THE EFFECTS OF TEXTURED INSOLES ON BALANCE IN INDIVIDUALS WITH KNEE OSTEOARTHRITIS

by

HYOUNGJIN PARK

(Under the Direction of Michael A. Horvat)

ABSTRACT

Osteoarthritis (OA) is a leading cause of disability and loss of function and characterized by pain, reduction of lower limb strength, and abnormal somatosensory function. Centers for Disease Control and Prevention (CDC) research has shown that individuals with arthritis have a higher chance of falls and reduced balance compared to matched healthy individuals. Evidence of the effectiveness of added plantar-surface texture to improve balance has been successful for various younger populations as well as elderly fallers, and clinical populations. However, to date, no studies have systematically investigated the potential benefits of this textured insole intervention, and potential interactions with people with knee OA. Therefore, the purpose of this study was to evaluate textured insoles for individuals with knee OA. Thirty individuals, fifteen with knee osteoarthritis and fifteen healthy, aged-matched controls completed this study and were evaluated on balance as measured by a NeuroCom EquiTest Sensory Organization Test and Motor Control test protocol. Data were analyzed with ANOVA, paired t-test, and independent t-test. The results demonstrated that there were significant improvements in ECF, EORF, VEST, and PMAN when wearing the textured insoles in knee OA group, and in healthy knee group, there were statistically significant improvements in EO-FP, EORF when wearing the textured insoles. Also, EO-SUR, ECF, EORF, VEST, PMAN, and latency were significantly higher and faster for healthy knee controls than for individuals with knee OA. Additionally, there were no interactions between groups and improvements. Thus, it was concluded that although the textured insoles did not produce statistically greater improvements on balance in individuals with knee OA compared to the healthy knee group, individuals with knee OA and healthy controls could improve balance in some tasks with textured insoles. Also, the benefits of this study for the individuals with knee OA are that this may lead to the development of an evidence-based footwear intervention which is noninvasive, simple to use, inexpensive, allows the user for self-management, and has the capacity to reduce the risk of falls, consequentially improving the quality of life.

INDEX WORDS: Knee osteoarthritis, Balance, Textures insoles

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CHAPTER 1

INTRODUCTION

Adults aged 45 yr and over with arthritis account for 52% of adults in the United States (Center for Disease Control and Prevention [CDC], 2013). Among the various forms of arthritis, osteoarthritis (OA) is the most prevalent and is a leading cause of disability and loss of function (CDC, 2001; Issa & Sharma, 2006). OA is characterized by a degradation of articular cartilage, sclerosis of the subchondral bone, and osteophyte formation with symptoms of joint pain and dysfunction, and in its advanced stages, joint contractures, muscle atrophy, and limb deformity, especially, in the knee joints are the most commonly affected and characterized by pain, reduction of lower limb strength, and abnormal somatosensory function (Buckwalter, Saltzman, & Brown, 2004; Tarigan et al., 2009; Van et al., 2013; Wylde, Palmer, Learmonth, & Dieppe, 2012). These characteristics limit the ability to perform functional activities of daily living such as rising from a chair, standing, walking, or climbing stairs (Barrett, Cobb, & Bentley, 1991; Eyigor, Hepguler, & Hepguler, 2004; Steultjens, Dekker, Baar, Oostendorp, & Bijlsma, 2001; Slemenda et al., 1997; Wylde, Palmer, Learmonth, & Dieppe, 2012). For example, pain reflexively inhibits the voluntary muscle activation around the knee, which could compromise efficient and timely motor responses in the balance (Arvidsson, Eriksson, Knutsson, & Arner, 1986). Also, individuals with knee OA may deviate in their gait by walking slower or changing their kinematics to reduce the pain, resulting in shorter step length and a shorter single limb support phase and a longer double limb support phase (Brandes, Schomaker, Möllenhoff, & Rosenbaum, 2008; Debi et al., 2011; Kaufman, Hughes, Morrey, Morrey, & An, 2001). Another complicating factor for individuals with knee OA has reduced levels of muscular leg strength, especially quadriceps strength, with deficits between 20% and 70% (Hassan, Mockett, & Doherty, 2001; Hurley, Scott, Rees, & Newham, 1997; Slemenda et al., 1997). Functionally, the quadriceps weakness limits performance and independence in movements that require body support and position changes which may also precipitate the risk of falls (Carter et al., 2002). Further, individuals with knee OA have somatosensory dysfunction. It results in limited balance compared with age-matched healthy knees (Barrett, Cobb & Bentley, 1991; Hurley, Scott, Rees, & Newham, 1997; Knoop et al., 2011; Koralewicz & Engh, 2000; Pai, Rymer, Chang, & Sharma, 1997).

The somatosensory system is primarily used for controlling the balance, safely accomplishing the majority of activities in daily life (Bronstein & Adolfo, 2004; Horak, Nashner, & Diener, 1990). The abnormal somatosensory function can result in balance problems, as previous research has shown that loss of somatosensory sensation has been linked to balance instability (Tanaka et al., 1996). The impaired somatosensory function is believed to be associated with falls (Lord, et al., 2007; Shaffer, & Harrison, 2007). The combination of the factors such as pain, muscular weakness, and somatosensory dysfunction in individuals with knee OA reduce the capability of general balance function, and ability in initiating and correcting movements, all of which can contribute to fall risks.

Indeed, individuals with knee OA have also been reported to have reduced balance, evidenced by increased postural sway (Hinman, Bennell, Metcalf, & Crossley, 2002; Tarigan et al., 2009) and reduced dynamic balance function (Khalaj, Abu, Mokhtar, Mehdikhani, & Wan, 2014) as well as lower scores on clinical tests such as step test, single leg stance, functional reach test, and tandem stance test (Hatfield, Hammond, & Hunt, 2015; Khalaj, Abu, Mokhtar, Mehdikhani, & Wan, 2014). Also, higher incidence of falls can be important evidence that knee OA people have reduced the balance. Among fallers, the prevalence of falls and fall injuries is significantly higher among adults with arthritis compared to those without arthritis in the United States (Barbour et al., 2014). Those with arthritis are approximately 2.4 times more likely to have multiple falls and 2.5 times higher to experience fall injuries (Barbour et al., 2014). Considering knee OA is the most common type of arthritis, this high rate of falling in individuals with arthritis suggests that knee OA increases the risk of falls.

One approach that can be used to counteract these specific symptoms is the ability to enhance cutaneous information on the skin of the plantar surface, and it has been reported to be successful (Collins et al., 2003; Priplata et al., 2002; Priplata, Niemi, Harry, Lipsitz, & Collins, 2003; Priplata et al., 2006). More specifically, vibratory stimulation of the skin of the plantar surface in older adults and peripheral neuropathy during quiet stance improve static balance function (Kavounoudias, Roll, & Roll, 2001; Priplata et al., 2002; Priplata et al., 2006). Also, mechanical stimulation by changing pressure to the skin of the plantar surface can modify neuromuscular activity, alter walking, and attenuate muscle atrophy (Layne et al., 1998; Layne, Forth, Baxter, & Houser, 2002). De-Doncker, Picquet, and Falempin (2000) demonstrated that such mechanical stimulation of the cutaneous mechanoreceptors in the sole of rat feet prevents the decrease in muscle weight and the cross-sectional area of the soleus muscle as well as prevents the reduction in strength.

In contrast to vibratory and pressure devices that can be expensive and difficult to use in daily life, other simple and inexpensive interventions are available that could potentially enhance somatosensory feedback and counteract the lack of balance for those who have difficulty maintaining balance such as elders, individuals with the disease, and individuals with the previous injury. Orth et al. (2013) showed in a systematic review that the stimulation of sensory receptors in the skin through plantar surface deformation by adding texture, such as the addition of protuberances on the surface of an insole or a standing area, can improve balance function.

Evidence of the effectiveness of added plantar-surface texture has been successful for various younger populations as well as elderly fallers, Parkinson's disease, multiple sclerosis, and individuals with chronic ankle instability (Chen, Nigg, Hulliger, & Koning, 1995; Corbin, Hart, McKeon, Ingersoll, & Hertel, 2007; Dixon et al., 2014; Hartmann, Murer, Bie, & Bruin, 2010; Hatton, Dixon, Martin, & Rome, 2009; Hatton, Dixon, Rome, Newton, & Martin, 2012; Jenkins et al., 2009; Kalron, Pasitselsky, Greenberg-Abrahami, & Achiron, 2014; Kelleher, et al., 2010; Maki, Perry, Norrie, & McIlroy, 1999; McKeon, Stein, Ingersoll, & Hertel, 2012; Nurse, Hulliger, Wakeling, Nigg, & Stefanyshyn, 2005; Palluel, Nougier, and Olivier, 2008; Palluel & Nougier, 2009; Perry, Radtke, McIlroy, Fernie, & Maki, 2008; Qui et al., 2013; Qiu et al., 2012; Ritchie, Paterson, Bryant, Bartold, & Clark, 2011; Waddington & Adams, 2000; Waddington & Adams, 2003).

Qiu et al. (2012) and Maki and colleagues (1999) concluded that textured material could improve balance in older people in unstable surface conditions. These improvements were strongest under conditions where reliance on somatosensory information was emphasized by removal of visual information (eyes closed condition), indicating the somatosensory information received from the plantar surface is critical for maintaining balance.

In this regard, it is apparent that textured material enhanced somatosensation in the skin of the plantar surface. It might indicate that textured materials could help older adults maintain their balance by stimulating receptors that are otherwise not being stimulated (Palluel, Nougier, & Olivier, 2008; Palluel & Nougier, 2009). Also, Perry and colleagues (2008) showed the effectiveness of long-term usage of textured insoles in a cross-sectional study in which half of the participants were assigned to wear the shoes with a textured insole for 12 weeks, while the other participants wore smooth insoles. The textured insole group improved balance during gait without habituation effects after 12 weeks of wearing the textured insole. In contrast, nine participants who wore smooth insoles experienced one or more falls while five of the textured insole group fell, suggesting that balance performance can be facilitated through textured material.

However, to date, there are few studies that have evaluated the balance performance of individuals with knee OA using computerized dynamic posturography, and no studies have investigated textured insole effectiveness for individuals with knee OA (Takacs, Carpenter, Garland, & Hunt, 2013). As individuals with knee OA have compromised the somatosensory function of the affected joint and correspondingly increased the risk of falls (Roos, Herzog, Block & Bennell, 2011; Wylde, Palmer, Learmonth, & Dieppe, 2012), understanding the effects of textured insoles on balance of these individuals, therefore, is crucial.

General Predictions and Justifications of Predictions

It is predicted that a) knee OA individuals will have reduced balance compared to age-matched healthy individuals, and b) textured insoles will benefit not only healthy individuals of middle-age and early older adults, but would enhance to a greater degree the balance of corresponding individuals with knee OA.

For the first prediction, it is already known that individuals with knee OA have balance deficits (Hatfield, Hammond, & Hunt, 2015; Khalaj, Abu, Mokhtar, Mehdikhani, & Wan, 2014; Tarigan et al., 2009; Hinman, Bennell, Metcalf, & Crossley, 2002). Several reasons may account for the reduced balance. Neuromuscular deficits of people with knee OA may partly account for reduced balance (Takacs, Carpenter, Garland, & Hunt, 2013). Although decreased strength is a primary source of poorer balance (Fukagawa, Wolfson, Judge, Whipple, & King, 1995), pain, knee flexion contracture, and somatosensory abnormality also can be the reason of the poorer balance on individuals with knee OA. Joint pain which is the main characteristic of knee OA changes the responses and affects the muscle activity during automatic control, which could have an impact on balance (Arvidsson, Eriksson, Knutsson, & Arner, 1986; Takacs, Carpenter, Garland, & Hunt, 2013). And knee flexion contracture could cause a shift of the center of pressure, and thus it can be responsible for a possible cause of balance deficits (Potter, Kirby, & MacLeod, 1990). Furthermore, the somatosensory abnormality can negatively affect to maintain balance (Qiu et al., 2012).

For the second prediction, the possible mechanisms by which textured insoles improve the balance of knee OA may be due to the enhanced somatosensory input from the skin of plantar surface, triggering an increase in feedback from stimulated groups of receptors in the skin of the plantar surface. Standing on textured surfaces could alter the transmission of afferent signals from the skin of the plantar surface (Watanabe & Okubo, 1981). Textured insoles served to stimulate cutaneous receptors within the tissues of the plantar surface of the feet. These receptors can trigger the change in the rate of discharge that increases muscle activations of the lower limbs, and improve spatial awareness of body position, and improve recognition of the spatial changes in pressure distribution (Palluel, Nougier, & Olivier, 2008; Palluel & Nougier, 2009; Perry, Radtke, McIlroy, Fernie, & Maki, 2008). Thus, adding textured insoles into the shoes can increase sensory afferent feedback via enhanced stimulation of cutaneous receptors in the skin of plantar surface (Corbin, Hart, McKeon, Ingersoll, & Hertel, 2007; Palluel, Nougier, and Olivier, 2008).

Individuals with knee OA have been known to have significantly somatosensory dysfunction (Roos, Herzog, Block & Bennell, 2011), which is the factor of reduced balance in individuals with knee OA. Using textured insoles, the balance of individuals with knee OA may compensate for this shortage, and healthy matched controls also may have increased the balance with textured insoles. However, it may be less efficient for the healthy controls who are physiologically normal.

Purpose of the Study

Based on previous research, knee OA may negatively impact balance. However, it is unclear whether the enhanced somatosensory input provided by a textured insole would benefit an individual with knee OA as is known to occur in healthy individuals. Therefore, the purpose of this study was to determine if the enhanced somatosensory input provided by a textured insole would benefit not only healthy individuals but would enhance to a greater degree the balance of corresponding individuals with knee OA.

Specific Aims and Hypotheses

Two main tests were used to determine 1) the balance and how participants use their senses to maintain the balance from the sensory organization test (SOT) 2) participant's automatic reactions in response to support surface translations (moving backward or forward) from the motor control test (MCT). During the SOT, participants were asked to stand as still as possible several times, sometimes with their eyes open, sometimes with their eyes closed. Additionally, the walls and/or the surface they stand on (platform) may or may not tilt. The MCT consisted of six conditions: graded backward (3) and forward (3) translations. Small, medium and large translations produced a 1.25cm translation for 250ms, 3.14cm translation for 300ms, and 5.7cm translation for 400ms, respectively.

Specific Aim: to determine if the presence of textured insoles produces greater improvements in balance outcomes displayed by individuals with knee OA as measured using the NeuroCom EquiTest® system compared to the improvement demonstrated by healthy, matched individuals. Hypotheses: Individuals with knee OA will demonstrate the following:

- When wearing a textured insole compared to a smooth insole:
    - Higher equilibrium scores (ES) that represent the amount of body sway on the sensory organization test (SOT);
    - Improved sensory analysis ratios that represent the participant’s ability to use input from the sensory systems and to manage altered proprioceptive input for maintaining the balance;
    - Faster latency (LC), defined as the time in milliseconds between the onset of translation during the MCT and the onset of the participants’ response to the support surface translation movement.

- Compared to matched controls:
  - Greater improvement equilibrium scores (ES) on sensory organization test (SOT)
  - Greater improvement sensory analysis ratios
  - Faster latency on the motor control test (MCT)

Significance of the study

Falls are the leading cause of accidental or unintentional injury deaths in the U.S. (CDC, 2013). One out of three old adults aged 65 and older falls each year. (Tromp et al., 2001). Therefore, medical costs caused by falls are rising in the U.S. (Stevens, Corso, Finkelstein, & Miller, 2006). Fall prevention obviously is becoming more critical. Recently, Centers for Disease Control and Prevention (CDC) showed that adults with arthritis have a higher rate of falls and fall injuries compared with adults without arthritis (Barbour et al., 2014). The incidence rate of arthritis rises quickly with age, indicating, the prevalence and burden of this disorder are increasing rapidly (Buckwalter, Saltzman, & Brown, 2004).

Textured insoles have been shown to be efficacious in improving balance. Thus, the use of textured insoles in individuals with knee OA who have a higher risk of falls may be effective, and an inexpensive method to reduce the risk of falls in this population. However, to date, whether insoles may be effective for individuals with knee OA is not known. Therefore, if textured insoles are shown to improve balance significantly, then the findings would be the first evidence (as known to us) that textured insole could be an economical and efficient method to reduce the risk of falls in individuals with knee OA.

Assumptions

The textured insoles that were used in this study were considered adequate to produce sensory stimulation of cutaneous mechanoreceptors on the plantar surface. Therefore, it is assumed that improved performance due to the textured insoles on SOT and MCT tests correlate to improved balance and, by extension, potentially a reduced risk of falling. Also assumed is that the variables chosen are valid measures of balance, defined as the ability to maintain the equilibrium.

CHAPTER 2

LITERATURE REVIEW

Falls

The Kellogg Group (1987) defines falls as: a fall is an event which results in a person coming to rest inadvertently on the ground or other lower level and other than as a consequence of the following: Sustaining a violent blow, Loss of consciousness, Sudden onset of paralysis, as in a stroke, or an epileptic seizure. Unintentional injury following cardiovascular disease, cancer, stroke, and lung disease is the fifth leading cause of death in older adults and falls account for two-thirds of deaths (Rubenstein, 2006). Falls have become a significant public health concern with a high risk of severe injury and a socioeconomic impact (Takacs, Carpenter, Garland, & Hunt, 2013). In developed countries, life expectancy continues to rise, with the average life expectancy in the United States now 76.3 years for men and 81.3 years for women. Indeed, one-third of adults aged 65 years and older experience a fall at least once every year resulting in direct medical costs about $30 billion (Stevens, Corso, Finkelstein, & Miller, 2006). Falls cause not only serious injuries among older adults such as fractures, joint dislocations, and head trauma (Tromp et al., 2001) but also adverse consequences psychologically. The repeated experience of falling can develop a fear of falling that leads to a self-imposed reduction in activity level and independence and often results in social isolation and depressive symptoms despite the fact that the injuries experienced may not be functionally limiting (Gregg, Pereira et al., 2000; Myers, et al., 1996). Fear of falling, which leads to avoidance of activities, causes deconditioning and poor balance performance (Hadjistavropoulos et al., 2012). It finally results in the higher risk of falls. Consequently, developed countries where the aging population has already begun, concern in falls are inevitable because as the population ages, the number of falls continues to grow.

Falls locations and circumstances

In a 10-year follow-up study, Saari, Heikkinen, Sakari-Rantala, & Rantanen (2007) showed that the majority of the accidents and falls occurred indoors and in the home environment, reflecting the amount of time older people spend at home. This finding corresponds with other results (Bath & Morgan, 1999; Berg, Alessio, Mills, & Tong, 1997). Bath & Morgan (1999) concluded that the number of falls occurring outside decrease as people aged 75 and over, while more falls were reported to occur indoor. Previous studies (Berg, Alessio, Mills, & Tong, 1997; Pi, Hu, Zhang, Peng, & Nie, 2015) found that falls were more likely to occur at home than away from home, and trips and slips and loss of balance were the most prevalent causes of falls. These findings indicate that the preventive interventions for falls have to pay more attention to fall risk factors present in the home environment (Saari, Heikkinen, Sakari-Rantala, & Rantanen, 2007).

Risk factors for falls

In a systematic review study, Deandrea et al. (2010) found that history of falls, gait problems, use of walking aids, vertigo, Parkinson disease, and antiepileptic drug use was associated with risk factors for falls. Although this study may identify individuals with a higher risk of falls for the future, it did not include some other important fall risk factors such as abnormal balance function, environmental hazards. In other studies, Stalenhoef and colleagues (1997) concluded that the main risk factors for falls among the elderly were intrinsic risk factors, such as cognitive impairment, balance and gait disorders, use of sedatives and hypnotics, a history of stroke, advanced age, knee arthritis and a high level of dependence. Lord (2007) showed that fall risk factors include reduced muscle strength and muscle tone, impaired motor coordination, reaction time and sensory system, and the walking environment. In addition, physiologically main factors of fall in older adults include poor vision, muscle weakness, impaired somatosensory and balance impairment (Lord, Menz, & Tiedemann, 2003), and these factors were found to be prevalent in older adults with self-reported lower limb arthritis (Sturnieks, et al., 2004).

Balance

Balance is a critical element of skillful movement. The balance is often used in association with terms such as stability and postural control (Pollock, Durward, Rowe & Paul 2000). However, true equilibrium in human activities is practically nonexistent because the body is always experiencing some movement change (Kreighbaum & Barthels, 1990). Balance is the capability to maintain stability in a gravitational field by keeping or returning the center of body's center of gravity over its base of support (Horak & Nashner, 1986), and the ability to actively regulate the body position by responding to the perturbations and is necessary to recover from unexpected perturbations experienced in the environment (Takacs, Carpenter, Garland, & Hunt, 2013; Visser, Carpenter, Kooij, & Bloem, 2008). The base of support is the area in which your body interacts with the support surface, while the COG is in its base of support, the body can maintain balance. For example, the base of support is the area between the feet during standing. When the body sways over the base of support, a fall occurs unless the base of support is moved to maintain the location of the COG within the base of support. In a laboratory setting, external perturbations are usually made by translating or tilting the surface where the individual stands quietly, by pulling on a cable attached to the participant (Bloem, Visser, & Allum 2003). Maki & Mcllroy (1996) stated that there are two major responses to the perturbations. First, the center of mass is maintained in the base of support by generating muscle torque (called feet-in-place responses): during quiet standing, during voluntary movement, or in response to applied perturbation. Second, the base of support can be moved to maintain the center of mass within its bounds by the compensatory leg and arm movement such as taking a step or grasping an aid (called change-in-support responses). The abnormal function of balance and the increased fall risk have risen the importance of balance control strategies to avoid falls (Takacs, Carpenter, Garland, & Hunt, 2013). Previous research has shown a significant correlation between maintaining balance and increased fall risk (Maki, Holliday, & Topper, 1994; Tinetti, Speechley, & Ginter, 1988). Individuals with more sway are at higher risk of falling (Wegener, Kisner, & Nichols, 1997). Individuals who have suffered multiple falls perform more unstable on balance tests, exhibiting 20-30% greater balance instability compared to non-fallers when standing on various surfaces in different stances (Melzer, Benjuya, & Kaplanski, 2004).

The central nervous system and balance

Several parts of the central nervous system, composed of the spinal cord and the brain, are involved in the balance control. Input information to cerebral neurons comes primarily from the thalamic nuclei, which send information from the spinal cords, basal ganglia, cerebellum, the frontal lobe, and parietal lobe of the cerebrum. The spinal reflex causes the first response in a standing posture. Excitation in the central nervous system results from the excitation and inhibition of the synapses of sensory neurons and mediating nerves (Kejonen, 2002). The cerebrum plans a voluntary movement requiring postural balance. An output command signal is transmitted to muscles through the pyramidal tract and the extrapyramidal tract. Cells in the pyramidal tract send information to the motor and mediating nerves in the spinal cords, and the information controls partial reflexes to perform the voluntary movement and to maintain balance. The basal ganglia group forming the extrapyramidal tract plans reflexive and voluntary movements during posture control. The cerebellum adjusts the coordination of reflexive and voluntary movements (Kejonen, 2002).

Integration of information for maintaining balance

In order to maintain an appropriate balance, the inflow of sensory information should be integrated into the central nervous system to produce an optimal motion (Kejonen, 2002). The balance control requires organizing sensory information from the visual, somatic and vestibular sensory systems in connection with body position and movement in the environment. Once inaccurate sensory information is received from senses, individuals can compare it with information provided by other sensory systems, and then correct it by adjusting the weight of the sensory information to initiate an appropriate posture response (Jeong & Kwon, 1999). A sensory shock in the spinal cords produces a stretch reflex. The integration of nerves in the upper center makes a more complex motor response. To maintain the balance, the effector must select an optimal response. The response is revised based on sensory information, and muscle contraction is induced to maintain the posture. The appropriate response to a task or a change in the environment requires that all the information be integrated, and a response should be planned based on past experiences.

The motor system and balance

When the balance is disturbed during the motor performance, the motor system should respond with fast compensatory movements based on the environment, the task, and the current state of the body. To maintain the balance in a dynamic condition, different parts of the body should perform fine motions (Marieb, 2001). In order to maintain the balance in a static condition, the center of mass must be located in the bearing surface of the foot, and balance is maintained by changing the center of mass forward/backward and from side to side. On the contrary, in a dynamic condition, the balance is accomplished by continuously changing the center of mass of the body on the moving bearing surface (Shumway-Cook & Woollacott, 2001). The disruption of balance can be avoided by making optimal compensatory movements in advance. Recovering the balance after being disturbed can be accomplished by three types of motor systems. The first motor response is stretch reflex in the vertebrae, which restores the balance through an immediate response just after being disturbed. The second is an automatic response, which detects movements that threaten the balance of the body and then contracts selected muscles, thereby attaining the balance. The third, a voluntary response, maintains the balance by starting a compensatory muscle response prior to movement by the major muscle groups in preparation for an expected postural change resulting from a planned motion.

A. Stretch reflex

Through sensory input, muscular receptors can detect movements that threaten the balance. Reflexive postural response plays an important role in maintaining stability by contracting specific muscles. Stretch reflex provides feedback by contracting muscles while assuming a posture (Rothwell, 1987). In other ways, when one stands and sways forward and backward if the ankle joint muscle is stretched, the forward/backward sway can be controlled by activating stretch reflex. (Shumway-Cook & Woollacott, 2001). However, stretch reflex does not directly contribute to the recovery of balance.

B. Automatic response

The first automatic response can be observed in EMG (electromyograph) patterns. An example is a muscle response during mid-latency. This response, which is coordinated and transmitted through vestibular-spinal reflex, affects all muscles in the legs, trunk, and neck. In addition to such a mid-latency response, a long-latency response is also detected in antagonists. This automatic response is a type of learned reflex for a quick response to disturbance. As the automatic response is situation-dependent, the reflex pattern may vary according to tasks and experiences (Jacobson, Newman, & Kartush, 1993).

C. Voluntary response

Unlike reflexive or automatic responses, the voluntary response is made under one's consciousness and has diverse forms. The voluntary response is achieved by changing the position of the center of gravity (Kejonen, 2002). For example, by standing and raising both arms forward, the center of the gravity shifts backward. Before the arms are raised voluntarily, muscle activities are observed in the muscle. Such maintaining the balance occurs in coordination with voluntary movements. In a voluntary motion, maintaining the balance and limb movements are performed under the same motor plan. Representative voluntary postural control is preliminary postural control.

Sensory systems for the balance

Even simple motion like taking a step requires the contribution of various elements to motor performance and balance. These elements should be involved in controlling the head and the eyes for eye fixing, controlling the relative position of body parts, maintaining body position against gravity, initiating a new movement, etc. These controls require visual information on eye position, vestibular information for head direction in gravity space, and somatosensory information for bearing surface and the position of body parts. This sensory information should also be integrated appropriately and restructured in the central nervous system to perform optimal muscle contraction in muscles selected based on the task to be carried out. Appropriate movements should be made to compensate for forces disturbing the balance, and senses, muscles, and the central nervous system need to be coordinated to keep the center of mass within the bearing surface. In other words, the musculoskeletal system should interact with the nervous system complexly.

Sensory systems for maintaining the balance include the visual system, the vestibular sensory system, and the somatosensory system. These systems provide major information on a planned motion, the characteristics of the environment where the motion is performed, and the body position in that environment. The human body has sensory receptors that continuously detect the external environment while providing information on the position of the body. Therefore, the sensory systems, with their unique characteristics of structure and function, play the critical role of receiving and transmitting sensory information.

Visual system

The role of the visual system is to provide information about the environment, dangerous situations, distances, and the condition of the ground where movements occur. Furthermore, this system supplies information on the body position and the intensity and difficulty of the movements to enable individuals to change posture in consideration of the relation between them and their environment. In this way, the visual information provides not only information on the environment but also the orientation of the body in the environment (Galley & Foster, 1982). Visual information, consisting of images obtained from the retina, is transmitted to different regions in the brain: The visual sense is divided into a focal vision for object distinction and peripheral vision for motor control. The peripheral vision is involved in the movement of objects, thereby playing a major role in postural control. The visual sense affects balance by detecting movements according to the change in the relative image in the retina (Lee, Buchanan, & Rogers, 1987). Of the several roles of visual information, one of the most important is evaluating perturbing situations that affect balance. When a situation that may perturb balance is detected through visual information during a gait, the muscle force or the range of motion is adjusted rapidly to continue the gait. Although it has been known that vision is important for maintaining balance, it should be noted that one can stand in the completely dark and remain upright. However, the previous study has shown that spontaneous lateral body sways are largely reduced when the eyes fixate a small (LED) in an otherwise darkened environment (Guerraz & Bronstein, 2008). It means that postural control can increase with the improvement of the visual environment.

Vestibular system

The vestibular system contributes the central nervous system with information on the movement of the body and the position of body parts about gravity and inertial force and provides a gravity-inertia frame related to postural control (Shumway-Cook & Woollacott, 2001). It can interact with the proprioceptive system joined with corollary discharge of a motor plan allowing the brain to distinguish generated from passive head movements (Angelaki & Cullen, 2008). Also, the vestibular system interacts with both visual and proprioceptive systems throughout the central vestibular pathways for the balance control, and when the body or object is moving, it allows eyes to watch the objects apparently.

The vestibular system is part of the membranous labyrinth in the inner ear. The other part of the labyrinth is the cochlea, which responses to sound vibrations. The membranous labyrinth includes a continuous series of tubes and chambers which contain the receptors for the sense of equilibrium and hearing. The membranous labyrinth is surrounded by a called the perilymph and filled with a fluid called the endolymph (Shumway-Cook & Woollacott, 2001). The vestibular portion of the labyrinth consists of five receptors such as three semicircular canals, otoliths (the utricle, and the saccule). The semicircular canals contain endolymph and motion sensors. The canals sense turning acceleration in the forward-backward, side-to-side, and upward-downward directions. Also, the semicircular canals are sensitive to the change in moving speed, fast movements, and is triggered by the onset and stop of movements. In addition, they detect the angular acceleration of the head. The otoliths provide information about body position with reference to the force of gravity, linear acceleration, and linear head motion. Although the otoliths respond to the motion in all three dimensions like the semicircular canals, they have two sensory organs which are saccule and utricles for three axes of linear motion. The saccule senses linear acceleration in the sagittal plane, such as a forward pitch of the head. The utricle senses acceleration in its predominantly horizontal plane such as a roll of the head (Herdman, Clendaniel, Waltner, & O'Brien, 2014). The vestibular system plays a major role in maintaining equilibrium. However, it cannot always provide accurate information about the position of the body in space. For example, the central nervous system with only vestibular system information cannot differentiate between simple movements of the head on the unmoving trunk and the head and trunk movement together. Also, the semicircular canal detects head fast motions, but it is not okay at sensing the slow turning of the head. This limitation can be compensated by information from the visual system (Herdman, Clendaniel, Waltner, & O'Brien, 2014).

Somatosensory system

The somatosensory system senses: 1) the temperature, pain that receives information from perceived changes in temperature and pain peptides, 2) touch which includes light touch, pressure, vibration and texture perception, 3) proprioception which receives information from the receptors of tendons, the joints, and the muscle spindles. The somatosensory receptors for the balance control include muscle receptors, joint receptors, and cutaneous receptors (Shumway-Cook & Woollacott, 2001). There are two main types of muscle receptors, which are muscle spindles and Golgi tendon organs (GTOs) provide supplementary information of muscle conditions. Most muscle spindles are in the belly of the skeletal muscle, and when the muscle stretches, it stretches together like a spindle connected in parallel with the muscle. They consist of specialized muscle fibers, called intrafusal fiber innervated by gamma (ɣ) distal motor neurons and the group Ia and group II afferents. The muscle spindle sends signals into the nervous system via afferent fibers such as the group Ia and group II afferents, and it is controlled by the central nervous system via efferent fibers (Shumway-Cook & Woollacott, 2001). The muscle spindle is linked to alpha (α) motor neurons innervating the muscle, and when it is stretched, it provides excitation to the muscle. Golgi tendon organs (GTOs) are small spindle-shaped receptors in the junction at muscle-tendon. Afferent information from the GTO goes to the nervous system via the Ib afferent fibers. Also, there are no efferent connections. Thus, GTOs are not controlled by the central nervous system.

Joint receptors provide mechanical information necessary for movement control. The various types of receptors in joints include Ruffini-type endings, spray endings, Paciniform endings, ligament receptors, and free nerve endings, all scattered in different parts of joint capsules. These receptors monitor stretch in the joint capsules of synovial joints and provide information on joint position and movement. Information from joint receptors was found to be sensitive only at extreme joint angles, suggesting it delivers a risk signal for dangerous joint motions (Burgess & Clark, 1969). Other research has also reported that many different joint receptors respond to a limited range of joint movements. This phenomenon is called range fractionation, and many receptors are activated in overlapping ranges. Afferent information from joint receptors is transmitted up to the cerebral cortex and is involved in the perception of position in space. The central nervous system controls joint position by monitoring which receptors have been activated at the same time, thereby enabling the determination of accurate joint position (Shumway-Cook & Woollacott, 2001).

Cutaneous receptors detect information from the external environment and compose of several types of receptors such as mechanoreceptors, thermoreceptors, nociceptors. Mechanoreceptors, which respond to pressure or distortion due to touch, pressure or tensile strain are the major receptors of the somatosensory system (Bear, Connors, & Paradiso, 2016). There are four types of mechanoreceptors in the skin such as Pacinian corpuscles, Meissner's corpuscles, Merkel's discs, and Ruffini endings. The Thermoreceptors detect temperature changing, and nociceptors sense potential risks imposed on the skin. Information detected by cutaneous receptors is used in hierarchical processing by various methods. Skin information measured at a low level of the central nervous system causes reflexive movements (Shumway-Cook & Woollacott, 2001). For example, when a weak and broad stimulus is applied to the skin of the plantar surface, the leg is stretched, and such a reflex movement is called placing reflex. In comparison, if a sharp and narrow stimulus is applied to the skin of the plantar surface, the leg is bent, and such a reflex movement is called withdrawal reflex and plays the role of preventing injuries.

Falls and OA

Among fallers, the prevalence of falls and fall injuries is significantly higher among adults with arthritis compared to those without arthritis in the United States (Barbour et al., 2014). Those with arthritis are approximately 2.4 times more likely to have multiple falls and 2.5 times higher to experience fall injuries (Barbour et al., 2014). In a word, arthritis increases the risk of falling (Rubenstein & Josephson, 2006). Adults aged 45 and over with arthritis account for 52% of adults in the United States (Center for Disease Control and Prevention [CDC], 2013). Among the various forms of arthritis, osteoarthritis (OA) is the most prevalent and is a leading cause of disability and loss of function, affecting an estimated 26.9 million adults in the U.S in 2005 (CDC, 2001; Dore, et. al., 2015; Issa & Sharma, 2006). Although OA can damage any joint in the body, the knee joint is most commonly affected (Van et al., 2013). Also, knee OA is not only more prevalent than other types of OA but is also important because of its incidence in early age groups.

OA is characterized by a degradation of articular cartilage, sclerosis of the subchondral bone, and osteophyte formation with symptoms of joint pain and dysfunction, and in its advanced stages, joint contractures, muscle atrophy, and limb deformity (Buckwalter, Saltzman, & Brown, 2004). Individuals with knee OA also have been known to have pain, reduction of lower limb muscle strength, and significant decline of mechanoreceptors compared to age-matched healthy peers (Tarigan et al., 2009).

All of these characteristics limit the ability to perform functional activities of daily living such as rising from a chair, standing comfortably, walking, or climbing stairs, diminishing the capability of general balance and ability to initiate and correct movements, which is an indicator of fall risks (Barrett, Cobb & Bentley, 1991; Eyigor, Hepguler & Hepguler, 2004; Steultjens, Dekker, Baar, Oostendorp, & Bijlsma, 2001; Slemenda et al., 1997; Wylde, Palmer, Learmonth, & Dieppe, 2012). Furthermore, individuals with knee OA have demonstrated somatosensory abnormality (Roos, Herzog, Block & Bennell, 2011; Wylde, Palmer, Learmonth, & Dieppe, 2012). The abnormal somatosensory function results in balance problems, as previous research has shown that loss of somatosensory sensation has been linked to balance instability (Tanaka et al., 1996). Thus, somatosensory dysfunction of individuals with knee OA can also be associated with falls (Shaffer, Scott, Harrison, & Anne, 2007). Recently, a study of the relationship between falls and lower extremity OA concluded that those with symptomatic knee OA are at an increased risk for falls (Dore, et. al., 2015).

Somatosensory information from the plantar surface and effects of the artificially altered feedback

The skin of the plantar surface is unique that the plantar surface which is densely packed with mechanoreceptors is the only location on the body directly connecting humans to their environment. Various sources of sensory feedback come from mechanoreceptors found in the skin of the plantar surface. It has been shown that the plantar surface feedback is used to detect information about support surface characteristics in gait and the postural control by providing information about pressure changes and associated postural sway (Fitzpatrick, Rogers, & McCloskey, 1994; Zhang & Li, 2013). This information is important to initiate postural reflexes that help maintain balance (Kennedy & Inglis, 2002; Perry, 2006). Nurse & Nigg (2001) concluded that somatosensory feedback from the plantar surface was important in the maintenance of balance. Aniss, Gandevia, & Burke (1992) showed that when the muscles are active in standing or walking, cutaneous feedback from the foot sole may play a role in adjusting motoneuron output and thus contribute to the stability of stance and gait. Also, Wu & Chiang (1997) demonstrated differences in the muscular response latency when standing on soft foam surfaces. The authors concluded that sensory feedback from the feet was modified when participants stand on the different surfaces. It indicates that the central nervous system selectively controls the relative contributions of sensory information to maintain balance depending on the sensory environment and neuromuscular constraints acting on the body (Vuillerme & Pinsault, 2007).

Most likely, the different existing classes of mechanoreceptors are responsible for various tasks related to the balance control based on their functionality and response levels. Rapidly-adapting mechanoreceptors (Meissner, Pacinian corpuscles) are more involved in sensing of shear forces, potentially related to slips across the surface (Bent & Lowrey, 2012; Lowrey, Strzalkowski, & Bent, 2013), whereas slowly adapting mechanoreceptors (Merkel cells and Ruffini endings), associated with gait events, could be more critical for “sustained indentation” features (Lowrey, Strzalkowski, & Bent, 2013) and pressure changes around the foot sole surface and for detecting body sway (Stal, Fransson, Magnusson, & Karlberg, 2003). Also, Kimmeskamp and Hennig (2001) showed that the sensitivity of each foot area is correlated with the heel to toe motion during walking. Consequently, the somatosensory information received from the plantar surface is the essential for maintaining balance (Horak, Nashner, & Diener, 1990).

Horlings et al. (2008) also showed that the balance declined when the participants stand on a foam surface which alters somatosensory feedback caused by the reduced information from plantar cutaneous mechanoreceptors. Furthermore, reduced somatosensory feedback induced by anesthesia to the feet influenced the balance control. The iontophoretic delivery of anesthesia to the plantar surface increased mediolateral and anteroposterior sway, especially, during a less stable condition, such as a single- rather than double-leg stance or by reducing other sensory input (e.g., closed eyes) (Meyer, Oddsson, & De Luca, 2004). In a study using ischemic hypoxia to the feet and ankles, participants used of more hip movements and increased hip muscle activation compared to non-ischemia occurred (Horak, Nashner, & Diener, 1990), and increased body sway in the lateral plane caused by the galvanic stimulus was observed when the feet were anesthetized (Magnusson, Enbom, Johansson, & Wiklund, 1990). In addition, Roos, Herzog, Block & Bennell (2011) suggested that the somatosensory dysfunction underlying lower extremity OA is systematic rather than local, because previous studies have shown diminished vibratory perception threshold (VPT) which is co-localized with proprioceptive pathway in the dorsal columns (Waxman & Stephen, 2013) in the hands of the individuals with hip or knee OA, and impaired proprioception at the elbows in the individuals with knee OA. It means that abnormal somatosensory function may exist at the plantar surfaces in the individuals with knee OA.

Enhanced sensory intervention

Recently, Hatton et al., (2016) stated that providing enhanced sensory input to the feet has recently been thought a potential mechanism through which footwear interventions may improve balance, by way of modifying sensorimotor function. The ability to enhance somatosensory input on the feet has been reported to be successful (Collins et al., 2003; Priplata et al., 2002; Priplata, Niemi, Harry, Lipsitz, & Collins, 2003; Priplata et al., 2006). Several interventions have been conducted to improve balance by enhancing the somatosensory information received from the plantar surface of feet. Vibratory stimulation of the plantar surface in older adults and peripheral neuropathy during quiet stance improve postural control (Kavounoudias, Roll, & Roll, 2001; Priplata et al., 2002; Priplata et al., 2006). Also, mechanical stimulation by changing pressure to the skin of plantar surface could modify neuromuscular activity, alter gait, and attenuate muscle atrophy (Layne et al., 1998; Layne, Forth, Baxter, & Houser, 2002). De-Doncker, Picquet, and Falempin (2000) found that such mechanical stimulation of the cutaneous mechanoreceptors in the sole of rat feet prevents the decrease in muscle weight and the cross-sectional area of the soleus muscle as well as prevents the reduction in strength. Furthermore, increased cutaneous feedback received by athletic tape to ankle joints has been demonstrated improved balance (Vuillerme, & Pinsault, 2007). Therefore, it can be concluded that enhanced somatosensory input from the foot and ankle can help maintain the balance.

Textured insoles to enhance balance

Watanabe and Okubo (1981) showed the evidence that standing on textured surfaces can alter the transmission of afferent signals from the plantar surface of the foot. Simply deforming the skin surface with a textured material can improve balance (Orth et al., 2013). In contrast to vibratory and pressure devices which are expensive and difficult to use, the textured material can be inexpensive interventions that could potentially enhance somatosensory feedback and ultimately improve balance functionality for those who have difficulty maintaining balance.

Evidence of the effectiveness of added plantar-surface texture has been proven for various populations, such as young people, elderly, fallers, people with Parkinson’s disease, people with multiple sclerosis, and people with chronic ankle instability (Chen, Nigg, Hulliger, & Koning, 1995; Corbin, Hart, McKeon, Ingersoll, & Hertel, 2007; Dixon et al., 2014; Hartmann, Murer, Bie, & Bruin, 2010; Hatton, Dixon, Martin, & Rome, 2009; Dixon, Rome, Newton, & Martin, 2012; Jenkins et al., 2009; Kalron, Pasitselsky, Greenberg-Abrahami, & Achiron, 2014; Kelleher, et al., 2010; Maki, Perry, Norrie, & McIlroy, 1999; McKeon, Stein, Ingersoll, & Hertel, 2012; Nurse, Hulliger, Wakeling, Nigg, & Stefanyshyn, 2005; Palluel, Nougier, and Olivier, 2008; Palluel & Nougier, 2009; Perry, Radtke, McIlroy, Fernie, & Maki, 2008; Qui et al., 2013; Qiu et al., 2012; Ritchie, Paterson, Bryant, Bartold, & Clark, 2011; Waddington & Adams, 2000; Waddington & Adams, 2003). For example, Qiu et al. (2012) and Maki and colleagues (1999) demonstrated that textured insoles could reduce the postural sway of older people during walking in unstable surface conditions. Furthermore, these effects were strongest under conditions where reliance on somatosensory system information was emphasized by removal of visual information (eyes closed condition). Therefore, it can be assumed that textured material increased the body awareness (Palluel, Nougier, & Olivier, 2008; Palluel & Nougier, 2009). Also, Perry and colleagues (2008) showed the effectiveness of long-term usage of textured insoles in a study in which half of the participants were assigned to wear the shoes with a textured insole for 12 weeks, while the other participants wore smooth insoles. The textured insole group improved lateral stability during gait which did not habituate after 12 weeks of wearing the textured insole. In contrast, nine participants who wore the smooth insoles experienced one or more falls while five of the textured insole group fell, suggesting that balance performance can be facilitated through textured material.

CHAPTER 3

METHODS

This chapter examines the methods and procedures that were used in this study. The chapter outlines the participants, materials, instrumentation, data collection procedures, data reduction, and data analysis.

Participants

Seventeen individuals with knee OA (14 females and 3 males) who met the inclusion criteria were enrolled in the study. Of these, 2 females were unable to be tested due to mechanical errors of the force platform. Therefore, 15 individuals (12 females and 3 males) with knee OA were age-matched with 15 healthy controls. A given control participant was recruited to match a corresponding knee OA participant, based on the same gender and age (± 3 yr). The study was approved by the university's Institutional Review Board (IRB00001440) and written informed consent was obtained from all participants.

All participants from both groups were free from (1) concomitant medical illnesses which could deteriorate balance such as neurological or significant musculoskeletal disease, inner ear disease, permanent lower-limb injury, (2) unable to walk without an assistive device, (3) an abnormal optometric or ophthalmic examination in the 6 months. The diagnosis of knee OA was based on a diagnosis of mild to moderate knee OA in one or both knees. Exclusion criteria in this study includes the following: asymptomatic osteoarthritis of one or both knees, inflammatory arthritis, major lower extremity joint surgery (e.g., knee arthrotomy within the previous 6 months), any condition which severely limits local ambulation (e.g., amputation or stroke), use of gait aids for ambulation, and dementia or inability to understand and follow directions. Participants with knee

OA were matched with asymptomatic control participants based on gender and age. Control participants with evidence of rheumatoid or any other type of arthritis, a history of injury to the lower extremity, or prolonged knee pain that required medication and knee surgery were excluded. And control participants with recurring or prolonged knee pain occurring within the last month even if pain-free on the day of testing were excluded.

Materials

The textured insoles (flexible, polyvinyl chloride [PVC], 3 mm thickness, transparent) had small, round peaks with center-to-center distances of approximately 4 mm (Figure 3.1). Insoles were customized for both left and right feet based on the participant's foot width and length. This textured insole was considered adequate to deliver sensory stimulation, but not rough enough to cause skin discomfort.

Figure 3.1. The textured insoles used in this study

Instrumentation

Computerized Posturography assessment

Computerized dynamic posturography tests were administered using the NeuroCom EquiTest® (NeuroCom International, Clackamas, OR) to obtain the center of pressure data needed to calculate measures of balance. This device consists of two 9” x 18” forceplate connected by a pin joint which is a rod serving as the medial-lateral rotational axis, with the capability of measuring vertical forces applied by a person’s feet. The participant’s anterior-posterior sway is recorded by measuring the vertical force with two strain gauges mounted underneath on each of the two forceplates. A fifth strain gauge, mounted perpendicular to the other four beneath the center of the pin joint, measures the shear force.

The test area is enclosed on the front and sides by a moveable visual surround that prevents the participant from seeing anything else in the environment. The software (Version 8.5 NeuroCom, A Division of Natus, Clackmas, Oregon USA) controls the fore-aft tilt of the surround and forceplates. The electrical signals from the forceplates were collected at a sampling rate of 100 Hz (ADC = 12 bit). Signals were filtered using a 2nd order Butterworth filter (cutoff frequency = 0.85 Hz).

The NeuroCom System has been used in clinical and scientific research related to the balance control (e.g., see Cavanaugh et al., 2007; Wrisley et al., 2007). Also, The validity and internal consistency and test-retest reliability of the Sensory Organization Test (SOT) from Computerized dynamic posturography have been documented for older adults (Ford-Smith, Wyman, Eslwick, Fernandez, & Newton, 1995). Also, Jeffrey, Hebert & Mark (2016) concluded that the Sensory Organization Test (SOT) performed by individuals with multiple sclerosis (MS) had good to excellent reliability, and excellent reliability for composite and the SOT is a reliable and valid measurement of the disease-related progression of impaired balance related to sensory integration.

Table 3.1. Reliability of the Sensory Organization Test Scores in Older Adults from Ford-Smith, Wyman, Elswick, Fernandez, & Newton, 1995: ICC (intraclass correlation coefficients) and CI (confidence interval)

Condition	First Trial Only		Average of 3 Trials	
	ICC	90% CI	ICC	90% CI
1	.57	.32, .73	.51	.29, .68
2	.57	.37. .73	.42	.18, .62
3	.15	-.12, .39	.26	.00, .49
4	.34	.09, .55	.47	.24, .65
5	.70	.54, .81	.68	.51, .80
6	.43	.19, .62	.64	.45, .77

Data Collection Procedures

Overall, there were three main phases of participation: 1) Preparation 2) Practice Phase and 3) Testing Phase.

Procedures

Initial screening protocol: An investigator explained the study and obtained initial verbal consent to ask initial eligibility screening questions (Appendix A). Those individuals who were eligible were scheduled to be tested at the convenience of the participants.

Preparation Procedures: Upon arriving at the test facility, the potential participant was given written and verbal information about the testing procedures and asked to sign a consent form as per UGA Institutional Review Board protocol. Next, the potential participant completed the WOMAC (Western Ontario and McMaster University Arthritis), an in-house medical history and health status questionnaire (Appendix B). The answers were reviewed with the potential participant by the primary investigator to ensure that the participant met the inclusionary and exclusionary criteria. If the participants met the criteria, testing was continued.

Practice Phase: Prior to data collection, the participant underwent warmups before practice testing. Warm-ups included dynamic stretches, such as hip circles, arm circles, arm swings, and walking. The participant then practiced performing the two balance tests, described below.

Testing Phase: Then, the individual with knee OA with smooth insoles performed NeuroCom EquiTest SOT and MCT protocol. There was a ten-minute rest period to change insoles. The participant then wore the textured insoles and was tested again in NeuroCom Equi Test SOT and MCT protocol.

Test tasks

Two computerized dynamic posturography tests used to analyze the balance capabilities of the participants were the Sensory Organization Test (SOT) and Motor Control Test (MCT).

<u>Computerized Dynamic Posturography (SOT, and MCT)</u>

To prevent falls the participant wore a safety harness that was connected to two straps extending down from an overhead bar. The participant stands on the NeuroCom EquiTest® forceplate and then the safety harness was attached to the straps. Next, the participant's feet were positioned on the forceplate by the investigator as per the Neurocom instructions (Jacobson, Newman, & Kartush, 1993). The medial malleolus of each foot was centered directly over a thick line on the dual forceplate positioned perpendicular to the participant. The lateral heel part of the shoes was positioned according to the participant's height. The forceplate is marked with lines 'S', 'M' and 'T' where

S = Short 76-140 cm (30-55 inches)

M = Medium 141-165 cm (56-65 inches)

T = Tall 166-203 cm (66-80 inches)

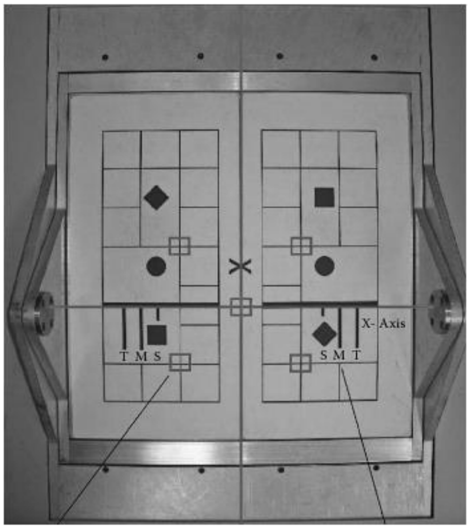


Figure 3.2. Dual forceplate

The Sensory Organization Test (SOT) measures the participant’s ability to make effective use of visual, vestibular and somatosensory information and to suppress inappropriate sensory information (Vouriot et al., 2004). SOT was performed by all participants with the smooth and the textured insoles. During the tests, somatosensory and visual environments were altered systematically, and the participant’s responses were measured. Visual and proprioceptive information is altered by ‘sway referencing’ the surrounding wall and the force plates. Sway referencing refers to the force plate and/or the surrounding wall moving proportionally to the anteroposterior sway of the participant thus altering their visual and proprioceptive feedback. The test required participants to be tested under six independent sensory conditions (Table 3.2).

The six sensory conditions (Figure 3.3) of the SOT are (1) eyes opened with fixed support (EO); (2) eyes closed with fixed support (EC); (3) eyes opened with sway-referenced surrounding (EO-SUR); (4) eyes opened with sway-referenced support (EO-FP); (5) eyes closed with sway-referenced support (ECF); and (6) eyes open with sway-referenced support surface and surroundings (EORF). During the balance assessments, the participants' feet were positioned according to the manufacturer's specification, and their arms remained at their sides while looking straight ahead into the visual surrounding room. Three trials for each sensory condition were presented in the manufacturer's suggested order, with increasing difficulty from condition 1 through condition 6.

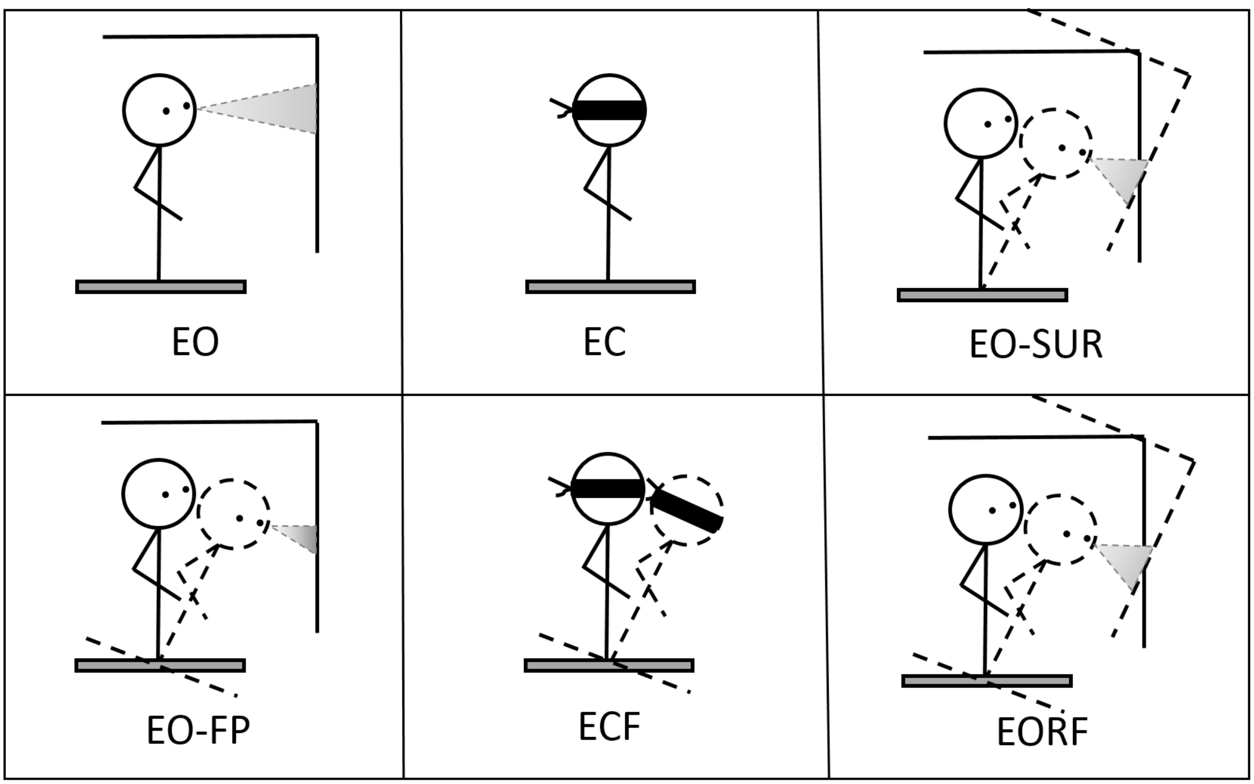


Figure 3.3. Sensory Organization Test.

Table 3.2. Description of the six sensory organization test tasks.

	Environment		Expected Sensory System Response	
	Vision	Surface	Removed and/or reduced	Using
1 (EO)	Eyes open	Fixed		Somatosensory
2 (EC)	Eyes closed	Fixed	Vision	Somatosensory
3 (EO-SUR)	Sway reference-visual surrounding	Fixed	Vision	Somatosensory
4 (EO-FP)	Eyes open	sway-referenced surface	Somatosensory	Vision
5 (ECF)	Eyes open	sway-referenced surface	Somatosensory & Vision	Vestibular
6 (EORF)	Sway-referenced visual surrounding	sway-referenced surface	Somatosensory & Vision	Vestibular

In the MCT, the participant's automatic reactions were measured in response to support surface translations. Each participant maintained their eyes open, and the surround remained stationary throughout the MCT. The MCT consisted of 6 conditions: graded backward (3) and forward (3) translations. The translations were scaled according to the participant's height, but durations were the same for everyone. Small, medium and large translations produced a 1.25cm translation for 250ms, 3.14cm translation for 300ms, and 5.7cm translation for 400ms, respectively. Small translations represented threshold stimulation, large translations produced a maximal response, and medium translations were midway between the small and large. Each translation occurred at a constant velocity and therefore transferred constant forward or backward angular momentum to the participant's body (Vanicek, Strike, McNaughton, & Polman, 2009).

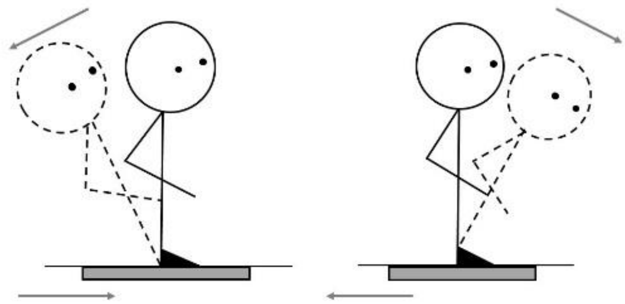


Figure 3.4. Forward/Backward Translations

Data Reduction

All outcome measures were calculated from measurements recorded by the forceplate during experimental trials. The primary outcome measures included the following:

Equilibrium Score (ES) and Sensory analysis ratios for the SOT (Sensory Organization Test);

Latency (LC) for the MCT (Motor Control Test).

Equilibrium Score (ES)

The equilibrium score (ES) indicates how well the participant’s sway remains in the expected angular limits of balance during SOT trials. The ES is generated from forceplate data of each trial (20 seconds @ 100Hz, 2000 data points) via NeuroCom software (NeuroCom, Clackamas, OR). An ES is computed for each trial using the following equation:

$$ES = \frac{12.5 - [\theta_{max} - \theta_{min}]}{12.5} * 100 \qquad \text{Equation 1}$$

The angular difference between calculated maximum ant-posterior COG displacements and a theoretical maximum are compared. For healthy individuals, 12.5 degrees are usually considered the theoretical limits of balance. The result is provided as an inverse percentage of 0-100. While no movement results in an ES of 100, a fall results in a score of 0. This outcome measure is clinically accepted and has been used extensively in motor control research (Cavanaugh, Mercer, & Stergiou, 2007; Wrisley et al., 2007).

Sensory Analysis

The NeuroCom EquiTest software computes sub-equilibrium scores which include the somatosensory (SOM), visual (VIS), vestibular (VEST), and the management (PMAN) ratios between the average equilibrium scores on specific pairs of sensory test conditions to describe the finding in the different perspectives (Table 3.4). They identified the significance of each sensory system influencing the balance allowing the determination of the use of somatosensation (SOM), visual (VIS), and vestibular (VEST) information, as well as the ability to manage altered proprioceptive inputs (PMAN).

Table 3.3. Descriptions of Sensory analysis (Gauchard, Vançon, Meyer, Mainard, & Perrin, 2010)

Ratios	Formula	Significance
SOM	EC/EO	Question: Does sway increase when visual information is removed? Low scores: Poor use of somatosensory references
VIS	EO-FP/EO	Question: Does sway increase when somatosensory information is removed? Low scores: Poor use of visual references
VEST	ECF/EO	Question: Does sway increase when visual information is removed, and the somatosensory information is incorrect? Low scores: Poor use of vestibular information or no vestibular information.
PMAN	(EO-FP+ECF +EORF)/ (EO+EC+EO-SUR)	Question: Does inaccurate somatosensory information result in increased sway compared to accurate somatosensory information? Low scores: Poor compensation for disruptions in selected sensory inputs.

Latency (LAT)

The latency (LAT) is defined as the time in milliseconds between the onset of translation during the MCT and the onset of the participants' response to the support surface translation movement. Latencies were the averaged performance of the right and left feet. Each participant maintained their eyes open, and the surround remained stationary throughout the MCT. The MCT required 6 conditions: graded backward (3) and forward (3) translations. Each translation moved at a constant velocity and transferred constant forward or backward angular momentum to the participant's body.

Data Analysis

This study was designed to determine if the presence of textured insoles produces greater improvements in balance outcomes displayed by individuals with knee OA compared to the improvement demonstrated by healthy, matched individuals and to explore the balance differences between individuals with knee OA and matched-healthy knee controls with smooth insole conditions. Statistical analyses were selected to detect group differences on tasks of the Sensory Organization Test (SOT) and Motor Control Test (MCT). All analyses were conducted using SPSS version 20.0 software with alpha set at 0.05.

Demographic variables assessed for this study included (a) gender, (b) age, (c) height, (d) mass and (e) body mass index (BMI). These data results were analyzed using multivariate analysis of variance (MANOVA) evaluate differences among variables. Box's test was then utilized to determine whether covariance matrices are equal.

In order to investigate if textured insoles produce greater improvements in knee OA groups, regression was performed to evaluate the interaction between groups. This analysis had two groups of subjects (knee OA and healthy knee groups) applied to the variables (difference scores between the smooth insole and the textured insole) of Equilibrium Scores, Sensory Analysis Ratios, and Latency). The dependent (Y) variable was set up the difference between smooth and textured insoles. The predictor variables (X) was the existence of knee OA (grouping variable), with covariates such as participants' age and the smooth insole scores. To find group interactions and effects of the textured insole, the following equation was used:

Y_Texrued insole - Y_Smooth insole = intercept + b1 grouping variable (knee OA = 1 and healthy knee group = 0) + b2* age + b3* Y_Smooth insole + e   Equation 2*

Where intercept is the change in the control group by assuming they have the same smooth insole scores and same ages, and *b1* is the group difference of differences, which is the interaction. If *b1* is significantly different, then there is an interaction, if it is not significant, the textured insole effects are parallel for these two groups. In addition, the effort was made to control the factor that accounts for variation in the outcome not due to balance. The covariates selected included age and smooth insole scores. The age as one of the covariates was chosen based on empirical evidence that has shown deterioration of balance performance associated with aging (Cohen, Heaton, Congdon, & Jenkins, 1996).

Furthermore, paired t-tests were conducted to determine whether the textured insole improved the balance performances in each group, and independent t-test was utilized to identify differences in the balance between the knee OA and healthy control group with smooth insole conditions. For the normality test, a Shapiro-Wilk analysis of the data was completed to determine if the assumption of normality had been met. Also, The Levene's test for equality of variances was utilized to assess homogeneity. In the instance of homogeneity violation of variance, the corrected t value was used. Wilcoxon signed-rank test for Paired t-test and Mann-Whitney U test for Independent t-test were used if the data violated normality test assumptions. The results of the evaluation of the significance of the differences were represented by the significance coefficient (p). The level of statistical significance was indicated by "*" – $p < 0.05$, and the tendency of difference between the group was indicated by: "Ŧ" – $p = 0.05 – 0.10$.

CHAPTER 4

RESULTS

Demographics

As can be seen in Table 4.1, no significant group differences for the four demographic variables (Wilks = 0.944, F (4, 25) = 0.369, p= 0.828, η_p^2 = .056). Box's test results (M = 9.490 associated with a p value of 0.628) indicated that the covariance matrices of the dependent variables were equal across groups based on Huberty & Petoskey's (2000) guideline.

Table 4.1. Participant Demographics

Participant Characteristics	Knee OA (*n*=15) Mean (S.D.)	Healthy Knee (*n*=15) Mean (S.D.)	*F*	*P* value	η_p^2
Age (yr)	52.67(±11.36)	51.40(±10.78)	0.098	0.756	0.003
Height (cm)	164.59(±10.30)	162.90(±6.57)	0.288	0.596	0.010
Mass (kg)	75.70(±13.96)	73.40(±13.74)	0.207	0.653	0.007
BMI (kg/m^2)	28.07(±5.38)	27.61(±4.68)	0.063	0.803	0.002

The balance was assessed by equilibrium scores, sensory analysis ratios, and latency. The regression was calculated to evaluate the group x insole interaction between groups to find out whether the knee OA group had greater improvement compared to matched controls. And paired t-tests and independent t-tests were utilized to find effects of textured insoles on each group and to identify differences between the knee OA and healthy control groups. For the normality test, a Shapiro-Wilk analysis of the data was completed to determine if the assumption of normality had been met. Wilcoxon signed-rank test for Paired t-test and Mann-Whitney U test for Independent t-test were used if the data violate normality test assumptions.

Equilibrium Score

Interactions between groups

Eyes Open (EO) Outcomes

Regression was calculated to evaluate the interaction between the groups on EO scores in the smooth insole and the textured insole. A significant regression equation was found ($F(3, 26) = 3.435$, $p = 0.032$), with an R^2 of 0.284. Table 4.2 showed that the textured insole scores – smooth insole scores are equal to 0.535 - 0.904 + 0.042 (age) - 0.441 (the smooth insole score). Also, the interaction between the knee groups was not significantly different, indicating that the textured insoles had similar effects to both groups.

Table 4.2. EO coefficients

Model	Unstandardized Coefficients		Standardized Coefficients	t	Sig.
	B	Std. Error	ß		
(Constant)	.535	.489		1.094	.284
Knee OA	-.904	.649	-.240	-1.393	.175
AGE	.042	.029	.241	1.437	.163
EO	-.441	.169	-.452	-2.606	.015

Eyes Closed (EC) Outcomes

Regression was calculated to evaluate the interaction between groups on EC scores in the smooth insole and the textured insole. A significant regression equation was found ($F(3, 26) = 17.520$, $p < 0.001$), with an R^2 of 0.669. Table 4.3 showed that the textured insole scores – smooth insole scores are equal to 1.198 - 0.341 - 0.021 (age) - 0.665 (the smooth insole score). Also, the interaction between the knee groups was not significantly different, indicating that the textured insoles had similar effects to both groups.

Table 4.3. EC coefficients

Model	Unstandardized Coefficients		Standardized Coefficients	t	Sig.
	B	Std. Error	ß		
(Constant)	1.198	.644		1.860	**.074**
Knee OA	-.341	.834	-.047	-.410	**.685**
AGE	-.021	.039	-.061	-.534	**.598**
EC	-.665	.093	-.816	-7.119	**.000**

Eyes Open, surrounding screen sway referenced (EO-SUR) Outcomes

Regression was calculated to evaluate the interaction between groups on EO-SUR scores in the smooth insole and the textured insole. A significant regression equation was found (F(3, 26) = 5.094, p = 0.007), with an R^2 of 0.370. Table 4.4 showed that the textured insole scores – smooth insole scores are equal to 2.456 - 0.892 + 0.118 (age) - 0.458 (the smooth insole score). Also, the interaction between the knee groups was not significantly different, indicating that the textured insoles had similar effects to both groups.

Table 4.4. EO-SUR coefficients

Model	Unstandardized Coefficients		Standardized Coefficients	t	Sig.
	B	Std. Error	ß		
(Constant)	2.456	1.063		2.310	.029
Knee OA	-.892	1.417	-.103	-.629	.535
AGE	.118	.063	.292	1.873	.072
EO-SUR	-.458	.138	-.543	-3.310	.003

Eyes open, force plate sway referenced (EO-FP) Outcomes

Regression was calculated to evaluate the interaction between groups on EO-FP scores in the smooth insole and the textured insole. A significant regression equation was found (F(3, 26) = 4.715, p = 0.009), with an R^2 of 0.352. Table 4.5 showed that the textured insole scores – smooth insole scores are equal to 4.099 - 2.687 - 0.208 (age) - 0.470 (the smooth insole score). Also, the interaction between the knee groups was not significantly different, indicating that the textured insoles had similar effects to both groups.

Table 4.5. EO-FP coefficients

Model	Unstandardized Coefficients		Standardized Coefficients	t	Sig.
	B	Std. Error	ß		
(Constant)	4.099	2.728		1.503	.145
Knee OA	-2.687	3.694	-.123	-.727	.473
AGE	-.208	.163	-.203	-1.272	.215
EO-FP	-.470	.129	-.622	-3.646	.001

Eyes closed, force plate sway referenced (ECF) Outcomes

Regression was calculated to evaluate the interaction between groups on ECF scores in the smooth insole and the textured insole. A significant regression equation was found (F(3, 26) = 26.096, $p < 0.001$), with an R^2 of 0.751. Table 4.6 showed that the textured insole scores – smooth insole scores are equal to 7.938 + 2.993 - 0.043 (age) - 0.515 (the smooth insole score). Also, the interaction between the knee groups was not significantly different, indicating that the textured insoles had similar effects to both groups.

Table 4.6. ECF coefficients

Model	Unstandardized Coefficients		Standardized Coefficients	t	Sig.
	B	Std. Error	ß		
(Constant)	7.938	2.168		3.662	.001
Knee OA	2.993	3.097	.109	.966	.343
AGE	-.043	.128	-.033	-.332	.742
ECF	-.515	.073	-.813	-7.043	.000

Eyes open, force plate and surrounding screen sway referenced (EORF) Outcomes

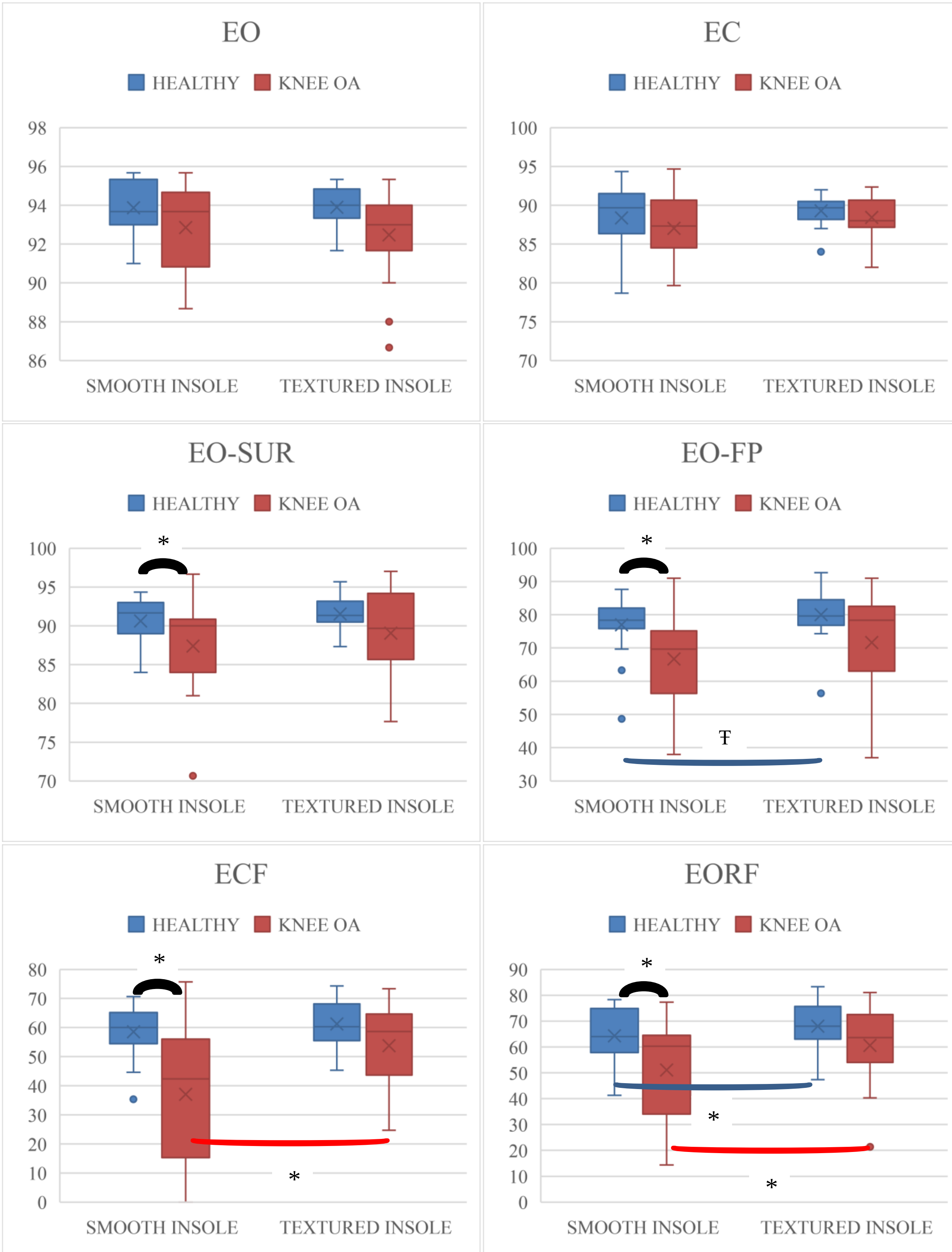
Regression was calculated to evaluate the interaction between groups on EORF scores in the smooth insole and the textured insole. A significant regression equation was found (F(3, 26) = 5.542, p = 0.004), with an R^2 of 0.390. Table 4.7 showed that the textured insole scores – smooth insole scores are equal to 4.710 + 1.676 - 0.173 (age) - 0.330 (the smooth insole score). Also, the interaction between the knee groups was not significantly different, indicating that the textured insoles had similar effects to both groups.

Table 4.7. EORF coefficients

Model	Unstandardized Coefficients		Standardized Coefficients	t	Sig.
	B	Std. Error	ß		
(Constant)	4.710	2.186		2.155	.041
Knee OA	1.676	3.031	.092	.553	.585
AGE	-.173	.135	-.204	-1.275	.213
EORF	-.330	.095	-.607	-3.485	.002

Effects of textured insoles on each group

The presence of the textured insole only affected EORF of both group; the textured insole (M = 60.578, SD = 16.084, conditions; t (14) = -3.323, p = 0.005, d = -0.858) and the smooth insole (M = 51.044, SD = 19.449) in the knee OA group and the textured insole (M = 68.00, SD = 10.262, conditions; t (14) = -2.446, p = 0.028, d = -0.632) and the smooth insole (M = 64.289, SD = 11.160) in the healthy knee control group. Also, in the EO-FP condition of the healthy knee group, because the data were not normally distributed, a Wilcoxon Signed-Ranks Test was run, and the output indicated that the textured insole scores were statistically significantly higher than the smooth insole scores ($Z = 2.445$, $p = 0.014$, $r = 0.45$). In ECF condition, there was significant higher score of the textured insole ($M = 53.734$, $SD = 14.485$, conditions; $t(14) = -4.039$, $p = 0.001$, $d = -1.043$) compared to the smooth insole ($M = 37.022$, $SD = 25.674$) in the knee OA group.



* Statistically significant mean difference ($p < 0.05$), Ŧ Tendency toward statistical difference ($p = 0.05 – 0.10$)

Figure 4.1. Box plots of each condition's equilibrium score

Knee OA group vs. healthy knee group (smooth insole)

Independent t-tests (Table 4.8) and Mann-Whitney U tests (Table 4.9) were conducted to compare the smooth insole's equilibrium scores in individuals with knee OA and healthy knee controls. For the four conditions in which either the force plate and/or surround moved, the groups differed for the smooth insole. Healthy knee group had significantly higher SOT scores (except EO-FP was only a tendency) than knee OA group.

Table 4.8. Results of independent t-tests

	Levene's Test		t-test for Equality of Means						
	F	Sig.	t	df	Sig.	Mean Difference	Std. Error Difference	95% CI of the Difference	
								Lower	Upper
EO	4.877	0.036	1.455	24.124	0.158	1.023	0.703	-0.427	2.472
EC	0.014	0.905	0.811	28.000	0.424	1.355	1.670	-2.066	4.776
ECF	10.645	0.003	3.035	17.997	0.007*	21.534	7.096	6.626	36.441
EORF	6.495	0.017	2.288	22.317	0.032*	13.246	5.790	1.248	25.243

Table 4.9. Mann-Whitney U tests results

	Mann-Whitney U	Wilcoxon W	Z	Sig.	Median (Healthy)	Median (Knee OA)	Effect Size *r*
EO-SUR	61.500	181.500	-2.118	0.033*	91.670	90.000	-0.547
EO-FP	65.500	185.500	-1.950	0.050 Ŧ	78.330	69.670	-0.503

Sensory Analysis Ratios

Interactions between groups

SOM

Regression was calculated to evaluate the interaction between groups on SOM ratio in the smooth insole and the textured insole. A significant regression equation was found (F(3, 26) = 28.919, $p < 0.001$), with an R^2 of 0.769. Table 4.10 showed that the difference of ratios between the type of insoles is equal to 0.736 + 0.726 - 0.054 (age) - 0.816 (the smooth insole score). Also, the interaction between the knee groups was not significantly different, indicating that the textured insoles had similar effects to both groups.

Table 4.10. SOM coefficients

Model	Unstandardized Coefficients		Standardized Coefficients	t	Sig.
	B	Std. Error	ß		
(Constant)	.736	.600		1.227	.231
Knee OA	.726	.772	.089	.940	.356
AGE	-.054	.036	-.143	-1.491	.148
SOM	-.816	.094	-.834	-8.724	.000

VIS

Regression was calculated to evaluate the interaction between groups on VIS ratio in the smooth insole and the textured insole. A significant regression equation was found (F(3, 26) = 5.370, p = 0.005), with an R^2 of 0.383. Table 4.11 showed that the difference of ratios between the type of insoles is equal to 3.997 - 2.249 - 0.259 (age) - 0.483 (the smooth insole score). Also, the interaction between the knee groups was not significantly different, indicating that the textured insoles had similar effects to both groups.

Table 4.11. VIS coefficients

Model	Unstandardized Coefficients		Standardized Coefficients	t	Sig.
	B	Std. Error	ß		
(Constant)	3.997	2.794		1.430	.165
Knee OA	-2.249	3.773	-.098	-.596	.556
AGE	-.259	.167	-.241	-1.548	.134
VIS	-.483	.127	-.632	-3.815	.001

VEST

Regression was calculated to evaluate the interaction between groups on VEST ratio in the smooth insole and the textured insole. A significant regression equation was found (F(3, 26) = 27.887, $p < 0.001$), with an R^2 of 0.763. Table 4.12 showed that the difference of ratios between the type of insoles is equal to 8.253 + 3.942 - 0.065 (age) - 0.513 (the smooth insole score). Also, the interaction between the knee groups was not significantly different, indicating that the textured insoles had similar effects to both groups.

Table 4.12. VEST coefficients

Model	Unstandardized Coefficients		Standardized Coefficients	t	Sig.
	B	Std. Error	ß		
(Constant)	8.253	2.252		3.666	.001
Knee OA	3.942	3.209	.135	1.229	.230
AGE	-.065	.133	-.047	-.485	.632
VEST	-.513	.071	-.807	-7.202	.000

PMAN

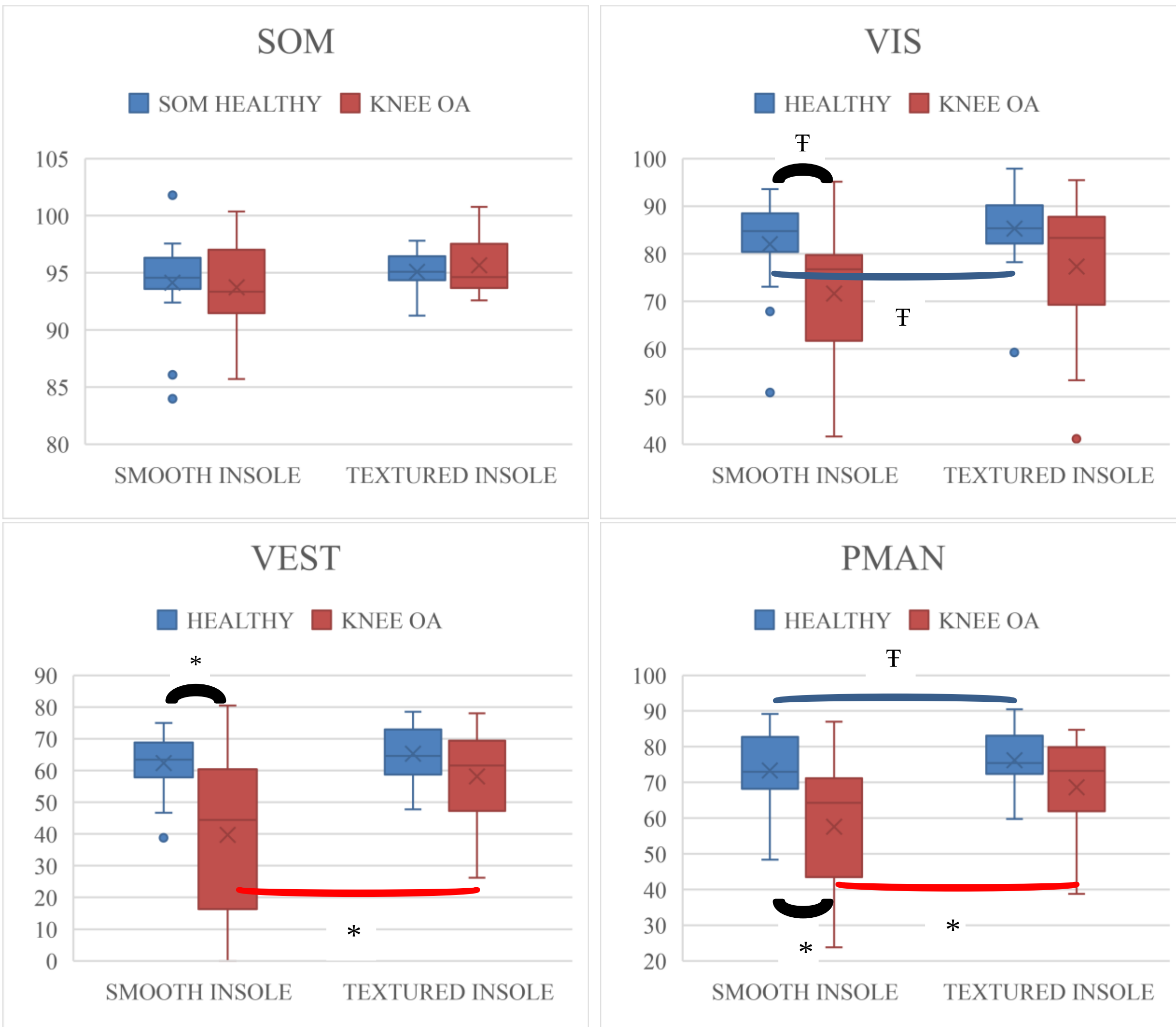
Regression was calculated to evaluate the interaction between groups on PMAN ratio in the smooth insole and the textured insole. A significant regression equation was found (F(3, 26) = 15.170, p < 0.001), with an R^2 of 0.636. Table 4.13 showed that the difference of ratios between the type of insoles is equal to 4.996 + 1.871 - 0.174 (age) - 0.416 (the smooth insole score). Also, the interaction between the knee groups was not significantly different, indicating that the textured insoles had similar effects to both groups.

Table 4.13. PMAN coefficients

Model	Unstandardized Coefficients		Standardized Coefficients	t	Sig.
	B	Std. Error	ß		
(Constant)	4.996	1.767		2.827	.009
Knee OA	1.871	2.492	.100	.751	.459
AGE	-.174	.107	-.199	-1.627	.116
PMAN	-.416	.074	-.773	-5.641	.000

Effects of textured insoles on each group

In VIS ratio of the healthy knee group, due to the fact that the data was not normally distributed, a Wilcoxon Signed-Ranks Test was used and the output indicated that the textured insole had a tendency for higher VIS than smooth insole (Z = 1.931, p = 0.053, r = 0.35) in the healthy knee group. In VEST, there were significant higher scores of the textured insole (M = 58.087, SD = 15.349, conditions; t (14) = -4.240, p = 0.001, d = -0.90) than smooth insole (M = 39.728, SD = 27.416) in the knee OA group. In PMAN, the textured insole had a tendency (M = 76.220, SD = 8.836, conditions; t (14) = -2.051, p = 0.059, d = -0.530) for higher ratio compared to smooth insole (M = 73.30, SD = 10.73) in the healthy knee control group, and the textured insole had a tendency (M = 68.663, SD = 13.925, conditions; t (14) = -3.892, p = 0.001, d = -0.68) for higher PMAN ratio compared to the smooth insole (M = 57.547, SD = 20.112) in the knee OA group.



* Statistically significant mean difference ($p < 0.05$), Ŧ Tendency toward statistical difference (p = 0.05 – 0.10)

Figure 4.2. Box plots of the sensory analysis ratios

Knee OA group vs. healthy knee group (smooth insole)

Independent t-tests results showed that there was a significant difference in the PMAN for the healthy knee group (M = 73.303, SD = 10.731) and the knee OA group (M = 57.547, SD = 20.112) conditions; t(21.374) = 2.677, *p* = 0.014. Mann-Whitney tests results indicated that VEST of the smooth insole condition was greater for healthy knee controls (*Mdn* = 63.410) than for individuals with knee OA (*Mdn* = 44.410), U = 48.0, *p* = 0.007, *r* = -0.691) and healthy knee controls had a tendency (*Mdn* = 84.780) for higher VIS compared to individuals with knee OA (*Mdn* = 76.750, U = 68.000, *p* = 0.067, *r* = -0.477). as well.

Table 4.14 Independent t-test result of PMAN

	Levene's Test		t-test for Equality of Means						
	F	Sig.	t	df	Sig.	Mean Difference	Std. Error Difference	95% CI of the Difference	
								Lower	Upper
PMAN	6.644	0.016	2.677	21.374	0.014*	15.755	5.886	3.528	27.983

Table 4.15 Mann-Whitney U results of the sensory analysis ratios

	Mann-Whitney U	Wilcoxon W	Z	Sig.	Median (Healthy)	Median (Knee OA)	Effect Size *r*
SOM	96.000	216.000	-0.684	0.51	94.570	93.360	-0.177
VIS	68.000	188.000	-1.846	0.067 Ŧ	84.780	76.750	-0.477
VEST	48.000	168.000	-2.678	0.007*	63.410	44.410	-0.691

Latency

Interactions between groups

Table 4.16 showed that difference latency between the type of insoles is equal to 0.394 - 0.579 + 0.138 (age) - 0.058 (the smooth insole score). Also, the interaction between the grouping variables (the knee OA and healthy knee groups) was not significantly different, indicating textured insoles had similar effects in all participant.

Table 4.16. Latency coefficients

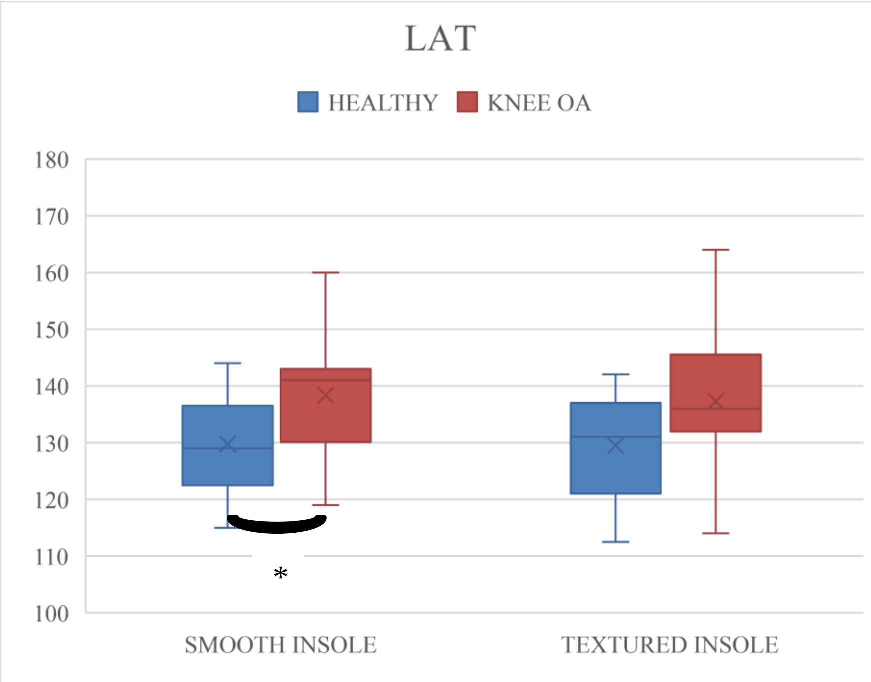
Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.
		B	Std. Error	Beta		
	(Constant)	.394	1.284		.307	.761
	Knee OA	-.477	1.777	-.054	-.268	.790
	AGE	.138	.080	.334	1.719	.098
	latency	-.058	.084	-.146	-.694	.494

Effects of textured insoles on each group

There was not a significant difference in the latency for the textured insole condition and the smooth insole condition in both groups (Table 4.7).

Table 4.17. Paired t-test results of latency

		Smooth insole		Texture insole		95 % CI for Mean Difference		t	df	*p*	*Cohen d*
		M	SD	M	SD						
LAT	Knee OA	138.367	11.578	137.267	13.172	-1.788	3.988	0.817	14	0.428	0.211
	Healthy	129.800	9.511	129.500	9.260	-1.798	2.398	0.307	14	0.764	0.079



* Statistically significant mean difference ($p < 0.05$), Ŧ Tendency toward statistical difference ($p = 0.05 – 0.10$)
Figure 4.3. Box plot of the latency

Knee OA group vs. healthy knee group (smooth insole)

An independent t-test was conducted to compare the smooth insole's latency in individuals with knee OA and healthy knee controls. An independent t-test indicated that latency of the smooth insole condition was faster for healthy knee controls (M = 129.80, SD = 9.511) than for individuals with knee OA (M = 138.367, SD = 11.578, t (28) = -2.214, p = 0.035).

Table 4.18. Independent t-test result of latency

	Levene's Test		t-test for Equality of Means						
								95% CI of the Difference	
	F	Sig.	t	df	Sig.	Mean Difference	Std. Error Difference	Lower	Upper
Latency	0.357	0.555	-2.214	28.000	0.035*	-8.567	3.869	-16.492	-0.642

CHAPTER 5

DISCUSSION

The aim of the study was to determine if the enhanced somatosensory input provided by a textured insole would benefit not only healthy individuals of middle-age and early older adults, but would enhance to a greater degree the balance of corresponding individuals with knee OA. It has been well documented that individuals with knee OA have increased fall risk because they have pain, reduction of lower limb muscle strength, somatosensory abnormality, and significant decline of mechanoreceptors compared to age-matched healthy peers (Tarigan et al., 2009). It has also been documented that people who have higher fall risks can improve their balance through the enhanced cutaneous information on the skin of the plantar surface. What is less known, however, is if this improvement for individuals with knee OA can be triggered with textured insoles. These insoles were surmised to provide greater somatosensory information to the skin of the plantar surface. Hence, it was hypothesized that a textured insole intervention would result in significant improvements in the balance performance outcome measures of both knee groups, and greater improvements would be displayed by the knee OA group than the healthy group. These hypotheses were partially upheld.

Interactions

Although It was expected that a textured insole intervention would result in greater improvements in knee OA group than the healthy group, there were no statistically significant interactions between groups, indicating textured insoles had similar effects to individuals with knee OA and healthy knee controls. However, regarding the results of the pair-t test and independent t test, there were small interactions between groups. This difference in results can be attributed to a small sample size. Also, it may be because the covariates were only in the regression models and not in t-tests.

Knee OA group vs. healthy knee group (smooth insole)

<u>Sensory Organization Test</u>

The results of the balance performances with smooth insoles between the individuals with knee OA and the healthy knee controls showed that EO-SUR, ECF, EORF, VEST, and PMAN were significantly higher for healthy knee controls than individuals with knee OA.

Lower SOT EQ values for knee OA group were evidence of larger displacements of the center of gravity in the forward–backward direction suggesting that the knee OA group was unable to maintain balance compared to healthy knee controls during the SOT test procedure. In ECF and EORF tests with smooth insoles, the differences between groups were the highest. However, there were small differences in conditions that did not stress balance. These results show that the balance differences appeared when the difficulty of the tests increased, especially in situations of conflicted sensory inputs. This observation should be taken into account in the fall prevention, especially, participants should place in dynamic situations with conflicted sensory environment, as these are found in daily life.

Furthermore, Sensory Analysis results showed that individuals with knee OA had lower VEST and PMAN ratios. These results suggest a lower use of vestibular and somatosensory afferents compared with the healthy knee controls. The VEST ratio demonstrated the usefulness of the signal from a vestibular system in maintaining body balance, traditionally indicating the quality of the vestibular afferent (Gauchard et al., 2010). In ECF, EORF conditions, all participants had to compensate for the visual deprivation and the inaccurate somatosensory information with an increased use of vestibular information (Vouriot et al., 2004). The previous study has shown that poor balance function was related to the lower reliance on vestibular afferent (Cohen et al., 1996). And Figueiro and colleagues (2011) stated that people with deficits in the vestibular system relied heavily on visual cues, and they lost balance if the visual information was removed by eyes closed (Paulus, Straube, & Brandt 1987). In this study, when the visual input was removed and somatosensory inputs altered (ECF), a significantly decreased EQ scores followed (four of fifteen knee OA participants lost balance). However, the increased number of falls and dropped equilibrium scores during the conditions where visual and somatosensory information were distorted or removed could also indicate a deficit in sensorimotor processing rather than a vestibular system dysfunction (Wolfson et al., 1992). In order to maintain balance, the central nervous system (CNS) should be able to select the appropriate information which is from sensory systems and ignore inadequate sensory information. Then, the CNS compares them to an internal model and generates motor commands to the muscles (Mergner, Huber, & Becker, 1997). However, this central processing may provide inappropriate responses based on the sensory information available which causes losing balance (Peterka, & Black, 1990).

The function of the vestibular system or the central processing in knee OA people is unknown in this study, and whether these balance deficits reflect reduced functionally in individuals with knee OA remain unknown. However, several potential mechanisms may account for the balance deficit observed in the OA group, although this cross-sectional study does not allow these to be confirmed. Individuals with knee OA often exhibit several factors that affect the balance negatively, including muscle weakness (Hassan, Mockett, & Doherty, 2001; Hurley, Scott, Rees, & Newham, 1997; Slemenda et al., 1997), impaired somatosensory (Barrett, Cobb & Bentley, 1991; Hurley, Scott, Rees, & Newham, 1997; Knoop et al., 2011; Koralewicz & Engh, 2000; Pai, Rymer, Chang, & Sharma, 1997; Wylde, Palmer, Learmonth, & Dieppe, 2012), and significant decline of mechanoreceptors compared to age-matched healthy peers (Tarigan et al., 2009). Wylde and colleagues (2012) concluded that individuals with knee OA showed somatosensory abnormalities, most common ones being tactile hypoesthesia and pressure hyperalgesia. Tactile hypoaesthesia and pressure hyperalgesia were found at the pain-free forearm, suggesting more widespread changes within the CNS (Wylde, Palmer, Learmonth, & Dieppe, 2012).

Also, Shakoor, Agrawal, & Block (2007) showed that the vibratory perception threshold (VPT) is reduced to the lower extremity (first metatarsophalangeal joint, medial malleolus, lateral malleolus, medial femoral condyle, and lateral femoral condyle) of individuals with knee OA. Abnormal somatosensory is commonly associated with knee OA and highly assumed that the balance abnormalities could occur along with other characteristics of knee OA. Maintaining the balance is a complicated process. The stable balance requires the integration of information that comes from the sensory systems such as the visual, somatosensory, and vestibular sensory system as well as precise motor control. It means that if one of sensory systems is abnormal, it can affect the balance function. Therefore, it is possible for individuals with knee OA who have somatosensory abnormalities to obtain the lower scores when exposed to adverse environmental conditions where the one needs to increase the use of somatosensory information. Furthermore, a joint contracture which is another knee OA characteristic is a limitation in the range of motion (ROM) of the joint and occurs secondary to shortening of periarticular connective tissues and muscles (Trudel & Uhthoff, 2000). Clavet and colleagues (2008) stated that the joint contractures restrict movements, can have an adverse impact on quality of life, and prevent physical activities of daily living. A limitation of full extension of the knee is called a knee flexion contracture (Campbell, Trudel, & Laneuville, 2015). Potter, Kirby, & MacLeod (1990) concluded that knee flexion contractures could cause a shift of the center of pressure, and thus it can be responsible for a possible cause of balance deficits.

Latency

The generation of torque for maintaining a secure upright body position with the center of gravity placed vertically over the base of support during an unexpected perturbation (MCT conditions) was associated with changes of exerted forces on the surface (forceplate) from the feet, which affected the center of pressure. To maintain the balance during perturbation, the participants had to perform corrective movements involving long-loop pathways of the automatic response (Brooks, 1986). These corrective movements can be used to decide the onset of responses and magnitudes (Müller & Redfern, 2004). Balance perturbations evoke muscular responses from the lower leg first to more proximal muscles such as the thigh and the trunk (Lin & Woollacott, 2005). Muscular responses to perturbation consist of a reflexive response, an automatic response, and a voluntary response. The reflexive response is elicited by muscle length changes which were caused by the initial perturbation (Bloem, Visser, & Allum 2003). This reflexive response is often unstable during rotational disturbances, but it is helpful during horizontal translations, and the automatic response is a type of learned reflex for a quick response to disturbance and referred to a balance-correcting response (Jacobson, Newman, & Kartush, 1993). The automatic response is elicited with a latency that is late for a reflexive response, yet too early for a voluntary response (Carpenter, Allum, & Honegger, 1999). Latency quantifies the time between translation (perturbation) onset and initiation of the participant's active response (force response in each leg). The onset of activation is based on a sudden movement change caused by force generation at the feet. The voluntary response is achieved under one's consciousness within the bounds of voluntary control (350-500 ms and on), and muscle activity continues and tends to be stabilizing during this phase (Carpenter, Allum, & Honegger, 1999; Takacs, Carpenter, Garland, & Hunt, 2013). In this study, individuals with knee OA displayed a longer neuromuscular response latency to balance perturbations, indicating a reduced ability to begin in recover balance quickly following an unexpected disturbance.

The previous research has shown that the triggering of the automatic balance corrections depends on hip and trunk proprioceptive inputs, and knee inputs provide a supplementary trigger signal, allowing the generation of the very early part of the triceps surae responses (Bloem, et al., 2002; Gauchard, et al., 2010). The current study showed that the presence of OA in the knee joint might inhibit the generation of an adequate strategy, resulting in slower latency compared to the healthy knee controls. Vouriot et al. (2004) stated that this long latency response could also result from the lack of dependence on somatosensory and vestibular information (Gauchard, Gangloff, Jeandel, & Perrin, 2003) which are used to activate and modulate balance correcting responses (Allum, & Shepard, 1999). Also, joint pain associated with the knee OA may play a role in slower latency, leading a reduced ability to maintain balance. Joint pain changes the responses and affects the muscle activity during the automatic response (Takacs, Carpenter, Garland, & Hunt, 2013). Pain is the main characteristic of knee OA and is part of the American College of Rheumatology's criteria for the clinical diagnosis of knee OA (Altman, et. Al., 1986). All knee OA participants of this study had mild-moderate knee joint pain when they were assessed. Experimentally-induced thigh pain results in larger sway area, increased sway displacement, increased electromyographic (EMG) activity, and increased time to return to an equilibrium position after unexpected perturbation (Hirata, Ervilha, Arendt-Nielsen, & Graven-Nielsen, 2011). Arvidsson, Eriksson, Knutsson & Arner (1986) concluded that pain might reflexively inhibit the voluntary muscles activation around the knee, which could compromise efficient and timely motor responses for maintaining balance. Also, pain in individuals with knee OA can cause decreased loading in the affected joint, possibly reducing their ability to maintain their center of mass within the base of support (Hurwitz et al., 2000).

Effects of textured insoles on each group

Although there were no interactions, paired t-tests were conducted to find out whether the textured insoles improved the balance of each group. In knee OA group, there were significant improvements in ECF, EORF, VEST, and PMAN when wearing the textured insoles. In healthy knee control group, there were statistically significant improvements in EO-FP, EORF when wearing the textured insoles.

EORF, where the visual and somatosensory information was altered, was the only score that both groups affected by textured insoles. This finding is consistent with previous work by Qui et al. (2012), demonstrating that textured insoles improved balance further in a challenging situation where visual and somatosensory inputs were conflicted. However, it is important to note that this research did not attempt to add textured insoles into shoes, but rather explored the effects of a textured standing surface in healthy older adults. A point of interest could be the improvements of the PMAN in both groups (a tendency in the healthy control group). All participants with the textured insoles were able to better manage balance in inaccurate somatosensory situations, leading to a higher reliance on somatosensory orientation, which was not possible without the textured insoles.

This result may be due to hyperesthesia of the plantar surfaces of the feet, resulting in increased cutaneous afferent receptor activity while participants wore the textured insoles. In more detail, the underlying physiological mechanisms by which textured insoles can cause changes in the balance suggest that textured insoles provide enough stimulation to alter the discharge rate from mechanoreceptors or firing patterns of sensory afferents located in the skin of the plantar surface (Hatton, et al., 2016). This effect would result in an overall increased neural feedback from the cutaneous receptors to the central nervous system and potentially contribute to improving the balance.

Overall, the textured insoles improved balance in the knee OA group most likely due to the enhancement of somatosensory information from the plantar surfaces. These results contribute to current understanding of the research by complementing the extant data. For instance, our results are in agreements with data reported by Priplata et al. (2002) who studied the use of vibration insoles, showing that balance can be improved during quiet standing through enhanced somatosensory feedback. Besides Priplata’s research (2002), providing stimulation to the plantar surface of the feet through the vibration stimulation has been considered as a potential mechanism through which footwear intervention could improve the balance (Collins et al., 2003; Kavounoudias, Roll, & Roll, 2001; Priplata et al., 2006; Priplata, Niemi, Harry, Lipsitz, & Collins, 2003) by altering sensorimotor function. The difference between previous research and the current study was the characteristics of the stimulation to the feet. In this study, the plantar surface persisted in contact with the indentations of the textured insole. When the cutaneous afferents respond continuously to prolonged indentations, they are classified as slow adapting mechanoreceptors (Kennedy & Inglis, 2002). In comparison, vibratory interventions could manipulate the frequency, intensity, phase, and duration of stimulation. These interventions may affect fast-adapting mechanoreceptors which show burst responses to stimulation (Hatton, Dixon, Rome, Newton, & Martin, 2012). Textured insoles used for this study did not work on the same principle because those textured insoles did not provide electrical stimulation.

In addition, such vibration devices may be expensive and difficult to use as effective interventions to improve balance in daily life. Textured insoles may provide a practical alternative and act as an inexpensive way of improving balance (Qiu, et al., 2013).

A systematic review conducted for the effects of textured interventions demonstrated that the stimulation of sensory receptors in the skin through simple mechanical deformation of the plantar surface by added texture could improve the balance performances in various populations, such as young people, elderly, fallers, individuals with Parkinson’s disease, multiple sclerosis, and chronic ankle instability under the static balance test, dynamic balance test, gait analysis, and proprioception test (Orth et al., 2013). In this respect, the effects of the textured insoles could lead to an increase in proprioceptive sensitivity and a higher reliance on the somatosensory information.

Although we do not know the structural integrity or functional capabilities of the sensory receptors in the superficial plantar tissues in the individuals with knee OA, it is surmised that textured insoles can successfully stimulate sensory receptors to increase their output, as known to occur in healthy adults and other clinical populations, and thereby improve balance.

Considering the improvement of VEST, it seems to be due to an improvement of ECF, because the improved ECF score is thought to be due to a higher reliance on somatosensory information by the use of textured insole, not by functional improvement of the vestibular system.

Also, the habituation of participants to the textured insoles is also one of the critical aspects of future research needed in this area. In Palluel et al. (2008, 2009) studies, the participants were instructed to stand or to walk for 5 minutes with textured insoles. However, effects of textured insoles in supporting perceptual-motor function need to be studied over a much longer period spanning several months (Qui et al., 2013). Although our participants testified that the textured insoles were comfortable during the assessments, it is important to assess over extended periods of time to ensure the long-term adherence will be comforted.

Conclusion

Although the presence of textured insoles did not produce greater improvements on balance outcomes in individuals with knee OA, the results indicate that a textured insole intervention can induce positive changes in balance partially as measured by the Sensory Organization Test. However, it is uncertain whether these changes were placebo or learning effects. It is possible that balance outputs were influenced due to the baseline test because the initial balance tests were performed with smooth insoles and only after with the textured insoles.

The benefits of this study for the individuals with knee OA are that this may lead to the development of an evidence-based footwear intervention which is noninvasive, simple to use, inexpensive, allows the user for self-management, and can reduce the risk of falls, consequentially improving the quality of life. We believe that this study has clinical significance based on the fact that falling is one of the leading causes of injury in the knee OA population. Future studies which examine effects of prolonged wearing textured insoles are needed to conclude if a textured insole intervention can produce significant changes in balance and function in knee OA population.

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APPENDIX A

Paired t-test results

		Smooth insole		Texture insole		95 % CI for Mean Difference		t	df	*p*	*Cohen d*
		M	SD	M	SD						
EO	Knee OA	92.844	2.278	92.466	2.565	-0.842	1.598	0.664	14	0.517	0.172
	Healthy	93.867	1.489	93.889	1.165	-0.925	0.881	-0.052	14	0.959	-0.013
EC	Knee OA	87.023	4.608	88.444	3.135	-3.519	0.677	-1.453	14	0.168	-0.375
EO-SUR	Knee OA	87.401	6.281	89.044	6.150	-4.767	1.480	-1.129	14	0.278	-0.291
	Healthy	90.621	3.355	91.533	2.254	-2.463	0.640	-1.260	14	0.228	-0.325
ECF	Knee OA	37.022	25.674	53.734	14.485	-25.586	-7.838	-4.039	14	0.001*	-1.043
EO RF	Knee OA	51.044	19.449	60.578	16.084	-15.689	-3.381	-3.323	14	0.005*	-0.858
	Healthy	64.289	11.160	68.000	10.262	-6.965	-0.457	-2.446	14	0.028*	-0.632
SOM	Knee OA	93.723	4.294	95.658	2.498	-4.568	0.699	-1.575	14	0.138	-0.407
	Healthy	94.140	4.339	95.078	1.915	-2.905	1.029	-1.023	14	0.324	-0.264
VE ST	Knee OA	39.728	27.416	58.087	15.349	-27.646	-9.072	-4.240	14	0.001*	-1.095
PM AN	Knee OA	57.547	20.112	68.663	13.925	-17.242	-4.990	-3.892	14	0.002*	-1.005
	Healthy	73.303	10.731	76.220	8.836	-5.968	0.133	-2.051	14	0.059 Ŧ	-0.530
LAT	Knee OA	138.367	11.578	137.267	13.172	-1.788	3.988	0.817	14	0.428	0.211
	Healthy	129.800	9.511	129.500	9.260	-1.798	2.398	0.307	14	0.764	0.079

Wilcoxon signed-rank test results

		Smooth insole		Texture insole		N	Standard Error	Z	Sig.	*Effect size r*
		M	SD	M	SD					
EC	Healthy	88.378	4.539	89.267	2.063	15	17.518	0.314	0.754	0.06
EO-FP	Knee OA	66.688	16.992	71.666	15.002	15	17.607	0.682	0.496	0.12
	Healthy	76.934	10.204	80.044	8.484	15	17.586	2.445	0.014*	0.45
ECF	Healthy	58.555	9.803	61.244	8.515	15	17.603	1.449	0.147	0.26
VIS	Knee OA	71.656	17.480	77.348	15.319	15	17.607	1.079	0.281	0.20
	Healthy	82.003	11.011	85.273	9.063	15	17.607	1.931	0.053 Ŧ	0.35
VEST	Healthy	62.357	10.316	65.246	9.126	15	17.607	1.420	0.156	0.26

Independent t-test results

	Levene's Test		t-test for Equality of Means						
	F	Sig.	t	df	Sig.	Mean Difference	Std. Error Difference	95% CI of the Difference	
								Lower	Upper
EO	4.877	0.036	1.455	24.124	0.158	1.023	0.703	-0.427	2.472
EC	0.014	0.905	0.811	28.000	0.424	1.355	1.670	-2.066	4.776
ECF	10.645	0.003	3.035	17.997	0.007*	21.534	7.096	6.626	36.441
EORF	6.495	0.017	2.288	22.317	0.032*	13.246	5.790	1.248	25.243
PMAN	6.644	0.016	2.677	21.374	0.014*	15.755	5.886	3.528	27.983
Latency	0.357	0.555	-2.214	28.000	0.035*	-8.567	3.869	-16.492	-0.642

Mann-Whitney U results

	Mann-Whitney U	Wilcoxon W	Z	Sig.	Median (Healthy)	Median (Knee OA)	Effect Size *r*
EO-SUR	61.500	181.500	-2.118	0.033*	91.670	90.000	-0.547
EO-FP	65.500	185.500	-1.950	0.050 Ŧ	78.330	69.670	-0.503
SOM	96.000	216.000	-0.684	0.51	94.570	93.360	-0.177
VIS	68.000	188.000	-1.846	0.067 Ŧ	84.780	76.750	-0.477
VEST	48.000	168.000	-2.678	0.007*	63.410	44.410	-0.691

APPENDIX B

MEDICAL HISTORY AND HEALTH QUESTIONNAIRE

[Medical history and Health Questionnaire]

For researcher use only
Participant ID: ______________ Date: __________________

Reviewed by: _______________

Do you have at present, or have you had any of the following:

- ☐ Heart problem not being treated
- ☐ Inner ear problem
- ☐ Broken bones
- ☐ Balance problem
- ☐ Sprains, or hurt an ankle, shoulder, hip, or knee
- ☐ Blurred or bad eyesight or other eye problem not corrected
- ☐ Foot problem
- ☐ Surgery to legs, hips, back
- ☐ Injury requiring major medical attention
- ☐ Other medical condition(s)

☐ Do you use any type of aid to help you walk, such as a cane or walker?

Have you had during the past 2 weeks or have today, any of these, yes/no/unsure:

- ☐ Back pain
- ☐ Feeling sick to your stomach
- ☐ Trouble breathing
- ☐ Trouble with balance
- ☐ Injury
- ☐ Trouble seeing
- ☐ Illness
- ☐ Feeling dizzy or light-headed
- ☐ Muscle soreness or tenderness
- ☐ Any other health problems that would affect your safety or ability or to heel-toe walking

APPENDIX C

WOMAC

[WOMAC Part 1]

OA people balance
PP ID: _______________
Date: _____________

1) *How much pain do you have during the following activities?*

	None(0)	*Slight(1)*	*Moderate(2)*	*Severe(3)*	*Extreme(4)*
Walking					
Climbing stairs					
During the night					
Resting					
Weight bearing					

[WOMAC Part 2]

2) *Stiffness: How severe is your stiffness?*

	None(0)	*Slight(1)*	*Moderate(2)*	*Severe(3)*	*Extreme(4)*
Morning					
Stiffness occurring later in the day					

3) *Physical function: What degree of difficulty do you have with…*

	None 0	*Slight 1*	*Moderate 2*	*Severe 3*	*Extreme4*
Descending stairs					
Ascending stairs					
Rising from sitting					
Standing					
Bending to floor					
Walking on flat surface					
Getting in or out of car					
Going shopping					
Putting on socks					
Lying in bed					
Taking off socks					
Rising from bed					
Getting in/out of bath					
Sitting					

Getting on/off toilet					
Heavy domestic duties					
Light domestic duties					

APPENDIX D

UNIVERSITY OF GEORGIA
CONSENT FORM

The Effects of Textured Insole on Balance Control in Knee Osteoarthritis

Researcher's Statement

I am Hyoungjin Park, a doctoral student at the University of Georgia, Department of Kinesiology, working under the supervision of Dr. Kathy Simpson and Dr. Michael Horvat and in collaboration with Dr. Ormonde Mahoney, Athens Orthopedic Clinic. We are asking you to take part in a research study. Before you decide to participate in this study, it is important that you understand why the research is being done and what it will involve. This form is designed to give you the information about the study so you can decide whether to be in the study or not. Please take the time to read the following information carefully. Please let the researcher know if there is anything that is not clear or if you need more information. When all your questions have been answered, you can decide if you want to be in the study or not. This process is called "informed consent." A copy of this form will be given to you.

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Purpose of the Study

Knee osteoarthritis (OA) may affect people's balance; we do not know if or why this is true. We do know that your brain uses information not just from your inner ears and eyes to stay in balance, but also from your feet. Therefore, we want to know if enhancing that information from your feet by wearing a textured insole inside your shoe improves balance, and, therefore, would benefit individuals who experience mild knee pain due to OA. Therefore, the purposes of this study are to determine:

(1) whether balance control of individuals with knee OA are different compared to healthy peers; and (2) if the presence of textured insoles improves balance control of individuals with knee OA.

Study Procedures

If you agree to participate, you will be asked to complete 3 main phases of participation: a) ***Session #1*** (today, for about 70 minutes), whereby you will complete pre-test tasks and tests of your balance and movement control; b) ***Adaptation*** (2 days), whereby you wear the shoe insoles for 2 days to get used to the insoles; and c) **Session #2** (requiring about 50 minutes), whereby you undergo a few of the pre-test tasks, then perform the test tasks again.

Total time of your participation: 2 days of wearing the insoles; about two hours of testing.

Session #1: Today, for the *pre-test tasks*, you will first complete a questionnaire asking about your medical history and health, as we want to make sure that you are feeling well and eligible to participate. You also will answer a questionnaire about your daily activities and rate your knee comfort/pain. The answers and your medical clearance form will be reviewed with you by the primary investigator. If eligible, the rest of the pre-test tasks and the test tasks will be completed. For the remaining pre-test tasks, we will measure your mass and height, and cut one pair of shoe insoles that will fit the shoes you are wearing at the first session. Last, you will undergo warmups before testing. Warm-ups include dynamic stretches such as hip circles, arm circles, arm swings, high-stepping, and walking. You then will practice first, then perform five balance tests, described later.

Adaptation Phase: You will wear one pair of insoles inside your shoes for 2 days while following your normal daily routine. The insoles go into the shoes that you use most often.

Session #2: You will return to the test location to complete the health status questions, rate your knee comfort/pain again, perform the warm ups, and then repeat all of the tests described later.

***Testing*:** Using specialized balance test equipment, you will perform each test (described below) several times; each time you perform the test, it changes slightly. You will be given time to sit and rest between each test performance as you desire.

Note. Throughout Sessions #1 and #2, we will continue to ask you to rate your knee comfort/pain. As described later, at any time during the testing, you may choose to stop participating for any reason; but we wish to emphasize here that you may stop at any time due to knee discomfort or pain.

Test Descriptions:

- Sensory Organization Test: You will be asked to stand as still as possible several times, sometimes with your eyes open, sometimes with your eyes shut. Additionally, the walls and/or the surface you stand on (platform) may or may not tilt. This tests your balance and how you use your senses to help you balance.

- Adaptation Test: While standing, the platform will tilt rapidly once, causing your toes to go up or down. Your goal is to stay as still as possible. This measures how your body's balance system automatically responds to this tilt.

- Motor Control Test: This test is similar to the Adaptation Test, but during this test, the platform will move backwards or forwards.

- Limits of Stability Test: You will lean your body to move a cursor projected on the screen to one of eight targets as quickly, accurately, as far as you can; and then to maintain this lean for a few seconds. This test measures how well you can lean without falling and to briefly maintain balance when leaning.

- Tandem walk: You will perform heel-to-toe walking on the forceplates as quickly as you can.

Risks and discomforts

There are minimal risks during testing, as the tests either use movements that are performed in daily life or involve only standing while you are harnessed in to the testing device to keep you from losing your balance. We anticipate little increase in knee OA symptoms while performing the tasks, because during daily life, appropriate physical activity can reduce OA symptoms. Moreover, these tasks also are not very demanding on your knees; each test does not last long; you can rest in between each test; and by engaging in an appropriate warmup, this will help your knees.

To prevent falls in case you begin to lose your balance, you will wear a harness; this is attached to one of the balance machines and will catch you. Also, the harness has handles that also allow a researcher to assist you in case you begin to lose your balance.

You may begin to experience discomfort when wearing the insoles. If this occurs during testing, let a researcher know immediately, and we will resolve the problem. If this occurs during the practice phase, you should stop using both insoles and contact Hyoungjin Park immediately.

It is also VERY important to tell a researcher immediately if you begin to feel <u>any</u> abnormal sensation, such as dizziness, nausea, discomfort, etc. We will stop immediately and determine whether the problem can be resolved or whether testing should be stopped. The investigators also reserve the right to stop testing at any time if we believe that it would be best for your health, safety or knee comfort.

Benefits

1. As a personal benefit, you will get a verbal assessment and written outcomes of your balance and movement control that will show how you compare to people similar to you in age and gender. As balance and arthritis are correlated to falls that can be serious, knowledge of your outcomes may be helpful to you. These outcomes and assessment are not medical advice or diagnoses; if concerned about your outcomes, please share them with your physician. 2. A

second personal benefit is that you may keep your insoles. 3. The benefit to others and society is that the findings from this project may provide useful information for people with knee osteoarthritis to help them and their doctors decide whether wearing insoles may help their balance and movement control.

Alternatives

Suggested alternatives include aquatic exercise, Tai-Chi, and weight training to improve balance control. Also, certain medications and surgical procedures may reduce knee pain, which could improve balance control. Discuss these alternatives with your doctor to determine if they would be beneficial.

Incentives for participation

You will receive a $25 gift card if you complete all participation phases; if you complete Session #1 only, you will receive a $15 gift card. Also, you will receive balance movement assessments.

Privacy/Confidentiality

The results of the research study may be published, but your name or any identifying information will not be used. Data *will be stored and used only for the purpose of the study.* *Only the researchers will have the authority to store with passwords, and use the data for the future. Participants' names and/or other personal identifiers are not used; participant ID codes only are used to identify data. The contact information that you provided will be deleted as soon as you complete data collection or choose to stop participation. This information is kept in a separate location from all other data. To prevent access by unauthorized users, computers are not connected to the Internet or any other network. All computers, backup drives and electronic files are in secured locations, and also require a password to use the computer and another password to access a file. Also, participants' consent forms will be stored in a locked file cabinet in a secure room; written questionnaires will be stored in a separate, secure location in a locked file cabinet; electronic files will be password protected and stored on a computer and separate backup-storage hard drives that are password protected.*

Taking part is voluntary

Your involvement in the study is voluntary; you may choose not to participate or to stop at any time without penalty or loss of benefits to which you are otherwise entitled. If you are a patient at Athens Orthopedic Clinic, your decision to participate/not participate or to withdraw your consent at any time if you so choose, will in no way affect any current or future medical treatments that you receive or will receive from Athens Orthopedic Clinic. If you decide to stop or withdraw from the study, the information/data collected from or about you up to the point of your withdrawal will be kept as part of the study and may continue to be analyzed.

If you are injured by this research

The researchers will exercise all reasonable care to protect you from harm as a result of your participation. In the event that any research-related activities result in an injury, the sole responsibility of the researchers will be to arrange for your transportation to an appropriate health care facility. If you think that you have suffered a research-related injury, you should seek immediate medical attention and then contact Dr. Kathy Simpson right away at 706-542-4385. In the event that you suffer a research-related injury, your medical expenses will be your responsibility or that of your third-party payer, although you are not precluded from seeking to collect compensation for injury related to malpractice, fault, or blame on the part of those involved in the research.

If you have questions

The researcher conducting this study is Hyoungjin Park (hjpark79@uga.edu), a doctoral student at the University of Georgia, under the supervision of Dr. Kathy Simpson, principal investigator (ksimpson@uga.edu; 706-542-4385) and Dr. Michael Horvat (mhorvat@uga.edu; 706-542-4455). Please ask any questions you have now. If you have questions later, you may contact Hyoungjin Park at hjpark79@uga.edu or at 706.308.0093. If you have any questions or concerns regarding your rights as a research participant in this study, you may contact the Institutional Review Board (IRB) Chairperson at 706.542.3199 or irb@uga.edu.

Research Subject's Consent to Participate in Research:

To voluntarily agree to take part in this study, you must sign on the line below. Your signature below indicates that you have read or had read to you this entire consent form, and have had all of your questions answered.

Name of Researcher	Signature	Date
Name of Participant	Signature	Date

Please sign both copies, keep one and return the other to the researcher.