	
QVPT Score (0-50 V)	Right	Left	Right	Left
<10	1	1	1	1
10-19	11	8	12	11
20-29	8	9	7	5
30-39	4	7	3	6
>40*	3	2	4	4

* scores in this category are considered pathological sensation loss

Chapter Four
Results

Introduction

The purpose of this study was to evaluate the utilization of an in-shoe orthotic system on the postural stability of older adults over an 8 week period. This chapter reports the results of the postural control assessments. The chapter contains four sections: 1) Clinical Measures, 2) Force Plate Measures, 3) Survey Measures, and 4) Sensation Measures. Within each section are subsections for each dependent variable that was analyzed. A summary of the important results is presented at the end of the chapter.

Clinical Measures

Table 4.1 presents the averaged scores and standard deviations of all 27 subjects for the Berg Balance Scale (BBS), Timed “Up and Go” (TUG), and the Four Square Step Test (FSST) for the 5 Test Days. It should be noted that the FSST average scores are from 26 subjects as one subject was unable to complete this task safely and independently.

Table 4.1: Average score and standard deviation for the 27 subjects for the Berg Balance Scale, Timed “Up & Go”, and Four Square Step Test.

Test Day	Berg Balance Scale (out of 56 points)	Timed “Up & Go” (sec)	Four Square Step Test* (sec)
1	42.63 ± 8.83	17.25 ± 8.12**	25.03 ± 24.42
2	43.00 ± 8.85	16.81 ± 9.73	25.95 ± 23.27
3	44.52 ± 9.67	17.28 ± 9.43**	25.09 ± 22.49
4	44.59 ± 10.23	17.23 ± 10.46	23.86 ± 22.10
5	43.89 ± 10.62	15.47 ± 7.68	22.09 ± 18.49

* Mean and Standard Deviation based on 26 subjects only
** values significantly different from Test Day 5 $p \leq .05$

Berg Balance Scale (BBS)

Results for the BBS are presented in Table 4.1. Means for the BBS ranged from 42.62 to 44.59 points out of a maximum of 56. There were no significant differences or trends for the 5 different Test Days.

Timed “Up & Go” (TUG)

Results for the TUG are presented in Table 4.1. Means for the TUG ranged from 17.28 to 15.47 seconds. A main effect for time was found, F(4,23) = 3.4, *p* = 0.025. Pairwise comparisons revealed that Test Days 1 and 3 were significantly slower compared to Test Day 5 (*p* = 0.012 and 0.009, respectively). No other significant comparisons were found.

Four Square Step Test (FSST)

FSST results are presented in Table 4.1. Means for the FSST ranged from 25.95 to 22.09 seconds. There were no significant differences between the five days of testing.

Data for the Functional Reach Test (FRT) and Lateral Reach Tests (LRT) are presented in Table 4.2 as the average distance and standard deviation, in centimeters, of the 27 subjects for the 5 Test Days.

Table 4.2: Average score in cm for the 27 subjects for the Functional Reach Test (FRT) and Lateral Reach Tests (LRT to the right and left fro all days of testing.

Test Day	FRT (mean ± SD)	LRT Right (mean ± SD)	LRT Left (mean ± SD)
1	14.78 ± 5.66*	11.76 ± 4.61	11.73 ± 4.05
2	17.05 ± 5.92	13.00 ± 3.70**	11.50 ± 4.52
3	16.00 ± 6.55	12.71 ± 3.93**	12.48 ± 4.02
4	15.31 ± 6.94*	12.52 ± 5.00**	11.49 ± 4.09
5	15.25 ± 7.01	11.23 ± 3.92	11.49 ± 5.24

* values significantly different from Test Day 2, $p \leq .05$
** values significantly different from Test Day 5, $p \leq .05$

Functional Reach Test (FRT)

FRT results are presented in Table 4.2. Means for the FRT ranged from 14.78 to 17.05 cm. A main effect for time was found, $F(4,23) = 2.93$, $p = 0.043$. Pairwise comparisons revealed that Test Days 1 and 4 were significantly less when compared to Test Day 2 ($p = 0.008$ and 0.043, respectively). There were no other significant differences.

Lateral Reach Test (LRT) Right and Left

LRT results are presented in Table 4.2 for both the right and left reach directions. Means for the LRT to the right ranged from 11.23 to 13.00 cm and to the left from 11.49 to 12.48 cm. A main effect for time was found for LRT while reaching to the right, (F(4,23) = 3.06, *p* = 0.037). Pairwise comparisons demonstrated that right direction reaching was statistically different for Test Days 2, 3, and 4 when compared to Test Day 5 (*p* = 0.018, 0.041, and 0.017). There was no significant main effect for time for the left direction of the LRT.

Force Plate Measures

Center of Pressure (COP) Displacement

Eyes Open (EO)

The results for EO anterior-posterior (AP) and medio-lateral (ML) displacement are presented in Table 4.3. Means ranged from 3.4 to 3.6 cm in the AP direction and from 2.2 to 2.9 cm in the ML direction. There was no significant main effect for time for displacement in either direction with EO.

Table 4.3: Average Displacement in cm for the 27 subjects for the Eyes Open condition during static standing for 50 sec.

Test Day	Anterior-Posterior Displacement (mean ± SD)	Medial-Lateral Displacement (mean ± SD)
1	3.4 ± 1.1	2.4 ± 1.0
2	3.6 ± 1.0	2.5 ± 1.3
3	3.5 ± 0.8	2.2 ± 1.0
4	3.5 ± 1.1	2.3 ± 1.0
5	3.6 ± 1.1	2.9 ± 2.0

Eyes Closed (EC)

The results for EC AP and ML displacement are presented in Table 4.4. Means ranged from 4.6 to 5.3 cm in the AP direction and from 2.8 to 3.9 cm in the ML direction. A main effect in the AP direction for time was found, F(4,23) = 2.93),*p* = 0.024. Pairwise comparisons revealed that AP displacement for Test Days 3 and 5 were significantly larger compared to Test Day 1 (*p* = 0.045 and 0.035) and Test Day 2 (*p* = 0.030 and 0.022). No other significant main effects were demonstrated.

Table 4.4: Average Displacement in centimeters for the 27 subjects for the Eyes Closed condition during static standing for 50 sec.

Test Day	Anterior-Posterior Displacement (mean ± SD)	Medial-Lateral Displacement (mean ± SD)
1	4.7 ± 2.2	2.9 ± 1.8
2	4.6 ± 2.1	2.8 ± 1.6
3	5.3 ± 2.1*	3.1 ± 1.7
4	5.1 ± 2.5	3.2 ± 1.5
5	5.3 ± 2.2*	3.9 ± 2.7

* values significantly different from Test Days 1 & 2, p≤.05

Feet Together (TOG)

The results for TOG AP and ML displacement are presented in Table 4.5. Means ranged from 3.9 to 4.3 cm in the AP direction and from 3.8 to 4.1 in the ML direction. There were no significant main effects for displacement in either direction with TOG.

Table 4.5: Average Displacement in centimeters for the 27 subjects for the Feet Together condition during static standing for 50 sec.

Test Day	Anterior-Posterior Displacement (mean ± SD)	Medial-Lateral Displacement (mean ± SD)
1	3.9 ± 1.2	4.0 ± 1.3
2	4.2 ± 1.4	4.1 ± 2.4
3	4.3 ± 1.7	4.1 ± 2.0
4	3.9 ± 1.3	3.8 ± 1.2
5	3.9 ± 1.3	4.0 ± 1.2

COP Distance

EO

The results for COP distance in the EO condition are presented in Table 4.6. Means ranged from 90.0 to 100.3 cm in the AP direction and from 57.1 to 60.4 cm in the ML direction. There were no statistically significant differences in either the AP or ML directions for this condition.

Table 4.6: Average total Distance in centimeters for the 27 subjects for Eyes Open condition during static standing for 50 sec.

Test Day	Anterior-Posterior Distance (mean ± SD)	Medial-Lateral Distance (mean ± SD)
1	90.0 ± 53.5	57.9 ± 19.9
2	93.0 ± 68.0	57.1 ± 22.7
3	96.3 ± 68.8	57.7 ± 23.4
4	96.7 ± 76.9	57.3 ± 30.2
5	100.3 ± 88.7	60.4 ± 27.7

EC

The results for EC condition COP distance are located in Table 4.7. Means ranged from 152.2 to 187.7 cm in the AP direction and from 79.5 to 90.1 cm in the ML direction. No statistically significant main effects were found for either the AP or ML directions for EC.

Table 4.7: Average total Distance in centimeters for the 27 subjects for Eyes Closed condition during static standing for 50 sec.

Test Day	Anterior-Posterior Distance (mean ± SD)	Medial-Lateral Distance (mean ± SD)
1	152.2 ± 140.0	79.5 ± 46.1
2	152.8 ± 141.3	83.9 ± 66.9
3	162.3 ± 138.7	82.8 ± 61.9
4	161.5 ± 126.7	80.9 ± 49.3
5	187.7 ± 184.0	90.1 ± 56.8

TOG

The COP distance results for the TOG condition are presented in Table 4.8. Means ranged from 111.0 to 121.4 cm in the AP direction and from 96.2 to 104.9 cm in the ML direction. There were no main effects for this condition in either the AP or ML directions.

Table 4.8: Average total Distance in centimeters for the 27 subjects for Feet Together condition during static standing for 50 sec.

Test Day	Anterior-Posterior Distance (mean ± SD)	Medial-Lateral Distance (mean ± SD)
1	113.2 ± 75.0	104.2 ± 61.2
2	111.0 ± 59.4	96.6 ± 48.7
3	121.4 ± 84.7	104.9 ± 64.0
4	119.5 ± 80.4	100.3 ± 54.5
5	117.9 ± 85.6	96.2 ± 53.7

COP Root Mean Square of Velocity (RMS_{vel})

EO

The average COP RMS_{vel} for the EO condition is located in Table 4.9. Means ranged from 2.4 to 2.6 cm/s in the AP direction and from 1.5 to 1.8 cm/s in the ML direction. No significant statistical differences were found in either AP or ML directions.

Table 4.9: Average Root Mean Square of Velocity in cm/s for the 27 subjects for Eyes Open condition during static standing for 50 sec.

Test Day	Anterior-Posterior RMS_{vel} (mean ± SD)	Medial-Lateral RMS_{vel} (mean ± SD)
1	2.4 ± 1.4	1.5 ± 0.5
2	2.4 ± 1.8	1.5 ± 0.6
3	2.5 ± 1.8	1.5 ± 0.6
4	2.5 ± 2.0	1.5 ± 0.7
5	2.6 ± 2.2	1.8 ± 1.0

<u>EC</u>

The average COP RMS_{vel} for the EC condition is located in Table 4.10. Means ranged from 4.0 to 4.9 cm/s in the AP direction and from 2.1 to 2.5 cm/s in the ML direction. No significant statistical differences were found in either AP or ML directions.

Table 4.10: Average Root Mean Square of Velocity in cm/s for the 27 subjects for Eyes Closed condition during static standing for 50 sec.

Test Day	Anterior-Posterior RMS_{vel} (mean ± SD)	Medial-Lateral RMS_{vel} (mean ± SD)
1	4.0 ± 3.6	2.1 ± 1.2
2	4.1 ± 3.9	2.2 ± 1.7
3	4.3 ± 3.8	2.2 ± 1.6
4	4.2 ± 3.4	2.1 ± 1.2
5	4.9 ± 4.8	2.5 ± 1.6

TOG

The average COP RMS_{vel} for the TOG condition is located in Table 4.11. Means ranged from 2.9 to 3.2 cm/s in the AP direction and from 2.5 to 2.8 cm/s in the ML direction. No significant statistical differences were found in either AP or ML directions.

Table 4.11: Average Root Mean Square of Velocity in cm/s for the 27 subjects for Feet Together condition during static standing for 50 sec.

Test Day	Anterior-Posterior RMS_{vel} (mean ± SD)	Medial-Lateral RMS_{vel} (mean ± SD)
1	3.0 ± 1.9	2.7 ± 1.6
2	2.9 ± 1.6	2.6 ± 1.3
3	3.2 ± 2.2	2.8 ± 1.8
4	3.1 ± 2.1	2.6 ± 1.4
5	3.1 ± 2.3	2.5 ± 1.5

Survey Measures

The average scores and standard deviations for the Activities-specific Balance Confidence Scale (ABC) and Activity Questionnaire (AQ) for all 27 subjects are presented in Table 4.12. These scores were collected on Test Days 1, 4, and 5 only.

Table 4.12: Average score and standard deviation for the 27 subjects for the Activities-specific Balance Confidence (ABC) Scale and the Activity Questionnaire (AQ) on Test Days 1, 4, & 5.

Test Day	ABC (out of 100)	AQ (out of 40)
1	73.6 ± 17.8	26.81 ± 8.04
4	70.7 ± 21.3	26.67 ± 9.57
5	68.5 ± 19.3	25.44 ± 9.02

Activities-specific Balance Confidence Scale (ABC)

The results for the ABC are presented in Table 4.12. Mean scores ranged from 68.5 to 73.6 points out of 100 possible. There was no significant difference found among the three days that this measure was taken.

Activity Questionnaire (AQ)

The AQ results presented in Table 4.12. Mean scores ranged from 25.44 to 26.81 out of a possible 40. There was no statistical difference in score among these three testing days.

Sensation Measures

The 2 sensation measurements, Semmes-Weinstein Monofilament (SWM) and Quantitative Vibration Perception Threshold (QVPT), results are presented in Table 4.13. Both of these sets of data were collected on both right and left feet on Test Days 1 and 5.

Table 4.13: Average score for the 27 subjects for the Semmes-Weinstein Monofilament (SWM) and the Quantitative Vibration Perception Threshold (QVPT) for both feet on Test Days 1 & 5.

Test Day	SWM (# out of 4)		QVPT (V)	
	Right Foot	Left Foot	Right Foot	Left Foot
1	3.37 ± 1.12	3.26 ± 1.29	24.28 ± 11.64	25.62 ± 11.23
5	3.44 ± 1.12	3.44 ± 1.19	23.89 ± 12.42	25.05 ± 12.94

Semmes-Weinstein Monofilament (SWM)

The SWM results are presented in Table 4.13. Mean scores out of a possible 4 ranged from 3.26 to 3.44. There were no significant differences in SWM from the first day of testing when compared to the last day of testing.

Quantitative Vibration Perception Threshold (QVPT)

The QVPT results are presented in Table 4.13. Mean scores ranged from 23.89 to 25.62 V out of a maximum of 50 V. There were no significant differences in QVPT from the first day of testing when compared to the last day of testing.

Summary

For the Clinical Measures, statistical significance was found for the TUG, FRT, and LRT to the right. It was found that the Test Day 5 average was significantly faster for the TUG compared to Test Days 1 and 3. The average FRT was less for Test Days 1 and 4 when they were compared to Test Day 2.

The LRT only elicited significant differences in the reach to the right direction. On average, Test Days 2, 3, and 4 had significantly greater LRT than Test Day 5.

The only statistically significant finding for the Force Plate Measures was the AP COP displacement in the EC condition. Test Days 3 and 5 were found to have significantly greater COP displacements compared to both Test Day 1 and 2. No significant differences where reported for the Survey or Sensation Measures.

Chapter Five
Discussion

Introduction

The purpose of this study was to evaluate the utilization of an in-shoe orthotic system on the postural stability of older adults over an 8 week period. This chapter begins by briefly summarizing the purpose and research hypotheses of the present study. The implications of the results are then discussed, and the relationship between our results and the existing body of knowledge is examined. Finally, the strengths and limitations of the present study are reviewed and a general summary is presented.

Purpose and Research Hypotheses

Decreased somatosensory input may be one cause of balance deficits in older adults. Utilizing an intervention that increases somatosensory input would be beneficial in older adults who have decreased balance and are at risk for falls. Presently, no study has been reported that has attempted to utilize an in-shoe semi-rigid orthotic to enhance somatosensory input and improve balance in older adults. The purpose of the present study was to test the hypotheses that were formulated to evaluate the efficacy of semi-rigid orthotics improving the balance of a group of older adults over an 8 week period.

The research hypotheses involved four types of dependent variables: 1) Clinical Measures, 2) Force Plate Measures, 3) Survey Measures, and 4) Sensation Measures. In general, the research hypotheses were organized such that if balance was improved with the in-shoe, semi-rigid orthotic, then 1) all improvements in test scores would occur in the first 4 weeks of orthotic usage, and 2) there would be no subsequent improvements from week 4 to week 8 of orthotic usage.

Clinical Measures

Berg Balance Scale (BBS)

The BBS is a test that has been utilized in many studies to monitor the status of patient's balance and to predict which older adults are at risk for falls. [161, 163-171] In the present study, there were no significant changes elicited in the 8 week period of in-shoe orthotic usage. The mean scores ranged from 42.6 to 44.6 points out of a maximum of 56 for the 5 Test Days. It has been suggested that a cutoff score of 45 can be used to separate older adults with good balance (least likely to fall) and those with poor balance (more likely to fall).[164, 172, 173] When the individual data were investigated, it was found that 13 of the 27 subjects started the study with a score of 45 or greater and all of these subjects remained above this cutoff level for the duration of the study. It has been suggested that the BBS has a ceiling effect[163] and it seems as though the 13 subjects who performed well on the BBS at the beginning of the study were affected by this phenomena. Of the 14 subjects who where below the cutoff at the start of the study, 5 (36%) increased their score to above 45 points by Test Day 5. There was one subject who improved her score from a 35 to a 44 in the first 4 weeks of orthotic usage. Even though this was not above the 45 point cutoff, the investigators thought it may be a clinically relevant improvement.

Shumway-Cook and Woollacott[171] reported BBS average scores of 56, 55.5, and 32.7 for groups of young adults, older adults with no falls, and older adults with a fall history, respectively. The current results were on average higher than Shumway-Cook and Woollacott's faller group, but not as high as their non-faller older adult group. The current study did not group subjects as to fall status, but one difference in our findings when compared to Shumway-Cook and Woollacott could be explained by the age of the subjects. The average age of their older adult, non-faller group was 74.6 years with a range of 65-85 years, while our average was 86.93 years with a range of 73-97 years. This age difference of more than a decade could explain why our average BBS scores were lower. When we compare our subjects' age to their older adult faller group (mean: 85.3 years, range: 76-95) the results are more similar, however our subjects performed better on all 5 Test Days.

In a 1991 study, Podsiadlo and Richardson[157] reported BBS scores for 60 community dwelling older adults with an age range of 60-90 years (mean: 79.5). They did not report the average score for the group, just a range of 6-56. The current subjects ranged from 15-56 over the 5 Test Days. Again, this conveys that the current study population was not as frail at the onset of the study as other populations. The fact that the subjects were not as low functioning may have contributed to the nonsignificant results that were reported. It has been suggested that the BBS may be better for older adults who have greater impairments versus active, healthy older adults.[170] The addition of the in-shoe orthotic may not have made improvements that were great enough to be measured by the BBS.

Timed "Up & Go" (TUG)

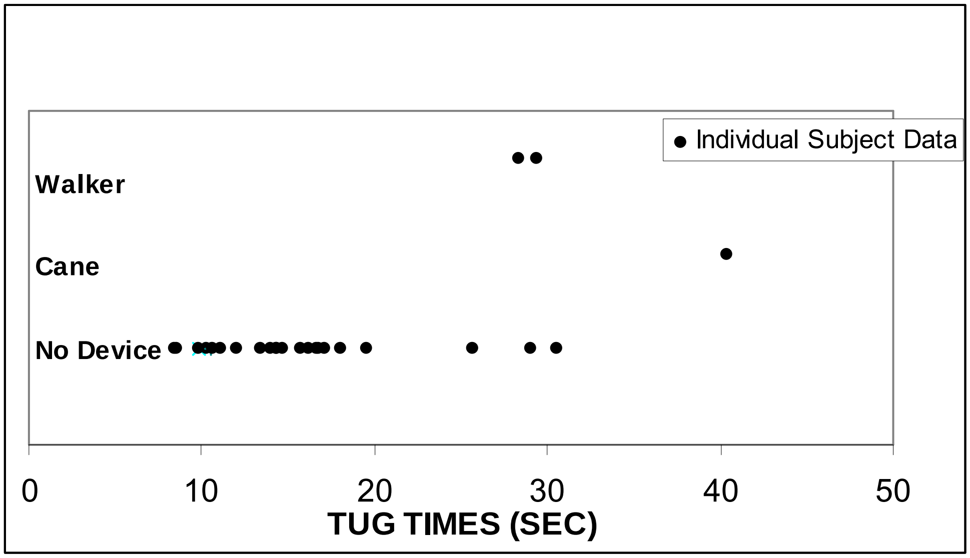
The TUG is a test that has been utilized to assess physical mobility in older adults by having both balance and gait components to the test.[157, 158, 168-170, 174-178] The current results demonstrated a significant improvement in average TUG scores for Test Day 5 compared to Test Days 1 and 3. Even though it was not significant, there was a trend that showed that Test Day 5 had a faster time than Test Day 4 ($p = 0.053$) as well. These data suggest that the 8 week usage of the in-shoe orthotic elicited an improvement in mobility in the current population. Podsiadlo and Richardson[157] concluded that "medically stable" patients vary little in TUG scores over time. The fact that the current study utilized medically stable subjects and is still reporting a significant finding after an 8 week period gives us confidence that this is a true improvement.

Even though there is no consensus in the literature in terms of the effect of aging on TUG scores,[169, 179-181] researchers have suggested using a cutoff of 10-12 sec[182], 13.5 sec[168], or 20 sec[157] when comparing independent older adults to those who are dependent on assistance. Podsiadlo and Richardson[157] reported that subjects who were able to perform the TUG in less than 20 sec were independently mobile and most were able to climb stairs and go outside alone. The subjects who took 30 sec or more were much more dependent and needed help with chair/toilet transfers, help in and out of the tub or shower, most could not climb stairs without assistance, and could not go outside alone. Using these

20 and 30 second categories to analyze the current data, it can be seen that on average the subjects performed faster than 20 sec on all 5 Test Days. On Test Day 1 there were only 2 subjects who where in the over 30 sec category and on Test Day 5 there was only 1 subject still in this category. When the more stringent cutoff of 13.5 sec is utilized to analyze the current data, individual improvements can be inferred. There were 10 subjects who were faster than 13.5 sec on Test Day 1 and all 10 of these subjects stayed below the cutoff for all Test Days. Of the 17 subjects who were slower than 13.5 sec on Test Day 1, 5 subjects (29%) improved to below the 13.5 sec cutoff by Test Day 5. One other subject improved to below the cutoff after wearing the orthotics for 4 weeks (Test Day 4), however their Test Day 5 was slightly above the cutoff (13.8 sec).

In past studies, and in the present study, subjects were allowed to utilize the assistive device (cane or front-wheeled walker) that they normally used during activities of daily living.[157, 168] Of the 27 subjects, 23 used no assistive device for all 5 Test Days, 1 used no device for Test Days 1-4 and a walker on Test Day 5, 1 used a cane for Test Days 1-3 and a walker for Test Days 4 and 5, and 2 subjects used a walker for all 5 Test Days. Shumway-Cook and Woollacott[168] reported that the times to complete the TUG were 9.0, 18.1, and 33.8 sec for subjects using no assistive devices, a cane, and a walker, respectively. Our results differed from Shumway-Cook and Woollacott's in that the average for the no device subjects was 15.3 sec, the 1 cane user had a time of 40.4 sec, and the walker average was 28.9 sec for Test Day 1.(Figure 5.1) This discrepancy of assistive device breakdown could be due to the fact that the majority of the subjects did not use any assistance and there were so few in the cane and walker categories. The fact that 2 subjects had to use a walker on Test Day 5 who had not done so previously, points to deterioration that occurred over the 8 weeks of data collection. Having a significant finding of improved TUG average even after this deterioration suggests that this is a true change that was brought about by the utilization of the SmartStep™.

Figure 5.1 TUG times for all 27 subjects on Test Day 1, using No Device, a Cane, or a Walker



Four Square Step Test (FSST)

The FSST is a relatively new test of dynamic balance that includes rapid stepping and obstacle avoidance.[158] Our results did not show any statistically significant improvement in FSST times following the 8 week usage of the SmartStep™. Dite et al.[158] identified an optimal cutoff score of 15 sec to characterize multiple fallers and nonmultiple fallers. The averaged FSST scores in the current studied ranged from 25.95 sec (Test Day 1) to 22.09 sec (Test Day

5). There seems to be a trend of faster times as the subjects wore the SmartStep™, however there were no statistically significant results. Comparing individual subject scores to the 15 sec cutoff that was proposed by Dite et al.,[158] revealed that 11 out of the 27 subjects were always below this cutoff for all 5 Test Days. Of the 16 subjects who had slower times on Test Day 1, 4 (25%) of them had improved their times to below the cutoff by Test Day 4 and this improvement remained for Test Day 5. Three subjects did not improve to the point of performing faster than 15 sec, however their improvements were substantial. Two of these subjects started with a time of 53 sec on Test Day 1 and by Test Day 5 their times were down to 20 sec. The third subject had a time of 114 sec on Test Day 1 and improved to 71 sec on Test Day 5. We feel that these improvements are clinically meaningful and it seems that the SmartStep™ had an affect on a subgroup of the subjects.

Functional Reach Test(FRT)

The FRT tests the subject's ability to move their center of gravity to the forward limits of the base of support and still maintain their balance.[159] Duncan et al. studied the predictive validity of the FRT in an older adult male population and found that if they were able to reach more than 10 cm that the likelihood that they were at risk for a fall was low.[183] Others have suggested a cutoff of 25 cm to differ between high functioning older adults and lower functioning.[158] If the present data are evaluated with the 25 cm cutoff, there was only 1 subject who reached this mark for all 5 Test Days, and only 1 subject who improved to over 25 cm on Test Days 4 and 5. When the present data are evaluated with the 10 cm cutoff, there are 18 subjects who have 5 Test Days above that level. Further investigation of the 11 subjects who started out below the 10 cm cutoff, revealed that 7 subjects were found to have at least a 5 cm improvement by Test Day 5 and 2 of these subjects improved over 10 cm. Even with these apparent improvements, the statistical testing showed that as a group, there was a significant reduction (worsening) in FRT scores on Test Day 5 compared to Test Days 2-4.

Lateral Reach Test (LRT)

The LRT is similar to the FRT, however it focuses on medial-lateral balance control instead of just anterior.[160] Brauer et al.[160] first described the LRT in 1999 and found no significant difference between performing the test to the right and left sides. They also reported that the LRT was negatively correlated with age, even though their subjects' mean age was 72.5 years with a standard deviation of 5. The reported LRT distances from this initial study were 20.04 cm for the right side and 21.01 cm for the left, the scores were not reported in age groups. In 2000, Brauer et al.[161] published a study that compared non-fallers to fallers, who were then partitioned into frequent fallers and recurrent fallers. The 2000 study did not report a significant difference between non-fallers and fallers in LRT reach distances that ranged from 18.6 to 20.4 cm. Compared to both of these studies, the present LRT results are noticeably lower. The group means ranged from 11.23 to 12.71 cm for the 5 Test Days. The present findings seem to follow the digression in scores as adults age that was reported by Isles et al.[174] This 2004 study reported that LRT scores averaged 18.37, 17.11, and 15.71 cm for adults in their 5th, 6th, and 7th decade of life. With our subjects being older than 70 years on average, it would make sense that their average LRT distance was less than those scores found by Isles et al. The current results add to the body of literature that reports that LRT performance declines due to aging[161, 174, 184] and especially after the age of 30 in women[174].

The current results revealed a statistically significant decline in reach distance on Test Day 5 when compared to Test Days 2,3, and 4. This difference was found for the right reaching direction only. There were no statistically significant differences found in the left direction comparisons. The fact that a difference was only found in the right direction was not expected since researchers have reported no difference in right and left side reaching.[160, 161, 184] It has also been suggested, that since there have not been side to side differences, that only testing to one side is sufficient. Our results revealed a response difference between the right and left reach directions that has not been reported in the literature to date. It is not known why there was a difference on the right side only, especially when it has been suggested that people tend to reach further to their dominant side, which is more likely the right.[174] We did not collect information about hand dominance so it is unknown which subjects were right or left handed.

There is no current literature that describes a cutoff score for defining high and low functioning older adults with the LRT like there is for some of the other tests. For this reason, we are unable to describe whether people improved to a predetermined level. Investigating the individual subject data, it was revealed that

6 out of the 27 subjects (22.2%) increased their LRT right reaching distance on either Test Day 4 or 5 by more than 5 cm. Evaluation of the left direction in the same way revealed 3 subjects who had 5 cm or more improvement for either Test Day 4 or 5. Even though statistically there was a decline in Test Day 5's scores, there were improvements by several of the subjects. The lower score after the 8 week period could be attributed to overall balance deterioration for the group as whole; however there seems to be a subgroup of subjects that had mild improvements.

Force Plate Measures

The 3 different force plate measurements (center of pressure displacement, distance, and RMS_{vel}) were analyzed for the 3 different conditions (eyes open, eyes closed, and feet together) in both the anterior-posterior (AP) and medial-lateral (ML) directions. Of all of these combinations, there was only one condition that demonstrated a significant difference. The center of pressure (COP) displacement in the AP direction with eyes closed was found to be greater on Test Days 3 and 5 when compared to Test Days 1 and 2. The increase in COP displacement on these Test Days was an unexpected result. The average difference between the scores was 0.65 cm, and this small distance may not be clinically meaningful even though it was statistically different.

When the current results are compared to other literature, our results are found to be slightly higher. For the eyes open condition the current results revealed COP displacements in the AP direction of approximately 3.5 cm compared to Laughton et al.[185] who reported scores of 2.06 cm for non-fallers and 2.4 cm for fallers. Comparing the results for COP displacement in the ML direction reveals that the present study has greater average scores of approximately 2.5 cm while Laughton et al. reported 1.41 cm for non-fallers and 1.53 cm for fallers. There were several differences between the 2 studies that may explain the higher scores in the present study. The first being the data collection duration of 30 sec for Laughton et al. compared to 50 sec in the current study. The second difference in these studies is the age of the subjects. Both the 33 fallers and 37 non-fallers in the study had a mean age of 75 years, and ranged from 65-92 years.[185] The 11 year difference in mean age may account for the difference in scores since it has been reported that postural sway increases due to aging.[13, 17] The increased age of the subjects combined with the longer data collection time period may explain the increase in COP displacement.

As there were no significant or meaningful changes in the data for most of the COP measurements, this could be explained two ways. The first explanation could be that the data analysis method that was utilized was not sensitive enough to detect changes in this population. While a second explanation could be that there truly was no change in the static postural control of this population over the 8 week period of utilizing the SmartStep™.

Survey Measures

The Activities-specific Balance Confidence Scale (ABC) is a measure of balance that rates an individual's perceived balance confidence while performing activities of daily living.[162] The ABC has been utilized frequently in the literature as a subject descriptor or as an outcome measure.[161, 162, 166, 168, 171, 186-195] It has been suggested that a score less than 50 is indicative of fear of falling.[161] Several studies have investigated ABC scores in fallers and non-fallers.[161, 162, 168, 194] Some of these researchers have reported that the non-fallers have significantly higher scores than fallers.[162, 168, 194] All three of these studies reported a scoring difference of approximately 40 that separated the fallers and non-fallers. Brauer et al.[161] reported no difference in ABC scores between fallers and non-fallers. Their results for both groups were in the high 80 point range. The results from the present study revealed average scores of 68.5 to 73.6 for the 27 subjects. These scores are less than the studies who reported a low of 80.9[162] and a high of 93.2[168] for non-faller subjects. However, the present results are not as low as the reported scores of 38.3[162] and 53.0[168] for fallers. There were 8 out of the 27 subjects (29.6%) who had an improvement of 9 or more points on the ABC by either Test Day 4 or 5. Of these 8 subjects who improved, 3 of them had scores improve by more than 20 points. Even though there were no statistical differences over the 8 week period, these improvements could be clinically meaningful.

The Activity Questionnaire (AQ) that was utilized in this study was a modification of other activity scales found in the literature so that it pertained more to the current study population.[196] There were no significant differences at either the 4 week Test Day or the 8 week Test Day. This questionnaire allowed the subjects to rate how difficult it was for them to perform differing activities of daily living and did not directly measure their daily activities. It has been reported in the literature that activity scores were lower in subjects who had a fear of falling.[189] Even though we expected an increase in AQ scores after wearing the SmartStep™ for 8 weeks, the lack of a decrease in scores indicates that the subjects' self-perceptions of their ability had not deteriorated in that time period.

Sensation Measures

The 2 sensation tests that were collected on Test Days 1 and 5 were the Quantitative Vibration Perception Threshold (QVPT) and a single location Semmes-Weinstein monofilament test (SWM). The collection of these 2 measurements on Test Day 1 was to screen the subjects for exclusion. To be excluded from the study the subject had to have a QVPT score 40 Hz or over and to not feel 2 or more of the 4 SW touches on the hallux. The collection of these data on Test Day 5 was to determine if any of the subjects had a sensory decline during the 8 weeks of the study. We did not expect there to be differences in these 2 measurements and the results confirmed that there were no changes.

Summary

Of all of the Clinical, Force Plate, and Survey Measures, the TUG appears to be the one test that elicited the expected response. Not only were the scores on Test Day 5 faster than Test Day 1, but there was a trend of improvement for Test Days 3 and 4 as well. The TUG is a functional test that contains tasks that are needed to be able to function independently and is considered more complex. Utilizing tasks that investigate greater dynamic balance situations may be more beneficial than static tasks. Tasks like the TUG and FSST force the subject to move their feet, which functions more like a real world scenario rather than just having the subject stand in a static position. The other Clinical and Force Plate Measures may not have been sensitive enough to detect balance changes in the current population. It has been noted that the BBS has a ceiling effect[161], and maybe this could be said of the other measures with reference to the subject population that was utilized in the current study. Unfortunately there are no other studies that have utilized an in-shoe orthotic with an older adult population that we can compare our results to so it is difficult to know if the responses that were elicited are normal.

We did not include a control group to compare to the 8 week SmartStep™ intervention for the Measures. Frederic et al.[176] had an activity intervention with older adults and reported that a control group of adults aged 63.5±3.7 years had a slight, though non-statistically significant, deterioration in balance capability after not participating in the intervention activity for 3 months. These researchers suggested that this finding further supported the theory that physical inactivity causes functional deterioration that has been shown by other researchers.[138, 176, 197] Since deterioration over a 3 month period was reported for subjects who are over 2 decades younger than our subjects, it can be assumed that our subjects would have experienced a deterioration during the 8 weeks that the current study was conducted. This was not the case; our results did not find statistically significant balance deterioration in this population after 8 weeks of wearing the SmartStep™. It is unknown whether this lack of deterioration was due to the utilization of the in-shoe orthotic or to other factors.

The age of the current study's subjects seems to be novel. The generally accepted age range for studying older adults is 55 to 99 years old. However, the age of the subjects in most of the studies average in the middle to high 70s or low 80s. Our average age was 86 years and appears to be uncommon. As older adults in America are becoming more active and having increased years of good health, it is difficult to compare individuals in their 60's to octogenarians. The terminology of "young old" and "oldest old" has been used by some, however most studies still define older adult as anyone 65 or over. Refining the definition and the normative data for "older adults" seems to be something that will be changing as the activity and abilities of people in this age range improve as a whole.

Although the results did not yield significant improvements in the subject population, several subjects commented that they thought the SmartStep was improving their balance (Appendix G). The hypotheses of this study were based on the assumption that the subjects were to be more active to be able to receive the beneficial effects of the orthotics. Several of the subjects expressed that they felt more "in balance" with the SmartStep. Because of this, perhaps they were more active than prior to the study. The exact amount of time that subjects were on their feet and doing activities prior to and during the study was not monitored, so it is unknown if there were any activity level changes. Also, there was no way of monitoring the effect that the researcher had on the subjects. The fact that there was an individual giving each subject attention over the study time period could have had facilitatory influence through extrinsic motivation. There was no way of quantifying this impact on the subject population.

The dynamical systems model is a motor control theory that suggests that movement that causes human actions is a result of the interaction of physical dynamics and neural components.[22] As explained by the dynamical systems theory, there is a large amount of redundancy within the degrees of freedom of the multi-joint segments of the lower extremity while performing movement and balance tasks. This redundancy allows the sensorimotor system multiple options when performing tasks.[198-200] Because of the complexity of the system, there is a need to address all aspects when trying to compensate for deficits. Not only is the physical control system complex, but while performing activities of daily living, an individual must be able to perform a multitude of tasks that are both discrete and continuous and that range in complexity.[22] While learning a new task, an individual first becomes rigid by decreasing the degrees of freedom, and then there is more flexibility introduced to the system as tasks become familiar. The dynamical systems theory states that the musculoskeletal system has many degrees of freedom that allows for variability while performing tasks. This variability is limited by constraints that are placed on the system.[199]

There are three constraints placed on the maintenance of the postural control system: the task, the environment, and the organism.[199, 201] Through the utilization of the SmartStep, the current study attempted to manipulate the somatosensory system of the organism but did not control for other organism constraints (i.e. illness, strength). The tasks that were performed for the study were comprised of activities that are considered activities of daily living, and therefore would not be considered to be unfamiliar tasks for the subjects. The environment during the testing sessions was relatively constant, however we did not control for what was happening in the subject’s environment between testing sessions. This included the amount and types of activities each subject was exposed to during the eight weeks of the study. To be able to have a positive effect on the postural control system, the interventions need to account for these three constraints on the system. For this reason, there is a need for research that accounts for the variability in individuals and that utilizes multidisciplinary methods of intervention to enhance the postural control system of older adults.

Chapter Six

Summary, Conclusions, and Recommendations

Summary

The development of interventions to prevent falls and injuries of older adults is important. One of the many documented risk factors for falling is a decrease in postural control due to normal aging.[19, 20] The somatosensory system is important for postural control and a decrease in somatosensory input due to declines in cutaneous receptor response has been shown to contribute to the decrease is postural control that is observed in older adults.

It has been demonstrated that in-shoe orthotics increase postural stability and have a positive effect on the somatosensory system in young adults.[41, 44-47] However, the application of an in-shoe orthotic to improve postural stability in older adults has not been reported. Our purpose of this study was to test hypotheses that were formulated to evaluate whether enhancement of the somatosensory system with in-shoe orthotics would improve the postural control of older adults. Additional knowledge concerning effective interventions that improve postural control will increase the ability of researchers and clinicians to develop comprehensive fall reduction programs.

The research hypotheses involved four types of dependent variables: 1) Clinical Measures, 2) Force Plate Measures, 3) Survey Measures, and 4) Sensation Measures. It was hypothesized that if the somatosensory system was enhanced with the usage of in-shoe orthotics then: 1) all improvements in test scores would occur in the first 4 weeks of orthotic usage, and 2) there would be no subsequent improvements from week 4 to week 8 of orthotic usage.

Postural assessments were performed on 27 healthy older adults on 5 Test Days spanning 8 weeks of orthotic usage. Two baseline measurements were collected followed by 3 Test Days while the subjects wore the in-shoe orthotic. The dependent variables included 6 Clinical Measures, 18 Force Plate Measures, 2 Survey Measures, and 2 Sensation Measures. A repeated measures ANOVA was performed to assess if there were differences among the 5 Test Days for all dependent variables ($p = 0.05$)

For the Clinical Measures, statistical significance was found for 3 of the dependent variables, however only the Timed “Up & Go” (TUG) supported the hypothesis that was expected. There was only 1 statistically significant finding for the Force Plate Measures, and it did not support the hypothesis that was expected. No significant differences where reported for the Survey or Sensation Measures. The results did not indicate statistically that the in-shoe orthotic enhanced postural stability in this group of subjects. However, there were indications that there was a subset of the current population that had benefitted from the intervention and this needs to be investigated further.

Conclusions

The present findings warrant the following conclusions for the formulated research hypotheses.

1. There will be significant improvements at the initial in-shoe orthotic system data collection when compared to the non-orthotic results for all Clinical Measurements and Force Plate Measurements. *This hypothesis was not confirmed,* as no significant improvements were reported for Test Day 3.
2. There will be significant improvements in Clinical Measurements and Force Plate Measurements at the 4 week collection compared to the initial and non-orthotic data collection data. *This hypothesis was not confirmed,* as no significant improvements were reported for Test Day 4.
3. There will be no significant subsequent improvements in the Clinical Measurements and Force Plate Measurements at the 8 week collection compared to the 4 week data collection period. *This hypothesis was not confirmed,* as no significant improvements were reported for Test Day 4 and Test Day 5 had 1 significant improvement (TUG).
4. There will be a significant increase in the Activities-specific Balance Confidence scale and the Activity Questionnaire at both the 4 and 8 week data collection period compared to the first data collection. *This hypothesis was not confirmed,* as no significant increase was reported for either Test Day 4 or 5.
5. There will be no significant difference in the Semmes-Weinstein Monofilament and Quantitative Vibration Perception Threshold when comparing week 8 data to the initial data. *This hypothesis was confirmed,* as no significant improvements were reported for Test Day 5.

Recommendations

The present results indicated that the in-shoe orthotic, in the form of the SmartStep™ Stabilization System, was not beneficial in improving postural stability in older adults. As this was the first study to document the effectiveness of this type of in-shoe orthotic, additional research in this area may provide greater insight. One recommendation would be to utilize a group of control subjects to ascertain whether an orthotic prevents regression of postural stability. Even though there were no improvements in balance with the present intervention, it is not known whether there was a decrease in the rate of natural decay.

The current intervention was an “off the shelf” orthotic system that included shoes also. It is unknown what the effects of custom molded orthotics would have been in this group of subjects. The utilization of molded orthotics would have accommodated to the individual subject footwear needs. Future research into the usage of custom in-shoe orthotics may be beneficial. Many of the subjective comments that were received from the subjects referred to feeling more “stable”. This could have been a result of the shoes only and not the orthotic insert. The shoes that were provided were wider and more supportive of the foot than what most of the subjects wore prior to the study. The more stable shoe construction alone may have influenced the subjects. A future study that included a group of subjects who wore the shoes only would allow the researchers to know whether any changes in performance were due to the orthotic or to the shoe.

The subjects were chosen due to their age and because they did not have major health problems. They were also screened for sensation deficits so that the orthotic would not induce skin breakdown due to decreased sensation. The utilization of this “healthy” population of older adults may have contributed to the lack of significant improvements. The current group of subjects may have been performing at their highest ability level and may not have had the capacity to improve. Utilizing a differing subject population may elicit different results if the subjects are lower functioning and have more improvements to be made.

The dependent variables that were chosen for this study may not have been robust enough to elicit improvements. It has been suggested that dual task conditions are more sensitive in assessing postural stability in an older adult population.[171, 202, 203] Future research that utilizes testing conditions that include dual tasks may be able to detect significant changes that the current study was unable to detect.

Along with the need to have differing types of tasks as dependent variables, there is a need to evaluate combinations of interventions. The postural control system is complex and consists of many sensory and motor components. Interventions that affect multiple components would be better able to influence this multidimensional system. The complexity is challenged even more by the wide variations in the older adult population as a whole. Research that is able to identify those older adults who are most likely to be positively influenced by the interventions would be beneficial. Postural instability should not be an inevitable consequence of getting older. Multi component interventions that allow older adults to remain active and not fearful of falling are needed and may include a component that positively influences the somatosensory system of the plantar surface of the foot.

Appendix A: Health History Questionnaire

Health History Questionnaire

Subject #_____ Date/Time_______

1. Have you had head injury within the last six months?
   Yes **No**
   ____

2. Have you had an injury to your hip, knee, or foot in the last six months?
   Yes **No**
   ____

3. Are you a diabetic?
   Yes **No**
   If yes, is it being controlled either lifestyle changes or medication?
   Yes **No**
   ____

4. Do you have a history of foot wounds?
   Yes **No**
   ____

5. Have you had your eyes checked recently?
   Yes **No**
   ____

6. Do you wear glasses?
   Yes **No**
   ____

7. Do you have a history of unexplained falls?
   Yes **No**
   ____

8. Do you have extreme pain that prevents you from performing normal activities of daily life?
   Yes **No**
   ____

9. Do you have any other medical conditions that you think will impair your ability to participate as a subject?

Appendix B: Consent to Participate in a Research Study

Consent to Participate in a Research Study

Effect of the SmartStep™ Stabilization System on Balance in Older Adults Living in an Independent and Assisted Living Residence

WHY ARE YOU BEING INVITED TO TAKE PART IN THIS RESEARCH?

You are being invited to take part in a research study about balance and a special shoe with an insert (SmartStep™ Stabilization System). You are being invited to take part in this research study because you are a resident of Richmond Place Retirement Community. If you volunteer to take part in this study, you will be one of about 60 people to do so.

WHO IS DOING THE STUDY?

The person in charge of this study is Ann Livengood of the University of Kentucky. She is being guided in this research by Carl Mattacola PhD, ATC. There may be other people on the research team assisting at different times during the study.

WHAT IS THE PURPOSE OF THIS STUDY?

By doing this study, we hope to determine the effect of the SmartStep™ Stabilization System (SmartStep™) on balance in older adults during an 8 week period. We also want to determine if there is a difference in balance between residents in the Independent Living and Assisted Living facilities of Richmond Place prior to being given the SmartStep™ and after they have been wearing it for 8 weeks.

WHERE IS THE STUDY GOING TO TAKE PLACE AND HOW LONG WILL IT LAST?

The research procedures will be conducted at Richmond Place Retirement Community. You will need to come to the conference room 5-7 times during the study. Each of those visits will take about 45 minutes. The total amount of time you will be asked to volunteer for this study is 3 ¾ - 5 ¼ hours over the next 8 weeks. With your permission, we would also like to contact you by telephone at 6, 12, and 18 months, to determine if you have had any difficulty with balance and falls.

WHAT WILL YOU BE ASKED TO DO?

Health History and Sensation Testing:

Every volunteer will be asked for a brief medical history to determine if they will be included. To be able to participate is this study you must be able to follow the directions given to you by the investigator and be able to answer all questions. To determine if you are able to follow directions and understand what is being asked of you, a short questionnaire called the Mini-mental State Exam will be given to you.

As part of the inclusion criteria to be a subject you must have a minimum level of sensation on the bottom of your foot. This will be tested with a machine called a Bio-Thesiometer. This machine has a small rubber tip that will be held onto the bottom of your big toe while you are lying down. The rubber tip vibrates, and the intensity of the vibration is increased slowly. You will have to tell the investigator when you are able to feel the vibration and this determines your sensation threshold. If your threshold is too high, you will not be able to be in the study. A second sensation test will performed on each foot. A small monofilament that is as fine as a human hair will be placed on the top of your foot, just next to the nail of your big toe. This filament will be placed several times on your foot and you inform the investigator when you feel it.

SmartStep™ Stabilization System Fitting:

If you meet the inclusion criteria, we will then fit you for the SmartStep™. The fitting will be performed by a certified pedorthist from the SmartStep Company. Your SmartStep™ will be ordered for you. The SmartStep™ consists of the following: 1) a pair of extra depth, diabetic shoes (Apex Foot Health Industries, Inc., St.Louis, MO) 2) a patented in-shoe orthotic (SmartStep, Inc.), 3) a pair of patented SmartKnit Seamless Socks, 4) a pair of Comfort System Lite Socks, 5) a pair of Sleep Socks with non-skid treads.

At this time, we will schedule your Test 1 and Test 2 appointments which will be performed in your regular shoes and will be 48 hours apart from each other. If your scores on the tests are significantly different between Test 1 and 2 because you are learning the tests, we will have to repeat Test 2 until the scores don't change significantly. Test 2 could be repeated up to 2 times. We will not test you more than 4 times before beginning the SmartStep™ testing days. When your SmartStep™ is delivered, we will schedule your Test 3 appointment which will be performed with your new shoe and in-shoe insert. After Test 3 you will be asked to start wearing the SmartStep™ on a daily basis. The first day with the SmartStep™ you should only wear it for 2 hours, and then add 1 hour a day until you are wearing it 8 hours, or whenever you are walking around. Four weeks after you receive your SmartStep™ you will come back for Test 4. Four weeks after Test 4 you will return for the final test, Test 5.

On all days of testing you will perform the same balance tests (described below). On the 1st day of testing and the last day of testing you will also fill out two questionnaires that ask questions about your daily activities and your confidence in performing daily activities.

The following is a timeline of events:

Initial Visit	**Test 1**	**Test 2:** **48 hours later**	**Test 2 Repeated**
Health Questionnaire Fit for SmartStep™ Schedule Test 1 and Test 2	Activity Questionnaires Balance Tests Wear your own shoes	Balance Tests Wear your own shoes	If your Test 2 is significantly different from Test 1, Test 2 will be repeated up to 2 times.

Test 3: **48 hours later**	**Test 4:** **4 weeks after**	**Test 5:** **4 weeks later**
Balance Tests Wear SmartStep™	Balance Tests Wear SmartStep™	Activity Questionnaires Balance Tests Wear SmartStep™

<u>Balance Tests</u>

Each of the following balance tests will be performed 1 time each test day, unless otherwise noted. As noted below, some of the tests will be performed while you are standing on a force plate. A force plate is an instrument that measures the amount of force that you press against the ground. It is like a large bathroom scale that collects data very fast. The force plate dimensions are approximately:

Length = 24 inches,
Width = 16 inches
Height = 4 inches

<u>Berg Balance Scale</u>

The Berg Balance Scale (BBS) consists of 14 movements that are common in activities of daily living. The 14 mobility tests are performed as follows:

1. Sitting unsupported in a standard chair
2. Change of position: sitting to standing
3. Change of position: standing to sitting
4. Transfer: move from one chair to another, and back again
5. Standing unsupported, eyes-open: stand on the force plate
6. Standing unsupported, with eyes-closed: stand on the force plate
7. Standing with feet together: stand on the force plate
8. Tandem standing: one foot in front of another: stand on the force plate
9. Standing on one leg: stand on the force plate
10. Looking over your shoulder (feet fixed)
11. Retrieving an object from the floor

12. Turning 360 degrees
13. Stool Stepping: tap one foot at a time on a stool
14. Forward reach with feet stationary: stand on the force plate

Timed "Up & Go"

The timed "Up & Go" (TUG) test measures your functional mobility. You will starts while sitting, with your back against the back of a standard arm chair. You will be asked to stand, walk a distance of 3 meters, turn, walk back to the chair, and sit down again. Three tests will be measured each day. A rest period of 2 minutes will be given between tests.

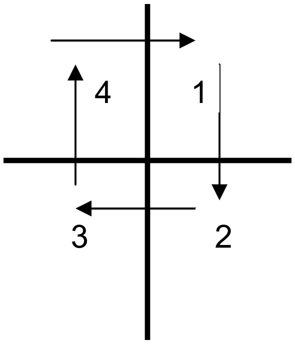
Functional and Lateral Reach Tests

The Functional Reach Test (FRT) and Lateral Reach Test (LRT) are measures of maximal forward and side distances reached beyond arms length while standing. A tape measure and strip of paper will be taped to the wall for both of these tests. For the FRT, you will stand on the force plate so that the tape measure is on the wall to your left. You will be placed in a standardized position with your feet 10 cm apart as measured between the inside edge of the heels. You will raise both arms up in front of you with your elbows straight. You will then be instructed to lean forward as far as possible without losing your balance or lifting your feet and then hold this position for 3 sec. You will perform this three times with a 30 second rest between trials.

A similar procedure will be performed for the LRT; however you stand on the force plate with your back toward the wall. With 1 arm at your side, and the other arm raised out to side, you will be asked to reach directly sideways as far as possible without lifting either foot, bending a knee, rotating or bending the trunk. The maximal reach will be maintained for 3 seconds. The lateral reach will be performed three times in both directions with 30 seconds between trials.

Four Square Step Test

The Four Square Step Test (FSST), is a dynamic test of postural stability. This test requires you to change directions and step over a one (1) inch obstacle. You will be asked to step over a one inch cane laying flat on the ground for each of the following directions: 1) forward, 2) sidestep to the right, 3) backwards, and 4) sideways to the left (Figure 1). This is repeated in the opposite direction (sidestep to the right, forward, sidestep left, backwards) and the time is recorded. The FSST will take approximately 2 minutes to complete.



This is then repeated in the reverse direction

Figure 1: Four Square Step Test

Questionnaires

You will be asked to fill out 2 short questionnaires on the first day of testing and on the last day of testing. These questionnaires will ask you questions about your confidence in performing daily activities.

ARE THERE REASONS WHY YOU SHOULD NOT TAKE PART IN THIS STUDY?

If you have had an injury to your head, hip, leg, or foot in the past 6 months you should not take part in this study. Also, if you have had an ear infection in the past 2 weeks you should wait until at least 2 weeks have passed before you participate in this study. If you have a history of foot wounds or have medical condition that is not being controlled by a physician you should not participate in this study.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

- There is a risk of falling from the force plate or while performing any of the testing. We will try to minimize this risk by having two investigators by your side at all times and there will be a safety strap around your waist in case you lose your balance.
- You may have foot soreness while accommodating to the SmartStep™. The investigator will have you gradually “break in” the insert over a week to minimize this discomfort.
- There is a risk that you might develop a blister or a wound from the SmartStep™ shoe insert. You will be contacted weekly in person or on the phone to determine if you have any signs or symptoms that are associated with foot wounds from shoe inserts.

There is always a chance that any medical treatment can harm you, and the treatment in this study is no different. We will do everything we can to keep you from being harmed. In addition to the risks listed above, you may experience a previously unknown risk or side effect.

WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?

There is no guarantee that you will get any benefit from taking part in this study. All participants will receive a free SmartStep™ Stabilization System.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any benefits or rights you would normally have if you choose not to volunteer. You can stop at any time during the study and still keep the benefits and rights you had before volunteering.

IF YOU DON'T WANT TO TAKE PART IN THE STUDY, ARE THERE OTHER CHOICES?

If you do not want to be in the study, there are no other choices except not to take part in the study.

WHAT WILL IT COST YOU TO PARTICIPATE?

You and/or your insurance company, Medicare or Medicaid will be responsible for the costs of all care and treatment you receive during this study that you would normally receive for your condition. These are costs that are considered medically reasonable and necessary and will be part of the care you receive if you do not take part in this study.

The University of Kentucky may not be allowed to bill your insurance company, Medicare, or Medicaid for the medical costs of procedures done strictly for research. Therefore, these costs will be your responsibility.

WHO WILL SEE THE INFORMATION THAT YOU GIVE?

We will keep private all research records that identify you to the extent allowed by law.

Your information will be combined with information from other people taking part in the study. When we write about the study to share it with other researchers, we will write about the combined information we have gathered. You will not be identified in these written materials. We may publish the results of this study; however, we will keep your name and other identifying information private.

We will make every effort to prevent anyone who is not on the research team from knowing that you gave us information, or what that information is. For example, your name will be kept separate from the information you give, and these two things will be stored in different places under lock and key. You should know, however, that there are some circumstances in which we may have to show your information to other people. For example, the law may require us to show your information to a court.

Someone from the University of Kentucky may look at or copy pertinent portions of records that identify you.

CAN YOUR TAKING PART IN THE STUDY END EARLY?

If you decide to take part in the study you still have the right to decide at any time that you no longer want to continue. You will not be treated differently if you decide to stop taking part in the study.

The individuals conducting the study may need to withdraw you from the study. This may occur if you are not able to follow the directions they give you, if they find that your being in the study is more risk than benefit to you, or if the agency funding the study decides to stop the study early for a variety of scientific reasons.

WHAT HAPPENS IF YOU GET HURT OR SICK DURING THE STUDY?

If you believe you are hurt or if you get sick because of something that is done during the study, you should call Ann Livengood at 859-323-1100 ext 80840 immediately. It is important for you to understand that the University of Kentucky will not pay for the cost of any care or treatment that might be necessary because you get hurt or sick while taking part in this study. That cost will be your responsibility. Also, the University of Kentucky will not pay for any wages you may lose if you are harmed by this study.

Medical costs that result from research-related harm can not be included as regular medical costs. The University of Kentucky may not be allowed to bill your insurance company for such costs. You should ask your insurer if you have any questions about your insurer’s willingness to pay under these circumstances. Therefore, the costs related to your care and treatment because of something that is done during the study will be your responsibility.

WILL YOU RECEIVE ANY REWARDS FOR TAKING PART IN THIS STUDY?

You will receive SmartStep™ Stabilization System for taking part in this study. You will be able to keep everything given to you even if you withdraw from the study early.

WHAT IF YOU HAVE QUESTIONS?

Before you decide whether to accept this invitation to take part in the study, please ask any questions that might come to mind now. Later, if you have questions about the study, you can contact the investigator, Ann Livengood at 859-323-1100 ext 80840. If you have any questions about your rights as a volunteer in this research, contact the staff in the Office of Research Integrity at the University of Kentucky at 859-257-9428 or toll free at 1-866-400-9428. We will give you a signed copy of this consent form to take with you.

WHAT ELSE DO YOU NEED TO KNOW?

SmartStep, Inc. is providing the SmartStep™ Stabilization System for this study.

You will be told if any new information is learned which may affect your condition or influence your willingness to continue taking part in this study.

____ _________

Signature of person agreeing to take part in the study Date

____

Printed name of person agreeing to take part in the study

____ ____________

Name of [authorized] person obtaining informed consent Date

____

Signature of Investigator

Appendix C: Center of Pressure Equations

Center of Pressure Equations

Both anterior-posterior (AP) and medial-lateral (ML) Center of Pressure (COP) data were exported from Motion Monitor software and the dependent variables of distance, displacement and root mean square of the velocity were then calculated using Excel® 2002.

COP Distance (DIST) was calculated as the length of the COP path for the entire 50 seconds of data collection. The equation to calculate DIST for each plane of motion was:

$$DIST = \sum_{i=1}^{n} \left| \left(COP_i - COP_{i-1} \right) \right|$$

COP Displacement (DISP) was calculated as the range for both the AP and ML planes. The equation to calculate DISP was:

$$DISP = COP_{max} - COP_{min}$$

The root mean square of the COP Velocity (RMS_{vel})[46] was calculated for the 50 seconds of data collection for both the AP and ML planes. The equation that was utilized was:

$$RMS_{vel} = \sqrt{\frac{\sum_{i=1}^{n} \left(\frac{COP_i - COP_{i-1}}{0.01} \right)^2}{4999}}$$

Appendix D: Berg Balance Scale

BERG BALANCE SCALE

Subject # ____________________ **Date/Time** ______________________

Test # __________

ITEM	DESCRIPTION	SCORE (0-4)
1.	Sitting to standing	_____
2.	Standing unsupported	_____
3.	Sitting unsupported	_____
4.	Standing to sitting	_____
5.	Transfers	_____
6.	Standing with eyes closed	_____
7.	Standing with feet together	_____
8.	Reaching forward with outstretched arm	_____
9.	Retrieving object from floor	_____
10.	Turning to look behind	_____
11.	Turning 360 degrees	_____
12.	Placing alternate foot on stool	_____
13.	Standing with one foot in front	_____
14.	Standing on one foot	_____
	TOTAL	_____

GENERAL INSTRUCTIONS

Please demonstrate each task and/or give instructions as written. When scoring, please record the lowest response category that applies for each item.

In most items, the subject is asked to maintain a given position for a specific time. Progressively more points are deducted if the time or distance requirements are not met, if the subject's performance warrants supervision, or if the subject touches an external support or receives assistance from the examiner. Subjects should understand that they must maintain their balance while attempting the tasks. The choices of which leg to stand on or how far to reach are left to the subject. Poor judgment will adversely influence the performance and the scoring.

Equipment required for testing are a stopwatch or watch with a second hand, and a ruler or other indicator of 2, 5 and 10 inches (5, 12.5 and 25 cm). Chairs used during testing should be of reasonable height. Either a step or a stool (of average step height) may be used for item #12.

1. **SITTING TO STANDING**
INSTRUCTIONS: Please stand up. Try not to use your hands for support.

( ) 4 able to stand without using hands and stabilize independently
( ) 3 able to stand independently using hands
( ) 2 able to stand using hands after several tries
( ) 1 needs minimal aid to stand or to stabilize
( ) 0 needs moderate or maximal assist to stand

2. **STANDING UNSUPPORTED**
INSTRUCTIONS: Please stand for two minutes without holding.

( ) 4 able to stand safely 2 minutes
( ) 3 able to stand 2 minutes with supervision
( ) 2 able to stand 30 seconds unsupported
( ) 1 needs several tries to stand 30 seconds unsupported
( ) 0 unable to stand 30 seconds unassisted

If a subject is able to stand 2 minutes unsupported, score full points for sitting unsupported. Proceed to item #4.

3. **SITTING WITH BACK UNSUPPORTED BUT FEET SUPPORTED ON FLOOR OR ON A STOOL**
INSTRUCTIONS: Please sit with arms folded for 2 minutes.

( ) 4 able to sit safely and securely 2 minutes
( ) 3 able to sit 2 minutes under supervision
( ) 2 able to sit 30 seconds
( ) 1 able to sit 10 seconds
( ) 0 unable to sit without support 10 seconds

4. **STANDING TO SITTING**
INSTRUCTIONS: Please sit down.

( ) 4 sits safely with minimal use of hands
( ) 3 controls descent by using hands
( ) 2 uses back of legs against chair to control descent
( ) 1 sits independently but has uncontrolled descent
( ) 0 needs assistance to sit

5. **TRANSFERS**

INSTRUCTIONS: Arrange chairs(s) for a pivot transfer. Ask subject to transfer one way toward a seat with armrests and one way toward a seat without armrests. You may use two chairs (one with and one without armrests) or a bed and a chair.

( ) 4 able to transfer safely with minor use of hands
( ) 3 able to transfer safely definite need of hands
( ) 2 able to transfer with verbal cueing and/or supervision
( ) 1 needs one person to assist
( ) 0 needs two people to assist or supervise to be safe

6. **STANDING UNSUPPORTED WITH EYES CLOSED**

INSTRUCTIONS: Please close your eyes and stand still for 10 seconds.

( ) 4 able to stand 10 seconds safely
( ) 3 able to stand 10 seconds with supervision
( ) 2 able to stand 3 seconds
( ) 1 unable to keep eyes closed 3 seconds but stays steady
( ) 0 needs help to keep from falling

7. **STANDING UNSUPPORTED WITH FEET TOGETHER**

INSTRUCTIONS: Place your feet together and stand without holding.

( ) 4 able to place feet together independently and stand 1 minute safely
( ) 3 able to place feet together independently and stand for 1 minute with supervision
( ) 2 able to place feet together independently and to hold for 30 seconds
( ) 1 needs help to attain position but able to stand 15 seconds feet together
( ) 0 needs help to attain position and unable to hold for 15 seconds

8. **REACHING FORWARD WITH OUTSTRETCHED ARM WHILE STANDING**

INSTRUCTIONS: Lift arm to 90 degrees. Stretch out your fingers and reach forward as far as you can. (Examiner places a ruler at end of fingertips when arm is at 90 degrees. Fingers should not touch the ruler while reaching forward. The recorded measure is the distance forward that the finger reach while the subject is in the most forward lean position. When possible, ask subject to use both arms when reaching to avoid rotation of the trunk.)

( ) 4 can reach forward confidently >25 cm (10 inches)
( ) 3 can reach forward >12.5 cm safely (5 inches)
( ) 2 can reach forward >5 cm safely (2 inches)
( ) 1 reaches forward but needs supervision
( ) 0 loses balance while trying/ requires external support

9. **PICK UP OBJECT FROM THE FLOOR FROM A STANDING POSITION**

INSTRUCTIONS: Pick up the shoe/slipper which is placed in front of your feet.

( ) 4 able to pick up slipper safely and easily
( ) 3 able to pick up slipper but needs supervision
( ) 2 unable to pick up but reaches 2-5cm (1-2 inches) from slipper and keeps balance independently
( ) 1 unable to pick up and needs supervision while trying
( ) 0 unable to try/needs assist to keep from losing balance or falling

10. **TURNING TO LOOK BEHIND OVER LEFT AND RIGHT SHOULDERS WHILE STANDING**

INSTRUCTIONS: Turn to look **directly** behind you over toward left shoulder. Repeat to the right.
Examiner may pick an object to look at directly behind the subject to encourage a better twist turn.

( ) 4 looks behind from both sides and weight shifts well
( ) 3 looks behind one side only other side shows less weight shift
( ) 2 turns sideways only but maintains balance
( ) 1 needs supervision when turning
( ) 0 needs assist to keep from losing balance or falling

11. **TURN 360 DEGREES**

INSTRUCTIONS: Turn completely around in a full circle. Pause. Then turn a full circle in the other direction.
( ) 4 able to turn 360 degrees safely in 4 seconds or less
( ) 3 able to turn 360 degrees safely one side only in 4 seconds or less
( ) 2 able to turn 360 degrees safely but slowly
( ) 1 needs close supervision or verbal cueing
( ) 0 needs assistance while turning

12. **PLACING ALTERNATE FOOT ON STEP OR STOOL WHILE STANDING UNSUPPORTED**

INSTRUCTIONS: Place each foot alternately on the step/stool. Continue until each foot has touched the step/stool four times.
( ) 4 able to stand independently and safely and complete 8 steps in 20 seconds
( ) 3 able to stand independently and complete 8 steps >20 seconds
( ) 2 able to complete 4 steps without aid with supervision
( ) 1 able to complete >2 steps needs minimal assist
( ) 0 needs assistance to keep from falling/unable to try

13. **STANDING UNSUPPORTED ONE FOOT IN FRONT**

INSTRUCTIONS: (DEMONSTRATE TO SUBJECT)

Place one foot directly in front of the other. If you feel that you cannot place your foot directly in front, try to step far enough ahead that the heel of your forward foot is ahead of the toes of the other foot. (To score 3 points, the length of the step should exceed the length of the other foot and the width of the stance should approximate the subject's normal stride width)

( ) 4 able to place foot tandem independently and hold 30 seconds
( ) 3 able to place foot ahead of other independently and hold 30 seconds
( ) 2 able to take small step independently and hold 30 seconds
( ) 1 needs help to step but can hold 15 seconds
( ) 0 loses balance while stepping or standing

14. **STANDING ON ONE LEG**

INSTRUCTIONS: Stand on one leg as long as you can without holding.

( ) 4 able to lift leg independently and hold >10 seconds
( ) 3 able to lift leg independently and hold 5-10 seconds
( ) 2 able to lift leg independently and hold = or >3 seconds
( ) 1 tries to lift leg unable to hold 3 seconds but remains standing independently
( ) 0 unable to try or needs assist to prevent fall

( ) TOTAL SCORE (Maximum = 56)

Appendix E: Activities-specific Balance Confidence (ABC) Scale

Subject #_________ Test #____ Date/Time________

Activities-Specific Balance Confidence (ABC) Scale

For each of the following, please indicate <u>your level of confidence in doing the activity without losing your balance or becoming unsteady</u> by marking on the line that is scaled 0-100%. If you do not currently do the activity in question, try to imagine how confident you would be if you had to do the activity. If you normally use a walking aid to do the activity or you hold on to someone, rate your confidence as if you were using these supports. If you have any questions about answering any of these items, please ask the researcher.

“How confident are you that you will not lose your balance or become unsteady when you….

1. …walk around the house?

____

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

2. …walk up or down stairs?

____

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

3. …bend over and pick up a slipper from the front of the closet?

____

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

4. …reach for a small can off a shelf at eye level?

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

5. …stand on tip toes and reach for something above your head?

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

6. …stand on a chair and reach for something?

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

7. …sweep the floor?

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

8. …walk outside the house to a car parked in the driveway?

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

9. …get into or out of a car?

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

10. …walk across a parking lot to a mall?

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

11. …walk up or down a ramp?

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

12. …walk in a crowded mall where people rapidly walk past you?

____

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

13. …are bumped by people as you walk through the mall?

____

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

14. …step onto or off of an escalator while you are holding onto the railing?

____

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

15. …step onto or off of an escalator while holding onto parcels such that you cannot hold onto the railing?

____

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

16. …walk outside on icy sidewalks?

____

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

Appendix F: Activity Questionnaire

Subject # _____ Test #_____ Date/Time____________

Investigator_______

1) Have you fallen in the past week?_____ month?_____ year____?

If yes, how many times?______ what were you doing at the time?

2) Today, do you or would you have any difficulty at all with…..

Activities	**Extreme difficulty or unable to perform activity**	**Quite a bit of difficulty**	**Moderate difficulty**	**A little bit of difficulty**	**No difficulty**
Any of your usual housework.	0	1	2	3	4
Your usual hobbies, recreational activities	0	1	2	3	4
Getting into or out of the bath	0	1	2	3	4
Walking between rooms	0	1	2	3	4
Putting on your shoes or socks	0	1	2	3	4
Getting into or out of a car	0	1	2	3	4
Walking 2 blocks	0	1	2	3	4
Walking a mile	0	1	2	3	4
Going up or down 10 stairs (about 1 flight or stairs)	0	1	2	3	4
Standing for 1 hour	0	1	2	3	4

Appendix G: Subject Comments

Subject number	Test Day that the comment was made	Comments
1	4	“I think the shoes help me balance.”
3	4	“I feel like I am balancing better”
3	5	“I stand better with the shoes. I do better with single leg standing in exercise class.”
4	4	“I love the shoes and I don’t want to wear another pair of shoes.”
4	5	“I love the shoes still and I don’t want to wear any other shoe.”
6	After 1 week with the shoes	“The shoes are too heavy and hurt my calf.”
9	4	“I wear them every day, even Sunday. My feet are tired by the end of the day, the shoes are stiff and heavy. My right arch hurts at the end of the day.”
9	5	“I don’t think my balance is any better.”
14	5	“These shoes are great!”
23	4	“I love the shoes, they are very comfortable. They are wide and help with my balance. I want another pair.”
28	4	“Shoes are heavy, but I like them. I feel steadier on my feet. I think that the shoes really help with balance.”
28	5	“I think the study is great. These shoes would be good for people around here.”
29	5	“Shoes are very comfortable.”
35	3	“Shoes feel good.”

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Vita

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Birthdate: January 9, 1975

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Education

PhD

Exercise Science (Biomechanics), University of Kentucky
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MEd

Sports Medicine/Athletic Training, Temple University, Philadelphia, PA (2001)
Thesis Title: Three-dimensional kinematics and kinetics of the lower extremity while landing from a lateral drop jump with a prophylactic ankle brace

BSEd

Sports Medicine, University of Virginia, Charlottesville, VA (1997)

Professional Experience

Eastern Kentucky University, Richmond, KY
Part-time faculty, 2006-2007

Asbury College, Wilmore, KY
Part-time faculty 2006

University of Kentucky, Lexington, KY
Teaching Assistant, 2003 - 2006

Lexington Christian Academy, Lexington, KY
Athletic Trainer, 2000-2002

Temple University, Philadelphia, PA
Teaching Assistant, 1997-2000
Gait Lab Technician, 1999-2000

Professional Publications

Invited Publications

Livengood, A.L., DiMattia MA, Uhl TL, "Dynamic Trendelenburg": Single-leg squat test for gluteus medius strength. *Athletic Therapy Today*, 2004, 9:24-25.

Refereed Articles

<ins>DiMattia,M.A</ins>., Livengood,A.L., Uhl,T.L., Mattacola,C.G., Malone,T.R. What is the validity of the single-leg squat test and its relationship to hip abduction strength? *Journal of Sport Rehabilitation*, 2005, 14:2, 108-123.

Invited Presentations

<ins>KAHPERD Summer Coaches Workshop:</ins> "Sports Medicine Overview for the Coach", University of Kentucky, Lexington, KY June 18, 2002.

Refereed Abstracts/Presentations

<ins>International:</ins>
Livengood, A.L., Sitler, M.R., Hillstrom, H.J. Three-dimensional kinematics and kinetics of the lower extremity while landing from a lateral drop jump with a prophylactic ankle brace. *IV World Congress of Biomechanics, August 2002, Calgary, Canada.* Podium Presentation.

<ins>National:</ins>
DiMattia,M.A., Livengood,A.L., Uhl,T.L., Mattacola,C.G., Malone,T.R. Validating the single-leg squat test as a function test for hip abduction strength. *Journal of Athletic Training*, 2004, 39:2, S-117.

<ins>Roller, S.J.</ins>, Livengood, A.L., Mattacola, C.G., Uhl, T.L., Malone, T.R. Effect of prophylactic ankle bracing on postural control and EMG of lower extremity and trunk muscles. *Journal of Athletic Training,* 2003, 38(2): S-89. Poster Presentation.

Baker, J.K., Mattacola, C.G., McCrory, J.L., Uhl, T.L., Malone, T.R., Livengood, A.L. Effect of ankle bracing on postural sway during single limb landing from a controlled height. *Journal of Athletic Training* 37(2)supplement:S-26-27, 2002. Poster Presentation.

<ins>Regional:</ins>
Roller, S.J., Livengood, A.L., Mattacola, C.G., Uhl, T.L., Malone, T.R. Effect of prophylactic ankle bracing on postural control and EMG of lower extremity and trunk muscles. *Southeast Athletic Trainers Association Annual Meeting,* March 2003, Poster Presentation.

Livengood, A.L., Sitler, M.R., Hillstrom, H.J. Three-dimensional kinematics and kinetics of the lower extremity while landing from a lateral drop jump with a prophylactic ankle brace. *Southeast Athletic Trainers Association Annual Meeting,* March 2002, Oral Presentation.

Baker, J.K., Mattacola, C.G., McCrory, J.L., Uhl, T.L., Malone, T.R., Livengood, A.L. Effect of ankle bracing on postural sway during single limb landing from a controlled height. *Southeast Athletic Trainers Association Annual Meeting,* March 2002, Poster Presentation.

Awards/Honors

2005-06	John E Partington and Gwendolyn G Partington Scholarship Recipient (University of Kentucky College of Education)
2004-05	John E Partington and Gwendolyn G Partington Scholarship Recipient (University of Kentucky College of Education)
2002-03	Sarah Ruth Geurin Scholarship Recipient (University of Kentucky College of Education)

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