Investigating balance, plantar pressure, and foot sensitivity of individuals with diabetes during stair gait

by

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A thesis submitted in conformity with the requirements for the degree of Doctor of Philosophy
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Abstract

Diabetic peripheral neuropathy (DPN) is a prominent issue for the diabetes population and may lead to ulceration and lower-extremity amputation. Individuals with DPN have diminished plantar sensation and exhibit abnormal peak foot pressure while walking, however, a direct connection between plantar pressure and extent of plantar sensation loss has not been entirely explored. Further, research has shown that environmental factors such as stair gait and insoles affect dynamic balance of healthy aging individuals, therefore individuals with DPN may be even more risk. The objective of this dissertation was to examine the effects on balance, plantar pressure and foot sensitivity of individuals with DPN, while considering both intrinsic (health) and extrinsic (stairs and insole) factors.

The three studies that make up this dissertation provide another perspective of the contributions of various health characteristics have in relation to DPN, as well as provide insight into the role of stair gait and insoles on balance and plantar pressure.

Specifically, the first study investigated the severity of sensation loss and plantar pressure during stair gait, while taking into account relevant health factors. The study
also attempted to better understand factors that may best predict pressure using a hierarchical multiple regression model. This model was utilized to observe the contribution of diabetes related factors, above and beyond factors of age, body mass, and walking characteristics. The second study compared balance and plantar pressure between individuals with diabetes and pronounced sensation loss and a healthy age-matched group. The third study provided much needed understanding to how insoles may offload pressure and affect dynamic balance of individuals with diabetes during stair gait.

These studies provide insight into the role of health factors on plantar pressure and sensation, as well as provide a dataset of balance and pressure during the task of stair gait. The balance and pressure results suggest that individuals with diabetes may have exhibited a cautious walking pattern, compared to the control group. Further, commercial pressure offloading insoles worn by individuals with diabetes were no better in reducing foot pressure than normal insoles, during the specific task of stair gait.
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Co-Authorship

This dissertation contains material from submitted manuscripts (Chapters 3, 4 and 5). The intended authorship is as follows:


Chapter 4: Antonio PJ and Perry SD. Investigating stair gait balance control and plantar pressures of individuals with diabetes and pronounced sensation loss. Submitted September 2018.

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List of Abbreviations

AFO – Ankle foot orthosis
ANOVA – Analysis of variance
AP – Anterior-posterior
BG – Blood glucose
BMI – Body mass index
BOS- Base of support
CEAL – Challenging Environment Assessment Laboratory
CNS – Central nervous system
COM – Center of mass
COP – Center of pressure
CPO – Commercial pressure offloading
DPN – Diabetic peripheral neuropathy
DV – Dependent variable
EMG – Electromyography
EVA – Ethylene vinyl acetate
HBA1c – Haemoglobin blood glucose level
IWGDF – International Working Group of the Diabetic Foot
kPa – kilopascal
kPa ∙ s – kilopascal times seconds

ML – Medial-lateral

MT – Metatarsal

N.S. – Not significant

PS – Plantar sensation

PTI – Pressure time integral

PV – Predictor variable

RCW – Removable cast walker

ROI – Regions of interest

RP – Region pressure

SD – Standard deviation

SPSS – Statistical Package for the Social Sciences

ST – Stance time

SWM – Semmes-Weinstein monofilaments

TCC – Total contact cast

TP – Total pressure

UHN – University Health Network

VPT – Vibration perception threshold

WHO – World Health Organization
Chapter 1. Introduction

Diabetes mellitus is a metabolic disorder resulting from defects in insulin secretion, insulin action or both (World Health Organization, 1999). Globally, there are approximately 327 million adults suffering from diabetes, with an estimated 11 million in Canada with diabetes, or pre-diabetic symptoms (Danaei et al. 2011; Diabetes Canada 2018). Of the current estimates in Canada, about 5 to 10% have type 1 diabetes, and 90 to 95% have type 2 diabetes (Diabetes Canada 2018). Type 1 diabetes occurs due to the body’s immune system destroying the insulin-secreting pancreatic beta cells, which increase glucose level in the blood stream (Mahaffy and Edelstein-Keshet 2007; Diabetes Canada 2018). Whereas, type 2 diabetes is in consequence to inadequate insulin production by the pancreas, resulting in an excess build-up of glucose in the blood (Diabetes Canada 2018).

Long term consequences of diabetes are retinopathy which can lead to blindness (Olafsdottir et al. 2014; Henricsson et al. 1996), nephropathy (Harvey 2003), and increased risk of cardiovascular, peripheral vascular and cerebrovascular disease (Grundy et al. 1999; American Diabetes Association 2014). Peripheral neuropathy is another long-term consequence prevalent in approximately half of individuals with diabetes (Boulton et al. 2005). Diabetic peripheral neuropathy (DPN) is a somatosensory dysfunction that diminishes sensation within the feet, and can impact mobility, balance, and quality of life (Resnick et al. 2000; van Schie 2008). In fact, it has been postulated that individuals with neuropathy were fifteen times more likely to report an injury (such as a fall) compared to individuals with diabetes without neuropathy.
Cavanagh et al. 1992). Thus, reduced foot sensation may place individuals at a higher chance of developing various co-morbid issues.

Early findings revealed that foot ulceration is a big concern to individuals with DPN (Veves et al. 1992), with approximately 15% developing at least one ulcer during their lifetime (Pendsey 2010; Palumbo and Melton 1985). When left untreated, ulcerations become the most important risk factor for lower-extremity amputations, possibly leading to mortality (Moulik et al. 2003; Apelqvist et al. 1994). It has been established that plantar ulcerations form because of high repetitive foot pressure during gait (Tang et al. 2015; Frykberg et al. 1998; Veves et al. 1992). In addition, pressure-time integral (PTI), which measures the duration and magnitude of pressure contact during the stance phase of gait, have demonstrated increased risk of plantar ulcer formation (Maluf and Mueller 2003; Burnfield et al. 2004; Van Netten et al. 2018).

Abnormal peak foot pressure may occur as a result of changes to the individual, the environment, or the task. For example, when an individual develops a foot deformity such as claw toes, the bony prominence of the forefoot are exposed to pressure during gait (Bus 2008). Likewise, the environment of stairs has shown to increase an individual’s plantar pressure at the region of the toes and forefoot (Maluf et al. 2004). Moreover, the task of gait, specifically faster walking has been shown to increase peak foot pressure (Burnfield et al. 2004).

Independent mobility is of utmost importance to an individual and is necessary to accomplish many tasks. Mobility is defined as an individual’s purposeful movement within the environment (Ross et al. 2013), which includes the ability to stand up from a bed or chair, or to walk or run (Shumway-Cook & Woollacott, 2007). Another definition
of mobility extends to include the interaction with built environments, such as level ground, stairs and ramps (Clarke et al. 2008). The activity of stair gait is markedly different than other activities such as level walking, with noticeably altered gait patterns, kinematic elements of balance, and kinetic measures of force and pressure (McFadyen & Winter 1988; Zietz et al. 2011; Wervey et al. 1997; Rao and Carter 2012). Moreover, there is a potential risk for falling during stair gait as a fall from a height would be hazardous to an individual (Canadian Institute for Health Information 2015-2016; Startzell et al. 2000).

A framework used by Patla (1991) established that locomotion is characterized by three essential requirements: 1) progression of gait; 2) postural control of the body to maintain upright stability; and 3) adaptation to avoid obstacles and react to complex environments. Sensory information, specifically the somatosensory, visual, and vestibular contribute to the adaptation that is required for successful locomotion (Shumway-Cook & Woollacott, 2007). Further, the somatosensory system is important for upright balance as it provides sensory feedback for the control of movement (Perry et al. 2007). With a loss of sensory information, individuals with DPN may exhibit problems with dynamic balance, however; more investigation is required to understand balance during the activity of stair gait.

Plantar pressure is defined as the perpendicular force applied to the foot surface per unit area, while interacting with contact surfaces (Abdul Razak et al. 2012). An increase in plantar pressure may result in the formation of plantar ulceration; fortunately, footwear exists to mitigate this risk. Various footwear devices and designs may influence changes to plantar pressure and gait behavior. For individuals with DPN, the
main goal of footwear is to offload foot pressure and reduce the risk of developing ulcerations (Bus et al. 2008). Footwear devices such as the total contact casts (TCC), removable cast walkers (RCW), orthopaedic shoes, and insoles are commonly prescribed by clinicians to reduce the pressure under the foot (Fleischli et al. 1997). While these devices can offload pressure, individuals may prefer another alternative based on appearance, mobility or cost. Commercial prefabricated insoles are a convenient substitute that may also offload pressure. With insoles, the priority has been to offload pressure, while the balance implications have often been unexamined. With few studies to suggest insoles and their material properties affect balance (Perry et al. 2007; Menant et al. 2008), it is worth investigating the influence of insoles on plantar pressure and dynamic balance for individuals with DPN. To date, limited work has focused on understanding both balance and pressure of individuals with DPN. Further research is needed to determine the intrinsic factors and extrinsic influences on balance and plantar pressure.

1.1. Dissertation Outline and Intent

The preceding overview demonstrates the ongoing research of intrinsic and extrinsic factors that influence pressure distribution and plantar sensation for individuals with diabetes during stair gait. It also highlights the need for more evidence-based research of commercial prefabricated insoles during stair gait. Within this context, the first aim of this thesis is to explore various health related factors that may explain the changes to foot pressure and plantar sensation loss. Specifically, this dissertation will include a model of factors that may account for plantar pressure change of individuals
with diabetes. This dissertation will also expand the current literature regarding dynamic balance of individuals with diabetes and pronounced sensation loss during stair gait. Lastly, the effect of commercial insoles will be examined by the adoption of a biomechanical approach to measure whole-body balance and plantar pressure distribution during stair gait.

Chapter 2 of the dissertation provides a comprehensive review of the current literature regarding diabetes, peripheral neuropathy, stair gait, and insoles. In addition, measures of dynamic balance and plantar pressures will be discussed.

To address the primary objectives of this dissertation, several studies were conducted and are presented in Chapters 3 – 5. Chapter 3 titled “An examination of health factors that influence plantar pressure and sensation of individuals with diabetes” is the first study of the dissertation and investigated the severity of sensation loss and plantar foot pressure of a group of individuals with diabetes and varying plantar sensation loss. This study also explored the relationship of factors such as age, body mass index, blood glucose level, walking stance time, with respect to plantar sensation. Lastly, the study considered these variables to indicate plantar pressure using a hierarchical linear regression model.

Chapter 4 of the dissertation titled “Investigating stair gait balance control and plantar pressures of individuals with diabetes and pronounced sensation loss”, focused on the effects of stair gait on dynamic balance and plantar pressure. These outcome measures were examined while comparing individuals with diabetes and pronounced plantar sensation loss with an age-matched group without diabetes and sensation loss. Most importantly, this study explored the dynamic balance during stair
gait using center of mass – base of support (COM – BOS) temporal stability margin, a measure that has seldom been utilized in dynamic gait research (Pai & Patton 1997).

The third study in Chapter 5 of the dissertation titled “Commercial Pressure Offloading Insoles: Dynamic stability and plantar pressure effects while negotiating stairs” was dedicated to the investigation of commercial prefabricated insoles, marketed as insoles that provided pressure offloading for individuals with diabetes. To understand the influence of the insoles, the study recorded overall plantar pressure and foot pressure at specific regions of interest (ROI). The study also compared the influence of these insoles on balance, a new concept for commercial prefabricated insoles.

The dissertation concludes with a general discussion of the project.
1.2. References


Diabetic peripheral neuropathy (DPN) is defined as a dysfunction of the peripheral nerves that limit sensation of the limbs (Argoff et al. 2006). DPN has been known to display symptoms of pain, tingling, and numbness, however, this varies from 11% to 32% of individuals (Ziegler et al. 1992). In severe cases DPN may cause burning pain, significant muscle atrophy, and paralysis (National Institute of Health, 2014). DPN has been suggested to affect the body in an ascending pattern, often presenting pain and numbness symmetrically in the feet, followed by progression up the legs (National Institute of Health, 2014). It has been established that the etiology of neuropathy is commonly due to a combined effect of hyperglycemia and nerve ischemia (Pendsey 2003; Bowker & Pfeifer 2001). The high level of glucose in the blood particularly in the vasa nervorum, small arteries that supply blood to peripheral nerves, decreases capillary blood flow resulting in poor nerve perfusion and endonural hypoxia (World Health Organization, 1999). In other words, the peripheral nerves are damaged because they are not getting sufficient oxygenated blood.

Peripheral neuropathy may target various nerves, such as the sensory, motor, and autonomic, and affect different systems of the body. Sensory nerves function to transmit information about touch, vibration, pain, or sense of position. Damage to the sensory nerves can result in abnormal sensation, such as pain or numbness. The motor nerves are responsible for the motor control of deliberate tasks, such as walking, grasping, reaching, and balance. Damage to this system may result in intrinsic foot muscle atrophy, prompting the development of foot structure deformities. Autonomic nerves control the regulation of organ function such as the lungs, heart, and glands.
Dysfunction in this autonomic control may lead to abnormal blood flow to the feet, and reduced function of the sweat glands callusing the feet (Tesfaye et al. 2010; National Institute of Health, 2014; Boulton et al. 2005; Vinik et al. 2003). The combination of these factors place an individual with DPN at risk for developing foot ulcerations since dry callused feet have been identified as high-risk sites for cuts, and reduced blood flow preventing adequate foot healing (Singh et al. 2005; Young et al. 1992).

2.1. The Progression of Diabetic Peripheral Neuropathy

Foot ulcerations, or cuts, are a common concern for individuals with DPN (Boyker & Pfeifer 2001). It has been estimated that foot ulcerations affect about 15% of individuals with DPN (Reiber et al. 1995), but more recent studies suggest that lifetime incidences may be as high as 25% (Singh et al. 2005; Lavery et al. 2003). Even after an ulcer has healed, the risk of recurrence is 40% after a median 126 days (Pound et al. 2005). A study by Apelqvist et al. (1993) revealed that of the 468 patients receiving foot ulceration treatment, 70% of patients developed new ulcers (within 5 years). The authors explained that prior ulcerations and the cumulative stress can be significant influencers to the formation of new ulcerations. This highlights that even with reduced plantar pressure; the plantar tissue is still susceptible to injury at low levels of stress due to the cumulative pressure (Bacarin et al. 2009; Maluf and Mueller 2003; Apelqvist et al. 1993).

If improperly managed, foot ulcerations may lead to infections, gangrene, and potentially amputations (Sohn et al. 2010). Early estimates suggest that 5 – 15% of
individuals with diabetes require lower-extremity amputations within their lifetime (Lavery et al. 1996; Lavery et al. 1999), while a more recent study suggest estimates closer to 15 – 20% (Pendsey 2010). In addition, patients with diabetes are 15 to 46 times more likely to have an amputation than patients without diabetes (Reiber et al. 1995). Economic cost analyses revealed that foot lesions and subsequent amputations are extremely costly complications to diabetes (Stockl et al. 2004; Apelqvist et al. 1994), which underscores the necessity for ulcer prevention. Aside from developing ulcerations and amputations, individuals with DPN may still encounter various other issues. Having DPN was found to be an independent fall risk factor among the elderly in the community (Menz et al. 2004; Schwartz et al. 2002) and nursing homes (Maurer et al. 2005). Increased falls risk has also been associated with poor health-related quality of life (Hamdan & Hailes 2011; Ahmed 2017).

2.1.1. Diagnosis of DPN

Early diagnosis of neuropathy is critical as this allows individuals an opportunity to prevent the development of ulcerations. Neuropathy diagnosis can be detected through various techniques, with the optimal method being nerve conduction (Dyck 1997). However, this technique may not be feasible during outpatient settings when financial cost and time are limited (Perkins & Bril 2003). More convenient quantitative sensory tests such as the vibration perception threshold (VPT) and the monofilament sensation test can detect neuropathy, both of which were found to be significantly correlated, with high specificity (93%) (Jayaprakash et al. 2011). VPT is a common and inexpensive tool to test vibratory sensation for the diagnosis of peripheral neuropathy.
As revealed in previous studies, high VPT values are independent predictors of high ulceration (Young et al 1994; Paisley et al. 2002). Foot sensation can also be measured by applying Semmes-Weinstein Monofilaments (SWM) to the plantar surface of the feet (See Appendix E-7). To administer this test, participants are reclined comfortably with their eyes closed, and monofilaments of varying thicknesses are applied to the bare feet. Loss of protective sensation is defined as the inability to sense the application of thick monofilaments (application of 10 grams of buckling force). SWM have been suggested to be the best for screening patients with neuropathy as it is useful in detecting the risk of ulceration and amputation (Tan 2010; Feng et al. 2009; Boyko et al. 1999; Olmos et al. 1995).

2.1.2. Prevention and management of DPN

Inherently, the prevention strategies used for DPN is similar to the prevention strategies for overall diabetes. The two most important modifiable risk factors of diabetes development are obesity and physical inactivity (Knowler et al. 2002). Research by Mitsuhashi et al. (2017) showed that overweight individuals with abdominal obesity were associated with higher risk of developing diabetes compared with non-overweight individuals. According to the World Health Organization (2000), body mass index (BMI) has been recognized as a proxy for obesity due to the practical approach in clinical and epidemiological setting. Thus, a focus on proper diet and nutrition, and physical activity will help reduce the likelihood of developing high blood glucose levels. With inaction, the blood glucose levels will continue to increase, and individuals may develop intermediate hyperglycemia or pre-diabetes (WHO 2006). Pre-diabetes is
diagnosed when an individual has high blood glucose level, but not yet high enough to be considered type 2 diabetes (Tabak et al. 2012). Moreover, there is a wide range of estimates from 5% (Nathan et al. 2007) up to 70% that suggest individuals with pre-diabetes progress to develop diabetes (Li et al. 2008). While incidence rates continue to be debated, it is clear the progression of diabetes brings about many complications.

Understandably, the longer an individual is suffering from diabetes and improper glycemic control, the higher the risk of developing neuropathy and other diabetes related complications (American Diabetes Association 2008; Lehto et al. 1996). Modifiable risk factors for the incidence of neuropathy have been known to include high body mass index, elevated blood glucose level, hypertension, sedentary lifestyle, and poor nutrition (Tesfaye et al. 2005; Bowker & Pfeifer 2001). Thus, regulation of these modifiable risk factors is critical. Along with monitoring these factors, individuals must also be mindful of the possibility of foot related complications.

There has been much research progress to understanding foot related complications and their role in modifying the distribution of pressure along the bottom of the foot. Foot deformities such as hallux valgus, or foot bunions, (Kernozek et al. 2003), and Claw or Hammer toes (Rodgers 1995) are complications that may directly influence pressure, as these structural deformities expose the bony prominences in the metatarsal region of the foot. Consequently these sites may influence callus build-up which may cause soft tissue to be less elastic and less able to redistribute plantar pressure effectively (Gefen 2003; Kwan et al. 2010).

Educating the patient is important to promote regular monitoring of the foot and effective self-care behaviour (Apelqvist & Larsson 2000). With consistent examination of
the foot, individuals can be watchful of the formation of calluses and foot deformities, preemptively diminishing the risk of foot ulcerations. Patient education also helps to emphasize the value of footwear and adherence in preventing the development of ulceration. It has been reported that for footwear to be effective, individuals must wear the footwear greater than 60% of the day, yet individuals with diabetes in one study only wore their prescribed footwear 42% of the day (Macfarlane & Jensen 2003). With a greater emphasis placed on footwear education, individuals may better adhere to their prescribed insoles.

For management of existing ulcerations, the focus shifts to preventing infection and adequate foot offloading at the ulcer sites (Cavanagh & Bus 2011). Specifically, healing time is the most important consideration for ulcer management, as these affect treatment cost and risk of infections. During the healing time, there is a high risk of ulcer recurrence if the area is not properly offloaded (Pound et al. 2005). Therefore, the prescription of appropriate footwear devices such as the TCC and the RCW, and the involvement of a health care professional can help prevent re-ulcerations, infections, and other foot complications (Armstrong et al. 2001; Caravaggi et al. 2000; Faglia et al. 2010). Like with prevention, ulceration management requires extensive patient education for treating foot ulcers and reducing the risk of re-ulceration and infection (Apelqvist & Larsson 2000; Ward et al. 1999). According to the International Working Group of the Diabetic Foot (IWGDF), the main objective of patient education is to change self-care behavior, enhance compliance, and enable patients to recognize potential foot problems (IWGDF 1999).
2.2. Stair Gait

Mobility is necessary to maintain independence and well-being. Mobility is defined herein as the ability to independently and safely move from one place to another, while taking into account built environments (Shumway-Cook & Woollacott, 2007). These mobility tasks include walking, running, transfers, sitting to standing. When taking into account the built environment, the ability to navigate stairs becomes an important factor in an individual’s independence. In Canada, as much as half of the individuals 65 years and older reported difficulties related to walking or climbing stairs, which is concerning since stair gait is one of the most common activities in our daily lives (Statistics Canada 2006).

The activity of stair gait involves a cyclical gait pattern of the lower limb with periods of stance and swing. The period spent in stance and swing during stair ascent and descent is similar to that of level gait at 60% and 40% (Livingston et al. 1991; Mena 1981). While the phases seem similar, the gait mechanics between level gait and stair gait are quite different. Unlike level gait where foot striking mechanics are characterized with a heel to toe stepping pattern, stair gait promotes a toe to heel foot stepping pattern (McFadyen & Winter 1988).

During stair ascent, the stance phase is subdivided into three parts 1) weight acceptance, 2) pull-up, 3) forward continuance, while the swing phase is subdivided into 1) foot clearance and 2) foot placement. During the initial sub-phase of weight acceptance, the body moves into an optimal position to be pulled up to the next step, in which the stance limb hip and knee are flexed, and the ankle is dorsiflexed. In the pull-up phase, stance limb hip and knee extend, and the ankle is less dorsiflexed to
progress the body from one step to the next subsequent stair surface. During forward
continuance, the stance limb fully extends at the hip and knee while the ankle moves to
a more plantar flexed position for forward propulsion. The body center of mass moves
forward, and the stance limb shifts into the swing limb. This first part of the swing phase
occurs with significant hip and knee flexion, and ankle dorsiflexion for successful foot
clearance. Lastly, the foot placement is accomplished with less flexed hip and knee, and
ankle dorsiflexion to position the foot on the surface (McFadyen & Winter 1988).

During descent, the stance phase is subdivided into three parts 1) weight
acceptance, 2) forward continuance, 3) controlled lowering, while the swing phase is
broken down into 1) leg pull-through, 2) foot placement. At weight acceptance, the
stance limb hip and knee are more extended, and the ankle moves from a plantar flexed
to a dorsiflexed position to control the step down from the height. In forward
continuance the hip and knee are more flexed, and the ankle is dorsiflexed for the
body’s center of mass to continue the motion of descent. There is a controlled lowering
of the body weight, in which the stance limb hip and knee are in a flexed position, and
the ankle is dorsiflexed. This limb shifts to the swing phase, where the leg swings
through to the subsequent lower step, exhibiting hip and knee flexion, and ankle
dorsiflexion. The swing limb prepares for the foot placement with the hip and knee
moving towards extension, and the ankle in plantar flexion (McFadyen & Winter 1988)
(Figure 2-1).

The negotiation of stair ascent and descent provides two distinct processes. For
stair ascent, there is considerable power produced involving the pulling and pushing of
the body through many concentric contractions of muscles, especially at the knee
during the pull-up phase, and the ankle during the forward continuance phase (McFadyen & Winter 1988). Stair descent requires greater eccentric control of lower limb extensor muscles during weight acceptance and is greatly dependent on gravity (Riener et al. 2002). For stair descent, the knee and ankle joint absorb energy, with the ankle joint playing a crucial role at the initial foot contact of the step, and during the propulsion (Picon et al. 2012).

Figure 2-1: Stair gait phases of (A) ascent and (B) descent. Reprinted with permission from Novak et al. 2010.
2.2.1. Balance implications

Falls are a leading cause of injury for adults between 20 – 64 years old, at 35%, and even greater for seniors 65 years and older, at 63% (Statistics Canada 2009-2010). As individuals get older, their cutaneous and pressure sensation diminishes, greatly affecting their balance control (Perry et al. 2008; Lord et al. 1994). According to the peripheral sensory neuropathy hypothesis, individuals with DPN experience diminished somatosensory information at the level of the feet, ankles, and legs, making them unstable (Bonnet & Ray 2011). The loss of plantar sensitivity has been independently associated with the risk of falling more than once a year and accounted for 3-6% of the relationship between diabetes and falling (Schwartz et al. 2002). It has been found that elderly women with diabetes, both in the community and in the home, were at higher risk of falling compared to individuals without diabetes (Schwartz et al. 2002; Maurer et al. 2005). Further, a comparative study of 878 adults with and without diabetes found that patients with diabetes had higher frequencies of falling (42% vs. 33.8%, albeit not statistically significant), and demonstrated worse clinical balance measures (Timed-Up and Go tests) versus patients without diabetes (Oliveira et al. 2012). Taken together, this demonstrates the impact diabetes may have on the prevalence of injury due to falls.

A report by the Canadian Institute for Health Information (2015-2016) revealed that unintentional falls made up about 31% of injuries resulting in hospitalization visits, and 13% of those causes were due to falling on and from stairs and steps. The activity of stair walking is a complex hazardous task that may place a variety of populations at risk of falling, especially during stair descent (Antonio & Perry 2014; Bosse et al. 2012; Zietz et al. 2011; Lee & Chou 2007), and in some instances, may even lead to an
increased risk of mortality (National Safety Council 2012; Startzell et al. 2000). A qualitative study of individuals with DPN found that most falls occurred because they misjudged the height of a step catching their toes (Paton et al. (2013). These findings suggest that both intrinsic and extrinsic factors play a critical role on an individual’s balance.

Early research on postural balance revealed that individuals with DPN had deficits in their ability to maintain postural balance compared to control groups. These balance differences were highlighted by greater body sway, faster mean velocity of their body (Uccioli et al. 1995; Boucher et al. 1995), and larger center of pressure (COP) excursions (Simoneau et al. 1995). While it may be argued that postural instability does not directly result in a fall, these measures may still provide a better understanding of one’s ability to control their upright posture. Moreover, dynamic gait studies have contended individuals with diabetes had more de-stabilizing gait demonstrated by their decreased walking speed and stride lengths compared to a control group without diabetes (Courtemanche et al. 1996; Mueller et al. 1994). This slower gait was suggested to be a function of increased attention to the cognitive process of walking due to their diminished sensation of their legs. When faced with more challenging motor tasks, individuals may be at higher risk of falling as their capacity to control their stability has reached its limit (Lajoie et al. 1993). The findings were later confirmed by Menz et al. (2004), where older people with DPN demonstrated a conservative gait pattern when walking on irregular surfaces, suggesting impairment to their stability. Interestingly, individuals with DPN were found to be fifteen times more likely than those without neuropathy to report an injury due to falling (Cavanagh et al. 1992), suggesting that
neuropathy may play a role in the incidence of falls. Further research findings corroborate this assertion, in which a prospective study found that older individuals with DPN had a high rate of falls while walking on irregular surfaces (Demott et al. 2007). In addition, findings by MacGilchrist et al. (2010) demonstrated a greater incidence of DPN among fallers (86%) compared to non-fallers. While these studies demonstrate the falls risk during dynamic tasks, balance measures were not directly examined.

Balance measures of center of mass (COM), and the COP are common indicators of dynamic balance (Doyle et al. 2007). COM is defined as the weighted average of the mass of each body segment in 3-dimensional space, and is a passive variable controlled by the balance control system (Winter 1995). During stair gait, the body’s COM moves in a typical pattern such that when the individual ascends and then descends the stairs, it is represented with an increase and decrease in the vertical direction (represented by the COM Z-coordinate) (Figure 2-2). Further, the medial-lateral oscillating movement of the COM (represented by the COM Y-coordinate) reflect the shifting of load between limbs. COP is defined as the weighted average of all the pressures over the surface of the area in contact with the ground. During the single leg stance of stair gait, the net COP lies within that one foot, however, when both feet are in contact with the ground, there are separate COPs for each foot, and the net COP lies between both feet (Winter 1995). Maintaining stability during gait is dependent on the ability to control the COM motion within appropriate limits to the COP (Mian et al. 2007). While, this COM-COP separation relationship has been conducted in healthy populations during stair gait (Zachazewski et al. 1993 Lee & Chou 2007; Mian 2007; Kim 2009), examination of individuals with DPN is lacking. Balance may also be
assessed using the COM relative to an individual’s base of support (BOS), where maintenance of stability is dependent on the control of the COM relative to constantly changing BOS during walking (Patla 2003). When the COM approaches the BOS limits, balance loss may be imminent, therefore a greater COM-BOS ‘stability margin’ may be indicative of better balance control (Figure 2-3).

In fact, one study by Perry et al. (2008) measured the COM-BOS of elderly adult individuals and falls frequency as they wore balance-enhancing insoles. When participants wore these insoles, their COM-BOS ‘stability margin’ was larger compared to when individuals wore normal insoles. Further to their point, participant falls data revealed that 9 of the 20 total individuals experienced one or more falls during the 12 weeks of the study while wearing normal insoles, compared to only 5 fallers while wearing balance-enhancing insoles. Although this study observed falls data, the researchers acknowledge that a larger sample size would be required to confirm these exploratory findings.

A recent stair gait study utilizing the COM-BOS measure examined a healthy aging population and found that older adults had smaller COM-BOS margins compared to younger adults (Antonio & Perry 2014). The findings provide evidence of balance discrepancies related to an aging population, thus balance risk for individuals with diabetes and pronounced sensation loss should also be observed.
Figure 2-2: Diagrammatic representation of the (A) COM displacements and (B) COM velocities during typical stair ascent and descent. X-coordinate represents anterior-posterior direction, Y-coordinate represents medial-lateral direction, and Z-coordinate represents the vertical direction.
However, simply investigating the spatial (position) components of balance may not provide a complete understanding of dynamic balance; the temporal element of the COM should also be considered (Pai and Patton 1997). The temporal COM-BOS stability margin highlights the time required to maintain balance and is defined as the time the body’s COM would reach the hypothetical BOS boundary if the individual did not adjust their COM trajectory (Hof et al. 2005) (See Appendix E-8). This measure accounts for the spatial displacement and the velocity of the COM. The combination of the spatial and temporal elements of the COM-BOS may be a useful measure of stability in dynamic gait.
2.2.2. Plantar pressure of individuals with DPN

Injurious falls are a hazard for individuals with DPN; however, a more prominent risk is the development of foot ulcerations. In the presence of neuropathy, elevated plantar pressures are strong predictors of subsequent ulcers (Masson et al. 1989). Further, the combination of high foot pressures and insensate feet demonstrate a strong association between abnormal vertical loads under the foot and a history of neuropathic ulcers (Veves et al. 1992; Boulton et al. 1983; Ctercteko et al. 1981). Ulcerations have been known to develop as a consequence of abnormal plantar pressure distribution which localizes higher than typical pressure at specific regions damaging the tissue, especially at the plantar side of the toes (Maluf et al. 2004; Apelqvist et al. 1989), metatarsal head regions (Maluf et al. 2004; Stess et al. 1997; Apelqvist et al. 1989), and the heel (Maluf et al. 2004). For individuals with DPN, this tissue breakdown becomes even more of a concern since their blood circulation may be compromised, reducing the oxygenation of blood to the tissue and subsequently delaying the tissue regeneration process (Pendsey et al. 2003). Further, metabolic processes of diabetes may affect the tissue structure and function, in which the increased glycosylation has been revealed to reduce tissue elasticity. This structural change has been thought to make the skin stiffer in the feet and may result in the reduced capacity of the skin to redistribute pressure effectively (Zilberberg 1998). While abnormal peak plantar (vertical) pressure is important to the development of ulceration, the shear stress (horizontal) during gait may also be an important factor. Shear stress occurs as a result of the foot interacting with the contact surface or shoe material producing friction and damage to the tissues (Delbridge et al. 1985). This concept was reflected in the concept of pressure gradients,
proposed by Mueller et al. (2005), in which the sharp change in pressure of the surrounding region adjacent to the peak (vertical) pressure may lead to shearing of soft tissues. Although research has proposed the importance of shear stress, conventional foot pressure measurement tools commonly only measure vertical pressure, and not shear (horizontal). Regardless, it is important to consider the mechanism of tissue breakdown and subsequent ulcer development as a result of foot plantar pressure.

Foot plantar pressure is the pressure field that acts between the foot and the support surface during everyday locomotor tasks (Abdul Razak 2012). Peak plantar pressure (kPa) can be defined as the maximum pressure generated on the plantar surface of the foot during gait. Pressure time-integral (PTI) (kPa·s) is another pressure measurement, defined as the product of the peak pressure over the time of gait, or the area under peak pressure time curve (Stess et al. 1997) (Figure 2-4). It has also been suggested that the time component to pressure is important, as it highlights the temporal behaviour of gait stepping and the accumulation of pressure (Hsi et al. 2002). The slower the individual walks, the more time is spent in foot stance and a greater change will be found in the PTI measurement. Maluf and Mueller (2003) took this temporal consideration one step further by multiplying forefoot PTI values and mean daily strides (via step counter) to estimate the daily cumulative stress on the plantar forefoot. This novel calculation took into consideration the task as a function of plantar pressure.
Research findings reveal that plantar pressure during stair walking is markedly different from other daily activities, such that stair walking generated significant higher pressures in the lateral forefoot compared to level walking (Wervey et al. 1997). Other research found that heel pressure was significantly offloaded during the task of stair descent compared to other daily activities, since stair descent limits the full weight acceptance placed on the heel (Lundeen et al. 1994; Rozema et al. 1996). A more recent study with young adults compared stair gait and level walking plantar pressure and found similar reductions in peak pressure at the heel and the forefoot. However, pressure time integral values of young adults during stair walking were elevated in the midfoot, forefoot, and big toe compared to level walking (Rao & Carter 2012).

Examining the influence of neuropathy during stair gait, one study found a reduction of...
peak pressure at the big toe during stair ascent than other daily tasks. Also, that overall stair walking resulted in lower plantar pressure compared to level walking (Guldemond et al. 2007). Conversely, one study found that the task of stair walking demonstrated an increase in the pressures in specific regions of the feet, particularly the toes and metatarsal heads (Maluf et al. 2004). Many of the authors concluded that the slower walking speed exhibited by the individuals with diabetes may have explained part of the difference in their pressure. This is an important consideration since plantar pressure is greatly influenced by walking speed, in which foot pressure increases because of faster walking speed (Burnfield et al. 2004; Hennig and Rosenbaum, 1991). Moreover, it has been previously established that walking speed is highly correlated with stance time; therefore, stance time should also influence foot pressure behaviour (Schwartz et al. 2008; Kirtley et al 1985). It is clear that pressures generated at specific regions of the foot are activity dependent, but plantar pressures may also be phase dependent, meaning the pressure distribution between stair ascent and descent may be dissimilar (Figure 2-5). Focusing on stair gait phases mentioned by McFadyen & Winter (1998), there may be regions exhibiting larger pressures than others.
Figure 2-6: Image of typical stair gait plantar pressure distribution during (A) stair ascent and (B) descent, taken from one participant’s trial. The stair ascent phases consist of right foot weight acceptance (A1), pull through (A2), forward continuance (A3), foot clearance (A4), and foot placement (A5). The stair descent phases consist of right foot weight acceptance (B1), forward continuance (B2), controlled lowering (B3), leg pull through (B4), and foot placement (B5).
2.3. Footwear devices as an intervention

Footwear can be utilized as a device to treat and manage various foot disorders. Footwear devices can consist of anything from shoes, insoles, ankle foot orthosis (AFOs), or casts (Bensoussan et al. 2015; Arts et al. 2014; Lavery et al. 2012; Cho et al. 2014; Ng et al. 2010; Armstrong et al. 2001). For individuals with diabetes, the main objective of footwear devices is to offload high foot pressure for ulceration prevention and/or maintenance of current ulcerations (Bus et al. 2008). Specifically, total contact casts and removable cast walkers are effective in ulcer healing (Beuker et al. 2005; Fleishcli et al. 1997; Caravaggi et al. 2000). These devices are effective in pressure offloading because the stiffness of the casts receiving the load redistributes the pressure away from the plantar region (Shaw et al. 1997; Armstrong et al. 2001; Begg et al. 2016). While these devices are considered gold standard in pressure redistribution, a survey of 895 US clinics revealed that less than 2% used TCCs for pressure offloading compared to shoes (41%) (Wu et al. 2008). In another survey, it was found that only 6% of patients with ulcers received TCCs (Fife et al. 2010).

Adherence to footwear devices are a problem because of difficulty with sleeping, driving a car, and reduced physical activity level. Further, the high visibility of wearing therapeutic shoes may be perceived with stigma and embarrassment (Johnson et al. 2006) and has been considered unsuitable for work or to a formal event (Knowles & Boulton 1996). While the TCCs and RCWs are effective in redistributing pressure, they have also been shown to increase the individual’s body sway, increasing their risk for falling (Lavery et al. 1998).
Alternatively, foot orthotic therapy has been a practical option for ulcer prevention. Orthotics or insoles are in-shoe devices intended to correct abnormal or irregular walking pattern (Whittaker et al. 2018). For foot insoles to be effective in ulcer prevention, they must accomplish specific objectives, one of which is to relieve areas of excessive plantar pressure (Paton et al. 2012; Janisse 1993; Tyrsell 1999).

2.3.1. Insole and pressure

Since each foot is different, insoles have become a suitable alternative for pressure offloading as they can easily cater to individual foot structure and function (Bus et al. 2004). Individuals with DPN must depend on clinician made custom insoles to adequately offload pressure. It has been understood that foot deformity (Piaggesi et al. 1998) and intrinsic muscle atrophy (Kumar et al. 2015) are strongly associated with peak pressure and foot ulceration. Thus, customized insoles are designed to offload pressure with individualized modifications based on the changing foot structure. A study examining pressure offloading of custom insoles, demonstrated 7 individuals with diabetes had reduced peak pressure at the first metatarsal head region, while another 7 cases did not show a difference compared to flat insoles (Bus et al. 2004). In a separate study, custom insoles with a metatarsal bar and a medial arch support were found to reduce the incidence of ulceration in the diabetic group who were at high risk of developing ulcerations (Rizzo et al. (2012)). Conversely, another study reported higher peak pressures when metatarsal bars were added into the insoles (Hastings et al. 2007). These contradicting findings suggest that custom insoles are only effective in pressure offloading if they adequately cater to the individual’s foot.
Unfortunately, manufacturing custom insoles are expensive and require clinical intervention. Alternatively, prefabricated (off-the-shelf) insoles are readily available, as they are general insoles available for purchase without specific modifications. A study conducted by Paton et al. (2012) found that custom-insoles were not significantly different than prefabricated insoles in pressure offloading, suggesting that cost effective prefabricated insoles should be considered as an alternative for individuals with DPN. In examining the market, there are countless prefabricated insoles available for purchase that claim to ameliorate various foot issues, unfortunately, many of these prefabricated insoles lack the evidence to back up their claim.

2.3.2. Insole and balance

Individuals with DPN utilize insoles for pressure offloading, while the influence of balance may be neglected. Various elements of the insole material have been shown to influence an individual’s balance system. It was revealed that when observing healthy adult populations, individuals who wore hard density insoles were associated with better balance, while wearing soft density insoles were thought to place an individual at risk of balance issues (Perry et al. 2007; Robbins et al. 1992). The soft insulating properties of the insole may dampen the individual’s ability to react to potential perturbations. Considering the peripheral sensory neuropathy hypothesis, individuals with DPN may be even more unstable because of the diminished somatosensory information at the level of the feet and ankles (Bonnet & Ray 2011). In support of this hypothesis, balance research confirms that individuals with DPN have significantly worse postural stability.
than their control counterpart (Simoneau et al. 1994; Uccioli et al 1995; Horak et al. 2002).

To date, there are limited studies that explore balance with respect to insoles. Two research studies created novel insoles with built-in vibrations to promote sensory feedback during postural standing. The findings revealed that individuals with diabetic peripheral neuropathy had improved body sway only during the eyes closed condition (Hijmans et al. 2008; Priplata et al. 2006). Another study tested novel shear-reducing insoles for balance on individuals with diabetes, and although no significant improvements in balance were found, the insoles did show a reduction in body sway, showing a trend to improvement (Wrobel et al. 2014). Lastly, various insole hardesses were tested on their influence on postural stability for individuals with diabetes and revealed there were no significant effect of insoles (Van Geffen et al. 2007). Interestingly, the insole hardness studies of a healthy adult population demonstrated significant balance constraints during gait, while postural insole studies of individuals with diabetes revealed no significant effect. These opposing findings reveal the importance of ongoing research into insoles and their material properties are necessary to understand the mechanism of the balance control.
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Chapter 3: An examination of health factors that influence plantar pressure and sensation of individuals with diabetes

3.1. Abstract

Introduction: Individuals with diabetes and peripheral neuropathy (DPN) are at risk of developing ulcerations due to diminishing sensation and higher than typical plantar pressure during gait. Modifiable risk factors for DPN include high body mass index and elevated blood glucose levels. The objective of this study was to 1) examine if severity of sensation loss may contribute to changes in plantar pressure distribution for individuals with diabetes, at plantar regions most impacted by stair gait, 2) examine the contribution of various health factors on the severity of sensation loss, and 3) understand if these specific health factors may help contribute to increased relative pressure during the task of stair gait.

Methods: Collected the self-reported health information (age, height, weight, and blood glucose) of individuals with diabetes and pronounced sensation loss (n = 14). Foot pressures and stance time were recorded during stair gait using pressure insoles placed inside standardized footwear. Correlation analyses and a hierarchical multiple regression was utilized to observe the contribution of the health factors to pressure distribution.

Results & Conclusion: Blood glucose levels ($r = 0.38; p < 0.001$) demonstrated significant, low positive relationship to plantar sensation. The hierarchical multiple regression utilizing these factors were statistically significant at the region of the big toe, medial MT and lateral MT, with $r^2$ changes of 10%, 22%, and 15% respectively. Finally,
the findings from this research study demonstrated that changes in relative pressure are associated with, and depends on changes to factors such as age, blood glucose level, stance time, and BMI.
3.2. Introduction

Peripheral neuropathy is often viewed as a ‘devastating chronic complication’, prevalent in half of the individuals affected with diabetes (Boulton et al. 2005; Sosenko 2009). The control of modifiable risk factors is essential for reducing the incidence of neuropathy. Consequently, individuals with DPN are fifteen times more likely than those without neuropathy to report an injury due to falling and may suffer from subsequent issues such as reduced mobility or foot complications (Cavanagh et al. 1992).

Aside from injurious falls, the risk of developing plantar ulcerations is also present because of the higher than typical pressures exerted on the plantar surface of the feet while walking (Tang et al. 2015; Waaijmann & Bus 2012; Wu et al. 2005; Frykberg et al. 1998; Veves et al. 1992; Stess et al. 1997; Armstrong et al. 1998). Moreover, the cumulative effects of repetitive high foot pressure may be an important factor in the development of ulcerations (Maluf & Mueller 2003). While research continues to explore level gait foot pressures, it is imperative to investigate the common activity of stair gait, as this provides another window into the foot pressure distribution during mobility.

High foot pressure is a key determinant in ulcer formation for individuals with DPN. However, the mechanisms of high pressure may be closely linked to diminishing plantar sensation. As one research study found, the abnormalities in foot sensitivity of individuals with DPN were correlated to increased pressures (Skopljak et al. 2014), however, diabetes-related factors such as body mass index and blood glucose levels were overlooked. While elevated blood glucose has not been found to directly influence pressure distribution under the foot, the contribution may still exist indirectly. It has been
established that an increase in blood glucose is directly linked to the development of neuropathy, and the presence of neuropathy combined with foot and gait changes may influence plantar pressure (Tang et al. 2015). Moreover, a comprehensive regression model by Morag & Cavanagh (1999) considered the change in foot structure and gait on the plantar pressure distribution, finding that foot structure influenced the model more than gait characteristics, but the combined (structural and functional) factors accounted for 49-57% of the variance in the overall model. In addition, other regression models focusing on the determinants of plantar pressure emphasized conventional clinical foot tests and change in foot structure (Payne et al. 2002; Menz & Morris 2006; Scott et al. 2007). Apart from the structural element of the foot, it is imperative to understand the influence of diminishing foot sensation on plantar pressure, while considering important diabetes-related factors.

High foot pressure can lead to the formation of ulcerations, yet the relationship of foot sensation to pressure has not fully been acknowledged, with limited focus on the extent of sensation loss and other relevant health factors of diabetes. The objective of this research study was to investigate the possible contributions between the severity of sensation loss (based on monofilament testing) and plantar foot pressure of individuals with diabetes during stair gait. Secondly, health factors such as age, body mass index (BMI), blood glucose level, walking stance time and their relationship to foot sensation were also considered. Lastly, while observing possible relationships between these health factors, it may be beneficial to investigate whether changes in foot pressure during stair gait may be associated with changes to BMI, age, walking stance time, plantar sensitivity, and blood glucose levels.
It was hypothesized that the sensitivity level of individuals with diabetes will highly correlate with increased pressures in the same regions of the foot during stair gait, specifically, with a reduction of foot sensitivity there will be an increase in foot pressure. Also, contributing factors such as age, BMI, stance time, and blood glucose levels will relate to diminished foot sensation, with blood glucose showing the highest contribution. Lastly, using a hierarchical multiple regression, it is hypothesized that the predictor variables blood glucose and plantar sensation would account for a significant amount of variance in pressure, over and above the contribution of age, BMI, and stance time during the task of stair gait.

3.3. Methods

Participants

Fourteen (14) individuals (6 female), age range of 52-77 years (mean = 64.6, SD = 7.4), with diagnosed type 1 or type 2 diabetes mellitus volunteered to take part in this research study. Individuals were purposively recruited from community regions within Toronto, and from various University Health Network (UHN) hospitals and clinics. Of the recruited individuals, 10 were participating in a diabetes education and exercise program at a clinic. Participant demographic information was collected and included sex, BMI, self-reported haemoglobin blood glucose levels (HbA1c) (Table 3-1). HbA1c reflects the average plasma glucose concentration for the last two to three months, and is expressed in % (American Diabetes Association, 2012). Participants were included if they reported to have physician diagnosed type 1 or type 2 diabetes, and reported some level of plantar foot sensation deficiencies, such as foot tingling, numbness, and/or pain.
Participants were screened and excluded if they reported medical, musculoskeletal, cognitive or vestibular impairments affecting their balance, prior injury (including foot ulceration) within the last 2 months, severe vascular disease (as diagnosed by their physician), and any other issues affecting their gait. In addition, individuals were excluded if they presented current foot ulcers or were currently wearing custom orthotics.

### Table 3-1: Participant Demographics (n=14)

<table>
<thead>
<tr>
<th>Age in years (SD)</th>
<th>64.6 (7.4)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex</td>
<td>8M, 6F</td>
</tr>
<tr>
<td>BMI (average, (kg/m(^2)) (SD)</td>
<td>29.9 (5.8)</td>
</tr>
<tr>
<td>Monofilament detected (Mean grams of target force) (SD)</td>
<td>3.51 (1.8)</td>
</tr>
<tr>
<td>Self-reported HbA1c Level (average %) (SD)</td>
<td>6.94 % (1.7)</td>
</tr>
</tbody>
</table>

**Plantar Sensation**

A plantar surface sensitivity test was conducted using Touch-Test® Sensory Evaluator Monofilaments (North Coast Medical, Inc. Gilroy, CA, USA) to confirm diminished plantar sensation (≥ diminished light touch). Participants were reclined comfortably with their eyes closed. Perceived sensation was obtained by applying the monofilaments randomized to four regions of interest (ROI): 1) big toe, 2) medial metatarsal (MT) head, 3) lateral metatarsal (MT) head, and 4) heel. Four different monofilament evaluator sizes were utilized. Inability to detect the 5.07 monofilament size indicated a loss of protective sensation and each evaluator size was equivalent to specific target force (buckling force in grams) (Table 3-2). Starting from the thickest size, the participant reported when they felt the pressure. The assessments were
repeated for each location, and 3 incorrect answers indicated a failure to detect the monofilament. Participant sensation scores were recorded for data analysis.

Table 3-2: Semmes Weinstein Monofilament Sensation Chart

<table>
<thead>
<tr>
<th>Evaluator Size</th>
<th>Target Force (g)</th>
<th>Plantar Thresholds</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.61</td>
<td>0.4</td>
<td>Normal</td>
</tr>
<tr>
<td>4.31</td>
<td>2</td>
<td>Diminished Light Touch</td>
</tr>
<tr>
<td>4.56</td>
<td>4</td>
<td>Diminished Protective Sensation</td>
</tr>
<tr>
<td>5.07</td>
<td>10</td>
<td>Loss of Protective Sensation</td>
</tr>
</tbody>
</table>

Study Protocol

Prior to the start of the study, a questionnaire was conducted to identify specific participant characteristics, which included existing foot deformities, body mass index (BMI) (kg/m²), reported HbA1c, health history of smoking, hypertension, and history of foot ulcerations. Classification of BMI was determined using the World Health Organization’s reported values (2004). After obtaining informed consent, participants were fitted with appropriately sized general athletic footwear (see Appendix E-6). Medilogic pressure sensors (Medilogic, Schonefeld, Germany) which demonstrated acceptable validity and reliability in vertical force measurements were placed between the participants’ foot and the insole (Koch et al. 2016) (see Appendix E-4). The study utilized a 7-step staircase called ‘StairLab’ (built in accordance to the National Building Code of Canada recommended stair design configuration) located inside the Challenging Environment Assessment Laboratory (CEAL) at the Toronto Rehabilitation Institute (Toronto, Ontario, CAN) (See Appendix E-1). For the experiment, the participants were instructed to walk up and down the stairway five times at their self-
selected pace, while being supported by a harness overhead in case of a fall.
Participants were given significant acclimatization time for the task. During the
experimental trials each step of stair ascent and descent was recorded and analyzed for
pressure data.

Data Processing

The pressure sensors measured pressure on the plantar surface of the foot
during each step of stair gait, specifically during the stance phase of gait. These insoles
contained between 160 to 200 individual pressure cells collected at a frequency of 60
Hz. The raw data values were used to calculate the total peak pressure (kPa), which is
the maximum value (across the entire foot) of each contact phase during stair gait. The
pressure time integral (kPa \cdot s) was also calculated from the raw data values as: $PTI = P_1 \times T_1 + P_2 \times T_2 + \ldots + P_N \times T_N$, where $P_1$ is the total pressure during the first frame of
the stance, $T_1$ is the time during the same frame of the stance, $P_N$ is the total pressure
during the last frame of the stance, and $T_N$ is the time during the final frame of the
stance (Tang et al. 2014). Individual pressure cells were grouped into 9 pre-determined
regions of the foot; 1) big toe 2) tarsals 3) medial metatarsals 4) central metatarsal 5)
lateral metatarsal 6) medial mid-foot 7) lateral mid-foot 8) medial heel 9) lateral heel
(Figure 3-1). The pressure analysis focused on specific regions of interests (ROI) most
impacted by stair gait (big toe, medial and lateral metatarsals, medial heel). All steps
and trials were inspected, and irregular and outlier data values were excluded from
analysis. The excluded data consisted of values outside $\pm 2$ standard deviations from
the mean, which typically fall outside the 95% percentile of data, and trials when
participants grabbed the handrails during the study experiment.
Figure 3-1: Foot regions of pressure cells based on 9 pre-determined regions, 1) big toe 2) tarsals 3) medial metatarsals 4) central metatarsal 5) lateral metatarsal 6) medial mid-foot 7) lateral mid-foot 8) medial heel 9) lateral heel.

Stance time was calculated from the initial time of foot contact to the time of lift-off of the same foot during the stance phase. The start time of foot contact occurred when the pressure threshold level was first above 5% of the maximum pressure value, and the end time of contact occurred when the pressure threshold level was last above 5% of the maximum pressure value:

\[
\text{Stance time} = \text{Step end time (s)} - \text{Step start time (s)}
\]

To understand pressures in a meaningful way, relative pressure (RP_x) was calculated by dividing the sum of the pressures (kPa) at each region (region_xP) (where x = region number), by the sum of the combined pressures (kPa) of all 9 regions (total_xP) during one frame of the trial, and then multiplying by 100 (Equation 1). Then the average relative pressure (RP_x) throughout each trial was determined by adding each RP_x value at each frame (n), (where n1 = frame number 1, n2 = frame number 2, n3 = frame number 3) and dividing by the total # of frames in the trial (N). Particularly, the
(RP_x)_n1 denotes relative pressure value at the first frame number, and the (RP_x)_N denotes the relative pressure value at the last frame number (Equation 2).

$$RP_x = \frac{region_x \cdot P_{total}}{total \cdot P} \times 100$$ \hspace{1cm} (1)

$$\text{Average } RP_x = \frac{(RP_x)_n1 + (RP_x)_n2 + (RP_x)_n3 + \ldots + (RP_x)_N}{N}$$ \hspace{1cm} (2)

Relative pressure at 4 of the 9 examined regions (big toe, medial MT, lateral MT, medial heel) were calculated for both feet at each trial. 3 to 5 accurate trials were used for each participant (14) (for a total of 128 observed trials) (Appendix A-3). The principles of this equation were derived from calculation of relative pressure by Zhang & Li (2013). The greater the RP (%) observed would indicate more overall pressures in that foot region.

The stair gait protocol consisted of ascent, turning at the landing platform, and descent. The full task of stair gait was observed for analysis to ensure the research design had high content validity to daily life, while also considering the cumulative effects of plantar pressure during the task.

*Statistical Analysis*

Data analysis was conducted using SPSS (v.23, IBM, SPSS). An independent samples t-test of stance time was conducted to compare between stair ascent and descent. Spearman’s correlations were conducted to observe the relationships of plantar sensation (g) and pressure (kPa, kPa·s). Respective Pearson and Spearman correlation analyses (based on parametric and non-parametric data) were conducted to examine the relationship between self-reported blood glucose level (Hba1C) (%), BMI.
(kg/m²), age (years), stance time (seconds) to plantar sensation of the foot of individuals with diabetes. A Pearson correlation was conducted to investigate the relationships of the predictor variables (BMI, age, stance time, blood glucose and plantar sensation) to the calculated relative pressure. Lastly, using the calculated value of relative pressure of each participant by trials, a hierarchical multiple regression analysis was conducted to predict factors such as blood glucose level and plantar sensation pressure, while controlling for BMI, age, and stance time. All tests were two-tailed and significant p value was set at <0.05. Mean and standard deviations (SD) were calculated for all variables. The interpretation of correlation coefficients was as follows: low (0 – 0.39), moderate (0.4 – 0.59), moderately high (0.6 – 0.79), high (0.8 – 1) (Feinstein, 1987).

3.4. Results

Mean participant data of pressure (peak and pressure time integral), touch-test sensation scores, BMI, age, and blood glucose level are provided in the Appendix A-4. An analysis of stance time revealed that stair ascent (0.92 seconds, SD 0.1) was not significantly different from stair descent (0.94 seconds, SD 0.1) (p = 0.52).

Correlation Outcomes

Correlation results of plantar sensation and pressure (peak pressure (kPa) and pressure time integral (PTI) (kPa ∙ s)), separated by walking direction (stair ascent and descent) and ROI (big toe, medial MT, lateral MT, medial heel) were reported in Table 3-3. Further, correlation results between plantar sensitivity and other health variables (BMI,
blood glucose, age, and stance time) were reported in Table 3-4. The significant result related to plantar sensitivity was plotted in Figure 3-2. Additional correlation plots of other variables can be found in Appendix E-9.

Table 3-3: Correlation results of plantar pressure and sensation. Correlation coefficient r values and p values of peak pressure and pressure time integral, separated by direction and regions of interest

<table>
<thead>
<tr>
<th></th>
<th>Peak Pressure</th>
<th>Pressure Time Integral</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>r</td>
<td>P value</td>
</tr>
<tr>
<td>Ascent</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Big Toe</td>
<td>-0.09</td>
<td>0.76</td>
</tr>
<tr>
<td>Medial MT</td>
<td>-0.05</td>
<td>0.87</td>
</tr>
<tr>
<td>Lateral MT</td>
<td>-0.09</td>
<td>0.76</td>
</tr>
<tr>
<td>Medial Heel</td>
<td>0.04</td>
<td>0.88</td>
</tr>
<tr>
<td>Descent</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Big Toe</td>
<td>-0.2</td>
<td>0.5</td>
</tr>
<tr>
<td>Medial MT</td>
<td>-0.08</td>
<td>0.78</td>
</tr>
<tr>
<td>Lateral MT</td>
<td>-0.19</td>
<td>0.5</td>
</tr>
<tr>
<td>Medial Heel</td>
<td>0.25</td>
<td>0.4</td>
</tr>
</tbody>
</table>

Table 3-4: Correlation analyses of variables during stair gait

<table>
<thead>
<tr>
<th></th>
<th>PS</th>
<th>BMI</th>
<th>BG</th>
<th>Age</th>
<th>ST</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plantar Sensation (PS)</td>
<td>-</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Body Mass Index (BMI)</td>
<td>0.15</td>
<td>-</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blood glucose level (BG)</td>
<td>0.38*</td>
<td>-0.09</td>
<td>-</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td>-0.14</td>
<td>-0.32*</td>
<td>-0.34*</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Stance Time (ST)</td>
<td>0.1</td>
<td>0.28†</td>
<td>0.28†</td>
<td>-0.61*</td>
<td>-</td>
</tr>
</tbody>
</table>

*Significantly greater at the level of p < 0.001
†Significantly greater at the level of p < 0.05
Regression analysis of relative pressure

A hierarchical multiple regression was performed to investigate whether diabetes related factors (plantar sensation and blood glucose levels) may be associated to relative pressure, after controlling for individual health factors (age and body mass index) and walking stance time. Recall, average relative pressure for each individual was calculated for each trial which resulted in a total of 128 trials. For full detail of data breakdown see Appendix A-4. Preliminary analyses were conducted to ensure no violation of the assumptions of normality, linearity, and homoscedasticity. Correlation data and regression models were separated by (4) region of interests (big toe, medial MT, lateral MT, medial heel). The correlations amongst the predictor variables were low.
to moderately high, ranging between $r = 0.28$, $p < 0.05$ and $r = -0.61$, $p < 0.001$ (Table 3-4). The correlations between the predictor variables (plantar sensation, blood glucose level, BMI, age, stance time) and the dependent variable (relative pressure) were low to moderate, ranging from $r = 0.16$, $p < 0.05$ to $r = 0.47$, $p < 0.001$ (Appendix A-5).

Four separate hierarchical multiple regressions were conducted. In each of the first step of the hierarchical multiple regression, three predictors were entered: BMI, age, and stance time. In the second model, entry of plantar sensation and blood glucose level were added to observe the unique contribution to relative pressure. For a summary of the regression model outcomes, see Table 3-5. (See Appendix A-6 for full details of regression model outcomes).

Table 3-5: Summary of regression model outcomes, separated by regions of interest.

<table>
<thead>
<tr>
<th>Region</th>
<th>Model 1</th>
<th>Model 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Big Toe</td>
<td>R</td>
<td>R²</td>
</tr>
<tr>
<td>Model 1</td>
<td>0.34</td>
<td>0.12</td>
</tr>
<tr>
<td>Model 2</td>
<td>0.47</td>
<td>0.22</td>
</tr>
<tr>
<td>Medial MT</td>
<td>R</td>
<td>R²</td>
</tr>
<tr>
<td>Model 1</td>
<td>0.41</td>
<td>0.17</td>
</tr>
<tr>
<td>Model 2</td>
<td>0.63</td>
<td>0.39</td>
</tr>
<tr>
<td>Lateral MT</td>
<td>R</td>
<td>R²</td>
</tr>
<tr>
<td>Model 1</td>
<td>0.47</td>
<td>0.22</td>
</tr>
<tr>
<td>Model 2</td>
<td>0.61</td>
<td>0.37</td>
</tr>
<tr>
<td>Medial Heel</td>
<td>R</td>
<td>R²</td>
</tr>
<tr>
<td>Model 1</td>
<td>0.23</td>
<td>0.05</td>
</tr>
<tr>
<td>Model 2</td>
<td>0.24</td>
<td>0.05</td>
</tr>
</tbody>
</table>
3.5. Discussion

The purpose of this study was to observe the contribution, if any, of plantar sensation to foot pressure of individuals with diabetes. The findings demonstrated there were no significant relationships between sensation and pressure (both peak and pressure time integral) which challenge the hypothesis that foot sensation loss may be connected to high foot pressures.

The findings of this study did not find that plantar sensitivity correlated with pressures exerted during stair gait. The design of this study initially intended to observe the various step of individuals with diabetes during stair gait, since each step may be subject to a level of variability as the task of stair gait consists of complex lower-limb movement to avoid uneven surfaces. However, further consideration of the steps as being independent were excluded from this analysis, and as a result the study had a low sample size. While this study did not find correlations, past research by Skopljak et al. (2014) demonstrated significant correlations between peak pressure and touch-test with 10g monofilaments, stating that patients with more significant changes to sensitivity had an increased value of plantar pressure. Perhaps, another reason for the insignificant results was this sample group demonstrated a low average sensitivity score (3.51 g of buckling force) compared to higher values presented by Skopljak et al. (2014).

This study also examined the contribution of the variables blood glucose level, age, walking stance time, and BMI to foot sensation. It was hypothesized these variables would be related to sensation loss in the plantar surface of the feet, with blood glucose showing the highest contributions. The study findings suggest that plantar sensation was associated with only blood glucose, \( r = 0.38, \ p < 0.001 \) where the
participants had higher than normal levels of HbA1c (6.94%). Individuals with diabetes are normally subject to abnormal sensation since the high blood glucose blocks adequate circulation to the feet resulting in poor oxygenation of the peripheral nerves (Pendsey et al. 2003). As evidence for this, Boulton et al. (2005) found that neuropathy was prevalent in half of the individuals with diabetes. This gives some indication of the importance of blood glucose monitoring for individuals with diabetes, and neglecting the regulation of blood glucose could possibly lead to further problems to the individual. It is worth noting that 71% (10/14) of the group were part of a diabetes education and exercise program, which provided patients with the resources and education to better control and monitor their blood glucose levels. Therefore, this sample group demonstrates a small subset of individuals with diabetes who actively participate in exercise for the regulation of their blood glucose level. It may be worth investigating a more representative population of individuals with diabetes who may have difficulties regulating their blood glucose level.

Finally, a hierarchical linear regression model was conducted to predict the foot pressures during stair gait. The dependent variable utilized for the model was the relative pressure, which represented the true nature of stair negotiation consisting of gait ascent, turning at the top of the staircase, then gait descent to the bottom of the staircase. Previous research studies have stressed the importance of identifying cumulative pressure under the feet over a prolonged period (Hsi et al. 2002; Maluf & Mueller 2003). Seldom used in the diabetic population, the concept of cumulative load has been explored in low back pain and knee osteoarthritis research, where the excessive and repetitive loads occurring over time may be critical in the development of
the injury (Coenen et al. 2013; Maly et al. 2013). Conventional methods of measuring load focused on one posture or activity, however the cumulative effects of an activity may better represent the impact it has on individuals. Most recently, Van Netten et al. (2018) examined cumulative plantar tissue stress of diabetic individuals and found that individuals with healed ulcers had a 25% reduction in cumulative plantar tissue stress. This consideration of cumulative load prioritizes the influence of frequency and repetition on pressure with respect to the activity.

The relative pressure across each trial was observed as the dependent variable for the hierarchical regression analysis. The regions at the big toe, medial MT and lateral MT demonstrated significant overall models. At the big toe, the first model demonstrated to be significant (F(3, 127) = 5.45, p < 0.05), where BMI and age significantly and uniquely predicted relative pressure by 12%, while the added contribution of diabetes related factors such as plantar sensation and blood glucose levels accounted for 22% of the overall variance in relative pressure (F(5, 127) = 6.81, p < 0.001). The standardized beta coefficient from the model demonstrated that age (β = -0.43) and blood glucose (β = -0.47) had stronger effects on relative pressure than body mass index, stance time, and sensation.

For the medial MT region, the first model was significant (F(3, 127) = 8.36, p < 0.001), where age and stance time significantly and uniquely predicted relative pressure by 17%, while the added contribution of plantar sensation and blood glucose levels accounted for 39% of the overall variance in relative pressure (F(5, 127) = 15.7, p < 0.001). In this model, the standardized beta coefficient demonstrated blood glucose (β =
0.58), age ($\beta = 0.43$) and stance time ($\beta = -0.31$) had stronger effects on relative pressure than body mass and sensation.

Lastly, for the lateral MT region, the first model was significant ($F(3,127) = 11.55, p < 0.001$), where body mass significantly and uniquely predicted relative pressure by 22%, while the added contribution of plantar sensation and blood glucose levels accounted for 37% of the overall variance in relative pressure ($F(5,127) = 14.3, p < 0.001$). The standardized beta coefficient demonstrated that blood glucose ($\beta = 0.50$) and BMI ($\beta = 0.35$) had stronger effects on relative pressure than the other variables.

Based on previous studies, it has been recognized that aging adults may suffer from plantar sensation loss (Yumin et al. 2016; Shaffer & Harrison 2007; Perry 2006), which may lead to high plantar pressures (Scott et al. 2007). Interestingly, the structure of the foot plays an important role in changes to the pressure distribution, in which bony structures and the absence of cushioning fat pad may contribute to higher pressures (Morag and Cavanagh 1999). As individuals get older the foot structure changes, which may consist of reduced plantar fat pads (Jahss et al. 1992a), atrophy of intrinsic foot muscles (Menz 2014), flattening of the longitudinal arch (Scott et al. 2007), and the development of foot deformities such as claw and hammer toes (Bus 2008). Moreover, a recent study found that the condition of diabetes may lead to greater intrinsic muscle atrophy and reduced plantar tissue thickness when compared to age-matched control individuals (Kumar et al. 2015). In fact, the physical structure of the foot could be a plausible explanation for why the model could not account for a greater variance. Previous regression studies on foot pressure demonstrated that soft tissue thickness in the metatarsal heads (Cavanagh et al.1997), foot deformity (Ahroni et al. 1999), and
muscle activity (Morag & Cavanagh 1999) may independently predict the variance in peak pressure. While our models explored health factors in pressure, these previous studies focused on structural components of the foot as influencers to pressure.

Some limitations of the study were that individuals with diabetes provided self-reported values of HbA1c blood glucose levels. Since it was not feasible to collect blood samples onsite, the researchers relied on the individuals to accurately report their blood glucose state. As such, there may have been a reporting bias closer to their desired levels possibly conveying less severe condition of their diabetes. Secondly, a larger sample size would help further elucidate the findings of this study, however feasibility of time and resources limited the recruitment of participants. Lastly, aside from peripheral neuropathy being a main factor of high foot pressures, joint mobility has also been found to produce high pressures in the feet (Rao et al. 2010). Due to research study design and feasibility, joint mobility was not assessed during the pre-screening process. While the study did not analyze joint mobility of the participants, the fact that participants were recruited from a diabetes exercise program may suggest conventional levels of mobility.

Although the study findings were not able to demonstrate large contributions of health factors to foot pressure, it brings attention the behaviour of pressure distribution at the great toe, medial metatarsal head, and the lateral metatarsal head during stair gait. With more focus on monitoring the health factors such as body weight and blood glucose and conducting regular sensation assessments during hospital and clinic visits, individuals may have a better chance of improving their overall health and reducing their chances of developing diabetes related plantar ulcerations. Furthermore, focusing on
the global task of stair gait and cumulative plantar pressure may help improve the understanding of the role of pressures on ulcer formation. Future studies should explore cumulative foot pressure of daily tasks over longer periods of time as it relates to diabetic peripheral neuropathy and ulcer development. Lastly, it is recommended that future research combine both structural elements of the foot and health related risk factors to predict foot pressures. The collection of simple, easily obtainable information regarding an individual's health along with structural foot changes may shed further information about foot pressure and provide an opportunity to recognize ulceration risk.

3.6. Conclusion

The study findings demonstrated that high blood glucose levels have a significant, low positive relationship to impaired plantar sensation. When the regions were separated for regression analysis, the big toe, medial MT, and lateral MT demonstrated that prediction of relative pressure to the health factors were significant during the task of stair gait. Finally, the findings from this research study demonstrated that changes in relative pressure are associated with, and depends on changes to factors such as age, blood glucose level, stance time, and BMI.
3.7. References


Chapter 4: Investigating stair gait balance control and plantar pressures of individuals with diabetes and pronounced sensation loss

4.1. Abstract

Background: Individuals with diabetes and peripheral neuropathy (DPN) have been known to have higher than typical plantar pressures, which may lead to complications such as foot ulcerations. Further, the reduced plantar sensation of individuals with DPN may place them at a great risk of falling. While stair gait is a common daily task, research concerning the balance control during this task is limited, especially in the diabetes population. Therefore, the purpose of this study was to investigate if there are differences in stair gait dynamic balance control and plantar pressure of individuals with DPN compared to an age-matched control group.

Methods: Twenty-nine individuals (14 individuals with diabetes and pronounced sensation loss; 15 age-matched healthy control individuals) were recruited to participate. Individuals were instructed to negotiate a seven-step staircase while being recorded with motion capture cameras and instrumented with pressure measuring insoles. Spatial and temporal elements of balance (center of mass-base of support) and plantar pressure (peak and pressure-time integral) were recorded.

Results: Individuals with diabetes displayed significantly lower peak pressure (62 kPa vs. 73 kPa, p < 0.05) and greater COM-BOS lateral minimum distances (0.11 m vs. 0.09 m, p< 0.001) than the control group. Further, the activity of stair descent produced greater peak pressure (70 kPa vs. 65 kPa, p < 0.001), and smaller COM-BOS lateral minimum distance (0.08m vs. 0.13 m, p < 0.001) compared to stair ascent.
Conclusions: Individuals with diabetes and pronounced sensation loss may have exhibited a cautious walking pattern as indicative of smaller foot pressure and better measures of stability. Further, stair descent generated greater pressure and worse balance than stair ascent, thus individuals should be mindful of the potential hazards of stair descent.
4.2. Introduction

The metabolic condition of diabetes brings about many complications, with peripheral neuropathy (DPN) being a primary issue. For individuals with DPN, diminishing foot sensation has been closely linked to the formation of foot ulcerations on the plantar feet (Frykberg et al. 1998; Stess et al. 1997; Veves et al. 1992). Also, high plantar pressures for individuals with DPN strongly predict the formation of ulceration (Veves et al. 1992). Aside from developing foot ulcers, individuals with DPN are also at an increased risk for falling because of poor proprioceptive control from their supporting feet (Ghanavati et al. 2012; Kanade et al. 2008). A longitudinal study surveyed 77 elderly individuals with diabetes and found the incidence of falling was 39%, with possibly higher values due to the likelihood of underreporting (Tilling et al. 2006). These falls can be attributed to proprioceptive and cutaneous sensation loss, lower-limb muscle weakness (Suzuki et al. 2000; Andersen et al. 2004), and environment obstacles.

Although stairs are very common in daily life, research of individuals with DPN during stair gait is limited. A recent study explored the spatial balance element of individuals with intact sensation. It was revealed that older adults demonstrated a reduced ability to control their COM balance during the activity of stair gait compared to younger adults (Antonio & Perry 2014). With the understanding that aging adults have diminishing foot sensation and problems with their balance (Perry 2006), it is worth investigating how individuals with diabetes and sensation loss may also be affected with balance problems.
In the task of stair gait, the literature review demonstrates the contradicting findings of plantar pressure. For DPN, considerable attention is placed on foot pressure offloading for the prevention of ulcerations. Diminishing plantar sensation poses a significant balance risk during stair gait and should also be explored. Therefore, the purpose of this study was to investigate if differences exist in stair gait dynamic balance control and plantar pressure of individuals with DPN compared to an age-matched control group. It was hypothesized that the DPN group would exhibit increased plantar pressure versus the age-matched control group. It was additionally hypothesized that individuals with diabetes would demonstrate a reduced spatial COM-BOS stability margin, and a shortened COM time to reach the BOS.

4.3. Methods

Participants

The research study consisted of 29 participants (14 = diabetic, 15 = age-matched control) for data analysis (see Table 4-1 for participant characteristics). The test group consisted of individuals diagnosed with diabetes (type 1 or type 2) and displaying symptoms of peripheral neuropathy based on monofilaments applied to the plantar surface of the feet, using Touch-Test™ monofilaments (North Coast Medical, Inc. Gilroy, CA, USA). Prior to the experiment, participants were screened and excluded if they reported medical, musculoskeletal, cognitive or vestibular impairments that affected their balance or gait. Diabetic participants were excluded if they presented foot ulcers or were dependent on wearing custom orthotics. Participants provided written
informed consent prior to the experiment and the protocol was approved by the Institutional Ethics Review Board.

<table>
<thead>
<tr>
<th>Table 4-1: Participant Characteristics</th>
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</thead>
<tbody>
<tr>
<td></td>
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<tr>
<td>Diabetes</td>
</tr>
<tr>
<td>Control</td>
</tr>
<tr>
<td>Significance (p value)</td>
</tr>
<tr>
<td>N</td>
</tr>
<tr>
<td>Males</td>
</tr>
<tr>
<td>Age mean (SD)</td>
</tr>
<tr>
<td>BMI (Average) (SD)</td>
</tr>
<tr>
<td>Sensation loss (N=)</td>
</tr>
<tr>
<td>Monofilament size detected</td>
</tr>
<tr>
<td>(mean grams of force) (range)</td>
</tr>
<tr>
<td>Self-reported HbA1c (mean %) (SD)</td>
</tr>
<tr>
<td>Stance time (SD)</td>
</tr>
</tbody>
</table>

*Study Protocol*

After obtaining informed consent, participants had anthropometric measurements taken (height, weight, foot tracing). Participants were instrumented with reflective markers placed on anatomical landmarks using a modified marker setup by Winter (1995), while being recorded by infrared motion capture cameras (Motion Analysis, Santa Rosa, California, USA) for the duration of their stair navigation (20 seconds) at a sampling frequency of 250 Hz (See Appendix E-3). Pressure insoles (Medilogic, Schonefeld, Germany) were placed inside standard athletic footwear (provided to the participants) of varying sizes (see Appendix E-5 and E-6). These pressure insoles recorded the duration of the participant’s stair navigation at a sampling frequency of 60 Hz. At their self-selected pace, participants ascended then descended ‘StairLab’, a 7-step staircase (10 times) located in the Challenging Environment Assessment...
Laboratory (CEAL) at the Toronto Rehabilitation Institute (Toronto, Ontario, Canada) (See Appendix E-1). The staircase design followed the dimensions set out by the National Building Code of Canada. Participants were given adequate acclimatization time with the equipment (10 to 15 minutes) and rest periods (3 to 5 minutes) between the blocked trials to prevent fatigue. For safety, participants were outfitted with a harness to arrest any potential falls.

Outcome Measures

The research study measured the individual’s dynamic balance, by calculating the relationship of the COM-BOS ‘stability margin’ (m) during the single stance phase of stair gait. The individual’s COM was calculated using a segmental weighted average of seven segments of the body (Figure 4-1), which is a simplified COM calculation derived from Winter 1995. In addition, the BOS border was determined using the 5th metatarsal head and the heel reflective markers (Figure 4-1). Once those two calculations were obtained, the minimum lateral distance of the COM relative to the BOS during the single stance phase of stair gait was determined. Measurements of dynamic balance was also measured using the temporal stability margin (τ) (See Appendix E-8). (For full methodology, see Hof et al. 2005).
Figure 4-1: COM 7-segment calculation using 12 markers. Segments consisted of the 1) head, 2) thorax and arms, 3) pelvis and abdomen, 4) right thigh, 5) left thigh, 6) right shank, and 7) left shank. The box demonstrates how the BOS lateral border was determined using the 5th metatarsal marker and the heel marker.

Another primary measure obtained was the plantar pressure distribution expressed as peak pressures (kPa), and the pressure time integral (kPa·s). The peak pressure was defined as the maximum pressure placed on the pressure sensor cells during the single stance of gait, while the pressure time integral (PTI) was defined as the product of the peak pressure and time. Individual pressure cells (consisting between 160 – 200) on the insole sensors were grouped and defined into 9 regional masks including: 1) big toe 2) tarsals, 3) medial metatarsal, 4) central metatarsal, 5) lateral metatarsal, 6) medial mid-foot, 7) lateral mid-foot, 8) medial heel, and 9) lateral heel (Figure 3-1).
Consecutive foot stance times (seconds) were recorded for stair gait ascent and descent. Participant mean values were obtained and used for analysis, which consisted of averaging each recorded step during the stance phase of gait for all 10 trials of each participant. In addition, the steady state of stair gait, represented as middle of the stairs (steps 3 to 6), was the phase of interest for both ascent and descent of stair gait. All steps and trials were inspected for irregular data and were excluded from analysis. Outlier data values ± 2 standard deviations from the mean, which typically fall outside the 95% percentile of data were also inspected for exclusion from analysis. In addition, trials in which participants were holding the handrail were excluded from overall group comparisons.

**Statistical Analysis**

Two-way repeated measures analysis of variance (ANOVA) was conducted using SPSS (v.23, IBM, Chicago IL) to allow for comparisons between the two groups (diabetes vs. age-matched control), and direction (ascent vs. descent). Outcome measures from individual mean values of balance (spatial and temporal COM-BOS), pressure (peak and pressure time integral) were considered for analysis. Data variables followed a normal distribution (Shapiro-Wilk Test) and variances were homogeneous (Levene’s Test). Independent samples t-tests were also conducted to compare differences in group characteristics, gait parameters, and foot sensitivity. Significance was set at p < 0.05.
4.3. Results

Differences in group and gait parameters

The results demonstrated that when comparing age, there were no differences between diabetic and age-matched controls (p = 0.56). Gait parameters of stance time (p = 0.14) were similar for both groups. In addition, stair walking direction showed no differences in stance time (p = 0.6) between stair gait ascent and descent. Group comparisons of foot sensitivity showed that individuals with diabetes detected significantly larger monofilaments (mean = 3.51 g, SD = 1.8) than age-matched control (mean = 2.11 g, SD = 1.1), t(27) = -2.59, p = 0.02) (Table 4-1).

Plantar Pressure

In comparing groups (diabetes vs. control), a main effect was found F(1, 14) = 10.35, p < 0.05, where individuals with diabetes had significantly lower peak pressure (mean = 62 kPa, SD =18.1) than the control group (mean = 73.3 kPa, SD = 14.9). A main effect of direction was also found F(1, 14) = 19.58, p < 0.001, where stair descent had significantly greater peak pressure (mean = 69.8 kPa, SD = 17.8) than stair ascent (mean = 65.4 kPa, SD = 17.1) (Table 4-2). Interaction effect between group and direction were not statistically significant (p = 0.8).

For pressure time integral analysis, a significant main effect of direction was found F(1,14) = 21.12, p < 0.001, where PTI was significantly greater during stair ascent (mean = 44.6 kPa·s, SD = 19.8) than stair descent (mean = 33 kPa·s, SD = 13) (Table 4-2). Lastly, the interaction effect between group and direction were not statistically significant (p = 0.72).
Table 4-2: Main effects of plantar pressure (peak (kPa) and pressure time integral (kPa·s)), and balance measures (COM-BOS spatial lateral minimum (mm), COM-BOS temporal anterior-posterior (seconds) and medial-lateral seconds).

<table>
<thead>
<tr>
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<th>Pressure Outcome Measures</th>
<th>Balance Outcome Measures</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Peak Pressure</td>
<td>Pressure Time Integral</td>
</tr>
<tr>
<td></td>
<td>Mean (kPa)</td>
<td>SD</td>
</tr>
<tr>
<td>Group</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diabetes</td>
<td>62</td>
<td>18.1</td>
</tr>
<tr>
<td>Control</td>
<td>73.3†</td>
<td>14.9</td>
</tr>
<tr>
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<td></td>
</tr>
<tr>
<td>Ascent</td>
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<td>17.1</td>
</tr>
<tr>
<td>Descent</td>
<td>69.8*</td>
<td>17.8</td>
</tr>
</tbody>
</table>

*Significantly greater at the level of p < 0.001
†Significantly greater at the level of p < 0.05

**Balance**

With respect to the COM-BOS lateral minimum distance (m), a main effect of group (diabetes vs. control) was found, $F(1, 14) = 16.53$, $p < 0.001$, where individuals with diabetes had significantly greater COM-BOS lateral minimum distance (mean = 0.11 m, SD = 0.02) than the control group without diabetes (mean = 0.09 m, SD 0.04). The main effect of stair gait direction was also significant, $F(1, 14) = 114.68$, $p < 0.001$, where the COM-BOS lateral minimum distance was significantly smaller during stair descent (mean = 0.08 m, SD = 0.03) than stair ascent (mean = 0.13, SD = 0.02) (Table 4-2). A significant interaction was found $F(1, 14) = 21.91$, $p < 0.001$, demonstrating that the control group during the task of stair descent displayed the smallest COM-BOS lateral minimum distance compared to the diabetes group (Figure 4-1).
In comparing the temporal COM-BOS medial-lateral stability margin (seconds) of group, and stair gait direction, no significant main effects were found. In contrast, the temporal COM-BOS anterior-posterior stability margin (seconds) of group and stair gait direction demonstrated a significant main effect of direction, $F(1, 14) = 7.63$, $p < 0.05$, where stair ascent had significantly longer time (mean = 0.24 s, SD = 0.03) than stair descent (mean = 0.23 s, SD = 0.02) (Table 4-2).

In comparing between group and stair gait with respect to the temporal COM-BOS medial-lateral stability margin, there were no significant interactions found ($p = 0.21$). However, for the temporal COM-BOS anterior-posterior stability margin, a significant interaction was found between group and direction, $F(1, 14) = 11.11$, $p < 0.05$. For the control group, stair ascent demonstrated the longest COM-BOS time, while demonstrating the shortest COM-BOS time during descent (Figure 4-2).
4.4. Discussion

The purpose of this study was to observe the plantar pressure and balance of individuals with diabetes during the mobility task of stair gait. The findings of the study challenge the hypothesis that individuals with diabetes would demonstrate greater pressure than age-matched controls. In addition, balance results contradict the hypothesis that individuals with diabetes would demonstrate a reduction in COM-BOS 'stability margin', and a shorter time to respond to COM-BOS balance issues.

To our knowledge, this is the first study to directly observe plantar pressure of individuals with diabetes during the task of stair gait. The pressure findings showed that individuals with diabetes had reduced peak pressure (kPa) compared to the age-matched control group. This demonstrated that individuals with diabetes exhibiting
pronounced sensation loss are no more at risk than the group without diabetes of developing future ulcerations during stair gait. Presumably, individuals with diabetes were aware of their diminishing foot sensation, and as a result may have walked more cautiously to minimize their mobility risk. As demonstrated in level gait research, when a healthy individual’s plantar sensation is temporarily reduced through ice immersion, there was a reduction of lower limb muscle electromyography (EMG) activity and foot contact forces, demonstrating a more cautious walking pattern (Eils et al. 2004). In addition, studies involving individuals with DPN demonstrated cautious walking behaviour during level gait with a reduction of vertical and horizontal ground reaction forces both at loading and push-off compared to healthy controls (Sacco & Amadio 2000; Katoulis et al. 1997; Mueller et al. 1994). For this study, only plantar pressure was obtained, therefore the vertical and horizontal ground reaction forces during stair gait were not observed. Conversely, in a study of foot and ground interaction during stair negotiation, the authors found that overall medial-lateral ground reaction forces were greatest during stair gait over level ground (Hamel et al. 2005). It can be assumed that since stair gait is a more treacherous activity, individuals may be exhibiting increased horizontal ground reaction forces during stair gait as a strategy to better control their body. With larger shear forces acting on the foot, there should consequently be a reduction of vertical ground reaction forces. Since pressure is directly influenced by force, a reduction in force would also reduce the pressure.

In addition, this study found that the control group compared to the diabetes group may be demonstrating a constraint imposed upon their balance as demonstrated by a smaller COM-BOS stability margin. Recall, the ‘stability margin’ is defined as the
minimum distance of the body’s COM relative to the individuals BOS in the lateral direction. With a smaller margin, the COM is closer to the BOS lateral border indicating that the individual may have a decreased ability to control the movement of their body in the lateral direction. In this instance, individuals with diabetes may have had better spatial control of their COM affording them with a more cautious stepping strategy during stair gait. Although, no falls occurred for either group, this COM-BOS relationship accentuates the sensitive changes to balance control with respect to the complexities of stair gait.

The present study found that individuals descending the stairs produced higher peak pressures compared to stair ascent. As highlighted by McFadyen & Winter (1988), stair ascent and descent mobility are biomechanically different. Stair descent depends greatly on gravity and leg extensor muscles to control the lowering of the body’s full weight down to the lower level (Riener et al. 2002; McFadyen & Winter 1988). Conversely, stair ascent requires coordinated concentric propulsion from the lower limbs to pull and push the body forward. It has been suggested that concentric contractions demand higher muscle strength production to overcome the individual’s body weight, while eccentric contractions require less EMG activation (Onodero et al. 2011). For this study, perhaps descent promoted similar muscle activation behaviour to that of previous findings, leading to less controlled motion down the stairs and resulting in higher pressures. The present study also showed a difference in the pressure time integral, with stair ascent producing higher PTI values (kPa·s) than stair descent. Pressure time integral calculations focus on the cumulative effect of pressure during one step (Sauseng et al. 1999). These results show that the behaviour of the pressure
over time will be drastically different depending on the direction of the stair gait. The overall contact of the foot during ascent is greater, and as articulated by Eils et al. (2002) when pressure is distributed over a large surface, the peak pressures will dissipate. Since stair ascent stepping requires more overall foot contact, as shown by large pressure time integrals, this may further explain the reduction of peak pressure during ascent.

Lastly, the study found that descending the stairs produced a smaller COM-BOS 'stability margin' and a shorter anterior-posterior temporal COM-BOS stability margin, compared to stair ascent. The temporal stability margin represents the theoretical time the COM would reach the anterior BOS border if there was no interruption. Thus, a shorter anterior posterior temporal COM-BOS margin indicates balance may be worse since the body has a shorter time responding to maintain the COM position. This result corresponds with established findings that stair descent is a more challenging aspect to stair negotiation than ascent with about 75% of accidents or falls occurring during descent (Startzell et al. 2000; Svanstrom 1974). In non-diabetic individuals, stair gait studies focusing on center of pressure (COP) velocity suggested older adults produce slow COP velocities to combat the difficulties in maintaining balance during stair descent (Kim 2009). The slow speed of the COP may potentially allow for the dynamic balance to be controlled. Since COP and COM are highly correlated (Winter 1995), the present findings confirm the combined balance measures may signify that stair descent is worse for balance than stair ascent.
4.5. Conclusion

Individuals with diabetes and pronounced sensation loss may have demonstrated a cautious walking behaviour during stair gait with reduced peak pressures and improved ability to control the movement of their body. The complexity of stair gait may have been acknowledged by individuals with pronounced sensation loss. Furthermore, stair descent generates increased pressures and worse balance than stair ascent, confirming that the task of stair descent is problematic and necessitates further investigation.
4.6. References


Chapter 5: Commercial Pressure Offloading Insoles: Dynamic stability and plantar pressure effects while negotiating stairs

5.1. Abstract

Background: Diabetic peripheral neuropathy (DPN) is a dysfunction of the peripheral nerves that restricts sensation from feet, compromising an individual’s mobility and balance. Individuals with DPN generate elevated (from typical) values of foot pressure while walking often leading to tissue ulcerations, and lower-extremity amputations. Currently, there are commercial pressure offloading (CPO) insoles that claim to reduce foot pressure, and limit ulcer formation; however, the insoles’ capacity to reduce pressures during common activities have not been examined. The aim of this study was to observe the effects of various insoles on balance and plantar pressure while negotiating stairs, in individuals with diabetes.

Methods: Twenty-nine (29) participants (14 individuals with diabetes and plantar sensation loss, and 15 age-matched healthy individuals were instructed to traverse a seven-step staircase at the Toronto Rehabilitation Institute, while wearing three different CPO insoles, and one normal insole. Spatial and temporal balance (COM-BOS), and foot peak pressures (overall foot and regions of interest) were recorded using pressure insoles placed inside standardized footwear.

Results: Overall foot peak pressures across insoles were not significantly different. With respect to the (spatial) COM-BOS lateral distance, an interaction was found between direction and insole where the normal insoles had the smallest lateral distance (mean = 0.08 m) among all insole conditions during descent. The Aetrex (mean = 0.09 m) and
Prothotics insoles (mean = 0.09 m) during descent had greater lateral distances than normal insoles. Further, the temporal balance demonstrated shorter time while wearing normal insoles (1.7 sec) compared to Prothotics insoles (1.9 sec).

Conclusions: Commercial pressure offloading insoles worn by individuals with diabetes did not significantly offload pressure compared to normal insoles. With respect to balance, descending the stairs wearing normal insoles may place an individual at a greater risk of imbalance, while the Prothotics insole may prove to be a better option.
5.2. Introduction

Diabetic Peripheral Neuropathy (DPN) is a condition that reduces the sensation to the feet, affecting approximately 50% of individuals with diabetes (World Health Organization 1999; Boulton et al. 2005). This loss of foot sensation can result in postural instability leading to an increased risk of falls (Van Deursen 1997; Simoneau et al. 1994). Most research studies investigate foot pressures and stability independent of each other; however, there is a need to further investigate whether a relationship exists between stability and plantar pressure, especially during daily activities (Van Deursen 2008).

Stair negotiation is a common activity that requires coordinated and complex motor control to accomplish. Naturally, stair negotiation greatly affects foot pressure (Guldemond et al., 2007; Maluf et al., 2004) in which the task has demonstrated higher pressures for individuals in the forefoot compared to level walking (Wervey et al. 1997), while other studies have found a reduction in peak pressure during stair negotiation compared to level walking (Rao and Carter, 2012). As such, there is a lack of absolute agreement with foot pressure findings during the task of stair negotiation. Further, stair negotiation has been shown to influence dynamic balance of an individual (Antonio and Perry, 2014; Bosse et al., 2012; Zietz et al. 2011; Reid et al. 2011; Lee and Chou, 2007; Mian et al. 2007).

A report by the Canadian Institute for Health Information revealed that unintentional falls made up about 31% of injuries, and about 13% of those were due to falling from a stair or step (2015-2016). Further, it was found that individuals with DPN were fifteen
times more likely than those without neuropathy to report an injury due to falling which may suggest that sensation loss plays a factor in falls (Cavanagh et al. 1992),

Most plantar pressure research focuses on standing posture (Jonely et al. 2011; Gefen 2003; Cavanagh et al. 1987) or mobility on level ground (Jonely et al. 2011; Maluf & Mueller 2003; Lavery et al. 1997; Veves et al. 1992), yet the built environment of stairs is very prevalent, which makes research in this field relevant. It has also been demonstrated that stair negotiation produces a change in foot pressure distribution, with more pressure occurring at the regions of the big toe, and metatarsal heads (Maluf et al. 2004). When foot pressures are elevated from their typical levels, individuals with DPN may be more susceptible to developing ulcerations (Tang et al. 2015; Waaijmann & Bus 2012; Veves et al. 1992). One solution to alleviating higher than typical pressures, are customized insoles, as they have been used to redistribute the pressure on the foot since they are inconspicuous and can be inserted into personal footwear.

Research suggests specialized insole materials, such as polyurethane and ethylene vinyl acetate (EVA) have the capacity to offload foot pressure during gait (Fauli et al. 2008). Additionally, soft and hard EVA custom-molded insoles were found to reduce plantar pressure at the heel region compared with commercial (prefabricated) insoles (Tang et al. 2014).

Previous research examining the pressure reduction capacity of insoles have found that customized insoles effectively reduced pressure of individuals with diabetes (Birke et al. 1999; Kastenbauer et al. 1998). Which is in agreement to specific guidelines from the International Working Group on the Diabetic Foot that recommend custom-molded
insoles be worn to achieve maximal reduction of peak plantar pressure (Bus et al. 2008a).

While customized insoles did demonstrate effective pressure offloading, the development of these insoles are expensive and requires extensive intervention from a health care professional. Alternatively, off-the-shelf insoles, or commercial pressure offloading (CPO) insoles as they will be termed herein, are available in an effort to provide adequate pressure offloading at minimal cost. As evidence for their general effectiveness, an older study conducted of individuals with DPN by Lavery et al. (1997) compared manufacturer’s stock insoles (normal insoles) with CPO insoles made of plastazote/urethane material, and indicated a significant reduction in plantar pressure while wearing plastazote/urethane material insoles. Another study compared the risk of ulceration for individuals with diabetes while testing custom-made and CPO insoles (Paton et al. 2012). The custom-made insoles were constructed with medium density ethylene vinyl acetate (EVA) material by experienced clinicians and addressed individual biomechanical needs. The CPO insoles consisted of full-length 3mm medium EVA contoured shell covered in 6mm Poron. The study found that both insoles provided similar reduction in peak pressure, concluding that the CPO insoles may be an optimal option, as they were most cost-effective and commercially available.

The notion that prefabricated insoles can ameliorate various foot related biomechanical issues is attractive since they are inexpensive, easily obtainable, and require minimal intervention from a health care provider. Unsurprisingly, many companies assert that their prefabricated insoles can adequately offload foot pressure
and limit ulceration; however, many of these insoles have not directly been examined for this purpose.

The aim of this study was to observe the influence of wearing three different CPO insoles on an individual with diabetes' balance and plantar pressure while negotiating stairs. It was hypothesized that these commercially available insoles will offload pressure more than normal insoles. In terms of dynamic balance, it was hypothesized that the diabetic insoles, like the offloading devices, will make an individual less stable compared to the normal insoles.
5.3. Methods

Participants

Twenty-nine (29) participants (14 diabetic individuals with plantar sensation loss, and 15 age-matched healthy individuals) were recruited from hospital and clinics within the Greater Toronto Area for the research study at the Toronto Rehabilitation Institute (Toronto, Ontario, Canada). Participant characteristics of both groups are reported in Table 5-1. Of the recruited individuals who had diabetes, 10 of 14 of them were currently participating in a diabetes education and exercise program at a clinic. The individuals with diabetes were diagnosed with type 1 or type 2 diabetes and reported diminished foot sensitivity. Loss of protective sensation was confirmed using the Touch-Test™ monofilaments (North Coast Medical, Inc. Gilroy, CA, USA). Participants were reclined comfortably with their eyes closed. Perceived sensation was obtained by applying various sizes of monofilaments randomized to four regions of interest (ROI): 1) big toe, 2) medial metatarsal (MT) head, 3) lateral metatarsal (MT) head, and 4) calcaneus. Failure to detect the thick monofilament size indicated a loss of protective sensation. During the screening process, potential participants were excluded if they reported medical, musculoskeletal, cognitive or vestibular impairments that affected their balance or gait. Individuals were also excluded if they had active foot ulcers or were currently wearing custom orthotics. The protocol was approved by the Institutional Ethics Review Board. Participants provided written informed consent prior to the experiment.
Table 5-1: Participant Characteristics

<table>
<thead>
<tr>
<th></th>
<th>Diabetes</th>
<th>Control</th>
<th>Significance (p value)</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>14</td>
<td>15</td>
<td>-</td>
</tr>
<tr>
<td>Males</td>
<td>8</td>
<td>7</td>
<td>-</td>
</tr>
<tr>
<td>Age mean (SD)</td>
<td>64.6 (7.4)</td>
<td>62.4 (11.7)</td>
<td>0.56</td>
</tr>
<tr>
<td>BMI (Average) (SD)</td>
<td>29.9 (6.1)</td>
<td>25.8 (2.9)</td>
<td>0.03</td>
</tr>
<tr>
<td>Sensation loss (N=)</td>
<td>14</td>
<td>0</td>
<td>-</td>
</tr>
<tr>
<td>Monofilament size detected (mean grams of force) (range)</td>
<td>3.51 (1.8)</td>
<td>2.11 (1.1)</td>
<td>0.02</td>
</tr>
<tr>
<td>Self-reported HbA1c (mean %) (SD)</td>
<td>6.94 (1.7)</td>
<td>N/A</td>
<td>-</td>
</tr>
<tr>
<td>Stance time (SD)</td>
<td>0.06 (0.04)</td>
<td>0.05 (0.03)</td>
<td>0.14</td>
</tr>
</tbody>
</table>

**Insoles**

With the objective to assess available commercial products, a marketplace database was accessed that reflected consumer preference, market trends, and popular products. Using the website Amazon.ca, many insole products were identified based on keyword searches of ‘diabetes’, ‘diabetic’, ‘insoles’, ‘shoes’, ‘footwear’, ‘socks’. Since the search result yielded numerous products that seemed to fit the criteria for the study, the search list was refined to identify the most appropriate insoles based on the ‘Highest bestseller ranked’ list and ‘Best rated customer reviewed’ (≥ 4 stars out of 5). Eligible insoles were selected if the product description mentioned ‘diabetic insoles’, ‘neuropathy’ and/or ‘pressure offloading’. Each eligible product was then cross referenced with an independently created list of recommendations from a local pedorthist. This search strategy provided us with three highly ranked and reviewed products. These insoles were New Balance IPR 3020 (Boston, Massachusetts, USA), Aetrex Lynco Sport L400 (Teaneck, New Jersey, USA) and Prothotics Gel Insole (North
Smithfield, Rhode Island, USA) (Figure 5-1). Specific details of each insole are reported in Table 5-2. Each insole was created with plastazote foam, a material comprised of cross-linked polyethylene material (Minns & Craxford 1984).

![Insoles](image)

**Figure 5-1:** Insoles selected for the experimental study. 1) New Balance IPR 3020 (Boston, Massachusetts, USA); 2) Aetrex Lynco Sport L400 (Teaneck, New Jersey, USA); 3) Prothotics Gel Insole (North Smithfield, Rhode Island, USA)

**Table 5-2:** Chart detailing the insole characteristics and Shore A hardness. The insoles were measured with Digital Shore A Hardness Tester (China)

<table>
<thead>
<tr>
<th></th>
<th>Normal</th>
<th>New Balance</th>
<th>Aetrex</th>
<th>Prothotics</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Material used</strong></td>
<td>-</td>
<td>Plastazote top Synthetic sole</td>
<td>Plastazote top Polyester cover</td>
<td>Plastazote top Polyurethane Gel cup</td>
</tr>
<tr>
<td><strong>Insole Design</strong></td>
<td>-</td>
<td>Metatarsal pad Heel pad</td>
<td>High medial arch</td>
<td>Heel pad</td>
</tr>
<tr>
<td><strong>Height of Arch (cm)</strong></td>
<td>-</td>
<td>2.5</td>
<td>3.5</td>
<td>2.5</td>
</tr>
<tr>
<td><strong>Arch to Back Distance (cm)</strong></td>
<td>-</td>
<td>13</td>
<td>9</td>
<td>11.4</td>
</tr>
<tr>
<td><strong>Shore A Hardness</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Average</strong></td>
<td>35.8</td>
<td>17.0</td>
<td>28.4</td>
<td>18.2</td>
</tr>
<tr>
<td><strong>Forefoot</strong></td>
<td>33.7</td>
<td>17.4</td>
<td>29.1</td>
<td>18.2</td>
</tr>
<tr>
<td><strong>Midfoot</strong></td>
<td>35.2</td>
<td>17.2</td>
<td>28.4</td>
<td>17.9</td>
</tr>
<tr>
<td><strong>Heel</strong></td>
<td>38.4</td>
<td>16.3</td>
<td>27.6</td>
<td>18.4</td>
</tr>
<tr>
<td><strong>Added Heel (under)</strong></td>
<td>-</td>
<td>14.8</td>
<td>-</td>
<td>18.4</td>
</tr>
<tr>
<td><strong>Added MT (under)</strong></td>
<td>-</td>
<td>16.9</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>
Figure 5-2: Detailed procedure for measuring insole Shore A Hardness values and distances. Hardness was tested five times at each location and the average value was recorded

**Equipment**

Participants were instrumented with reflective markers placed on anatomical landmarks, using a modified version of the marker setup by Winter (1995) and recorded by infrared motion capture cameras at a sampling frequency of 250 Hz (Motion Analysis, Santa Rosa, California, USA) (See Appendix E-3). Pressure insole sensors, (Medilogic, Schonfeld, Germany) consisting of 160-200 individual pressure cells, were instrumented inside matched footwear of varying sizes measured at a sampling frequency of 60 Hz (See Appendix E-6). Participants were asked to traverse 'StairLab', a 7-step staircase located in the Challenging Environmental Assessment Laboratory (CEAL) at the Toronto Rehabilitation Institute. The staircase dimensions were 1.96 m x 1.45m x 1.24 m (length x width x height), with step risings of 7 inches (0.18 m) and step runners of 11 inches (0.28 m) (based on National Building Code of Canada standards)
(See Appendix E-1). For safety, handrails and a harness system were used to arrest a potential fall.

Protocol

Prior to the start of the experiment, participants read and signed the informed consent forms. Their feet were examined for existing foot ulcers and plantar sensation was tested using Touch-Test™ monofilament (North Coast Medical, Inc. Gilroy, CA, USA). Researchers provided participants with standardized athletic footwear for the duration of the study. In a blocked randomization grouped by insoles, participants wore each of the four insoles along with the pressure insole sensors on top of the insoles as they ascended and descended the 7-step staircase. Each condition of insole was conducted a maximum of ten times. The typical duration of each trial ranged in length from 15 seconds to 20 seconds long. Participants were given adequate acclimation time with the equipment (10 to 15 minutes) and rest periods (3) between the blocked trials to prevent fatigue.

Outcome Measures

The middle steps of the stairs (steps 3-6) during ascent and descent were the phases of interest for data analysis. For the balance measure, the motion capture cameras were utilized to record the three-dimensional spatial location of the spherical markers, which were then used to calculate each participant’s dynamic balance using the center of mass – base of support (COM-BOS) lateral stability margin during the single stance phase of stair negotiation (Perry et al. 2000). Stance time was calculated
from the initial time of foot contact to the time of lift-off of the same foot during the stance phase: \( \text{Stance time} = \text{Step end time (s)} - \text{Step start time (s)} \). The location of the whole-body COM was calculated using a modified 7-segment model, derived from a marker setup adapted by Winter (1995). The BOS was defined by the location of the heel and toe markers of the foot in contact with the stair during single stance (Figure 5-3). The COM and BOS locations were used to calculate the spatial minimum distance (m) of the center of mass (COM) relative to the lateral border of the base of support (BOS).

Figure 5-3: COM 7-segment calculation using 12 markers. Segments consisted of the 1) head, 2) thorax and arms, 3) pelvis and abdomen, 4) right thigh, 5) left thigh, 6) right shank, and 7) left shank. The box demonstrates how the BOS lateral border was determined using the 5th metatarsal marker and the heel marker.
In addition to the spatial COM-BOS measure, the temporal COM-BOS stability margin (τ) was calculated (Hof et al. 2005) (See Appendix E-8). τ (seconds) represented the hypothetical time required of the COM to reach the boundary of the BOS without intervention using the COM velocity (m/s) as an indicator, calculated as:

\[ τ = \frac{\text{Spatial distance to BOS border}}{\text{COM velocity}} \]

Foot pressure distribution was recorded and expressed as peak pressure (kPa). The peak pressure was the maximum pressure placed on the foot during each single stance phase of stair negotiation. Two sets of peak pressure data were extracted for analysis, 1) overall plantar pressure, denoting all the peak pressures placed on the foot during a single stance phase; 2) peak plantar pressure of regions of interest (ROI), denoting the peak pressure values obtained from 4 regions of interest (big toe, medial and lateral metatarsal heads, medial heel). All balance and pressure measurements were subdivided by stair ascent and descent, and the 4 different insole conditions (3 experimental insoles, 1 normal insole).

**Statistical Analysis**

Mean values from multiple steps and trials were calculated for each individual separated by the outcome measures of balance and pressure. A two-way analysis of variance (ANOVA) was conducted using SPSS (v.23, IBM, SPSS) for data analysis. This model allowed for comparisons of overall peak pressure and balance of direction (2, ascent and descent) and insole (4). Further, analysis of peak pressure separated by regions of interest (big toe, medial and lateral metatarsal heads, medial heel) was conducted using a two-way ANOVA to understand pressure distribution at specific
regions. When necessary, the data were rank-transformed prior to analysis based on Shapiro-Wilk Test (Conover & Iman 1981). Levene’s test of equality of variance were conducted to identify homogeneity of the variables. Independent t-tests were also conducted to assess group differences of age, foot stance time, and foot sensitivity.

5.4. Results

An independent samples t-test was conducted to compare age between groups (diabetes vs control) and found no significant differences ($p = 0.56$) (Table 5-1). With respect to foot stance, an independent samples t-test was conducted to compare group stance time and found no differences in stance time between diabetic and age-matched controls ($p=0.14$)(Table 5-1). With respect to foot sensitivity, an independent samples t-test compared foot sensation between groups (diabetic vs. control) and found that diabetic individuals reported feeling thicker monofilaments (mean = 3.51 g, SD = 1.8) than the control (mean = 2.11 g, SD = 1.1), $t(27) = -2.59, p = 0.02$ (Table 5-1).

**Plantar Pressure**

In comparing between insoles, there were no significant differences in peak pressure of normal insoles and CPO insoles (New Balance, Aetrex, Prothotics) during the task of stair negotiation. With respect to stair direction, at the big toe region, a significant main effect of direction was found, $F(1,8) = 7.96, p < 0.05$, where stair descent produced significantly more peak pressure (mean = 12.7 kPa, SD = 1.4 ) than stair ascent (mean = 10.7 kPa, SD = 0.6). There was also a significant main effect of direction at the lateral MT head, $F(1, 8) = 7.86, p < 0.05$, where stair ascent produced
significantly more peak pressure (mean = 10.1 kPa, SD = 1.2) than stair descent (mean = 8.4 kPa, SD = 0.5). There were no interaction effects between stair direction and group for overall pressure, and at each region (p = 0.99). (For complete pressure data see Table 5-3).

Table 5-3: Stair negotiation direction and insole pressure results of overall peak pressure, and region peak pressures (separated into regions of interest). † denotes significant greater difference (p < 0.05).

<table>
<thead>
<tr>
<th>Insole</th>
<th>Overall Peak Pressure</th>
<th>Big Toe Peak Pressure</th>
<th>Medial MT Head Peak Pressure</th>
<th>Lateral MT Head Peak Pressure</th>
<th>Medial Heel Peak Pressure</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean (kPa)</td>
<td>SD</td>
<td>Mean (kPa)</td>
<td>SD</td>
<td>Mean (kPa)</td>
</tr>
<tr>
<td>Normal</td>
<td>67.7</td>
<td>15.7</td>
<td>11.5</td>
<td>1.9</td>
<td>11.9</td>
</tr>
<tr>
<td>New Balance</td>
<td>66.2</td>
<td>14.9</td>
<td>11.7</td>
<td>1.6</td>
<td>12.1</td>
</tr>
<tr>
<td>Aetrex</td>
<td>69.5</td>
<td>16.0</td>
<td>11.9</td>
<td>1.2</td>
<td>12.3</td>
</tr>
<tr>
<td>Prothotics</td>
<td>66.6</td>
<td>15.1</td>
<td>11.8</td>
<td>1.7</td>
<td>12.9</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Direction</th>
<th>Overall Peak Pressure</th>
<th>Big Toe Peak Pressure</th>
<th>Medial MT Head Peak Pressure</th>
<th>Lateral MT Head Peak Pressure</th>
<th>Medial Heel Peak Pressure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ascent</td>
<td>65.7</td>
<td>14.7</td>
<td>10.7</td>
<td>0.6</td>
<td>11.8</td>
</tr>
<tr>
<td>Descent</td>
<td>69.3</td>
<td>15.7</td>
<td>12.7†</td>
<td>1.4</td>
<td>12.8</td>
</tr>
</tbody>
</table>

Balance

*COM-BOS lateral stability margin*

There were no significant main effects found between insoles (p = 0.12). There was a significant main effect of stair negotiation direction, $F(1,27) = 190.64, p < 0.001$, where stair descent (mean = 0.09 m, SD = 0.02) had smaller COM-BOS lateral distances than stair ascent (mean = 0.13 m, SD = 0.03). An interaction was found
between direction and insole, $F(3, 81) = 3.24$, $p < 0.05$. During descent, the normal insoles had the smallest COM-BOS lateral distance (mean = 0.08 m) among all insole conditions. The Aetrex (mean = 0.09 m) and Prothotics insoles (mean = 0.09 m) during descent had greater COM-BOS lateral distances than the normal insoles (Table 5-4).

Temporal Stability Margin (Medial-Lateral (ML))

A significant main effect of insole was found, $F(3, 81) = 4.06$, $p < 0.05$, where the time for the COM to reach the BOS boundary was significantly shorter while wearing normal insoles (mean = 1.72 s, SD = 0.6) compared to Prothotics insoles (mean = 1.87 s, SD = 0.5).

A significant main effect of stair negotiation direction was found, $F(1, 27) = 124.34$, $p < 0.001$, where the time for the COM to reach the BOS boundary was significantly longer during stair ascent (mean = 2.1 s, SD = 0.4) than stair descent (mean = 1.5 s, SD = 0.5) (Table 5-4).

An interaction effect between stair negotiation direction and insole showed that during descent, normal insoles (mean = 1.3 s) demonstrated the slowest time among all the insole conditions, while the Aetrex insoles (mean = 1.6 s) and the Prothotics insoles (mean = 1.6 s) demonstrated a longer time, $F(3, 81) = 4.25$, $p < 0.05$ (Figure 5-4).
Figure 5-4: Interaction plot of COM-BOS temporal medial-lateral between stair direction and insoles

Temporal Stability Margin (Anterior-Posterior (AP))

No significant main effects were found between insoles (p = 0.3). A significant main effect for stair negotiation direction was found, $F(1,27) = 19.52, p < 0.001$, where the time for the COM to reach the BOS boundary during ascent was significantly longer (mean = 0.5 s, SD = 0.09) than stair descent (mean = 0.4 s, SD = 0.1) (Table 5-4). Additionally, there was no interaction effect found between direction and insole (p = 0.7)
Table 5-4: Stair negotiation direction and insole pressure results of balance outcome measures (separated into regions of interest). † denotes significant greater difference (p <0.05), * denotes significant greater difference (p <0.001).

<table>
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5.5. Discussion

The study aimed to investigate the influence of commercial pressure offloading (CPO) insoles on balance and foot pressure of individuals with diabetes and an age-matched group during stair negotiation. For foot ulceration prevention, CPO insoles have been considered as an alternative to full custom-made insoles and TCCs, since they supposedly redistribute the pressure placed on the foot. This study demonstrated that New Balance, Aetrex and Prothotics insoles did not display any significant difference in overall peak pressure compared to normal insoles found in athletic
footwear. Region specific foot pressure analysis was also considered since the activity of stair negotiation places plantar stress on the big toe, medial and lateral metatarsal heads, and the heel. This analysis highlights the influence of the insole material specifically at the site of the metatarsal and heel pads. The findings demonstrated that the influence of insoles on peak pressure in the big toe, medial and lateral MT head, and medial heel regions were not significantly different, challenging the hypothesis that insoles and their material significantly offload plantar pressure.

There are countless commercial pressure offloading insoles available in the market that vary in their design and material. To date, many prefabricated insoles lack substantive research to prove their effectiveness, yet, are commonly purchased since they are inexpensive and easily obtainable. In contrast, health care providers prescribe custom-molded insoles to cater to each individual’s foot structure and condition. Research reveals that custom-molded insoles offer considerable pressure reduction for individuals with diabetes (Tong & Ng 2010; Guldemond et al. 2007; Tang et al. 2014; Bus et al. 2008; Tsung et al. 2004). The CPO insoles used in this current study were constructed of plastazote material, a shock absorbing material proven to be effective in offloading pressures (Fauli et al. 2008), however, it has been suggested that plastazote material alone may not optimally offload pressure. Instead, the combination of plastazote with Poron, an open-celled urethane foam, may provide greater pressure offloading (Sobel & Levitz 2001; Tong & Ng 2010).

With respect to balance, it was hypothesized that CPO insoles would make individuals less able to control their body’s COM than normal insoles since the added cushioning would dampen the reactive response of the individual during the activity of
stair gait. However, all insoles demonstrated similar COM-BOS lateral stability margins during stair negotiation, suggesting that CPO insoles are no different in terms of balance risk. While no significant main effect of insole was found, an interaction showed that during descent, normal insoles had the smallest COM-BOS lateral distance, while Aetrex and Prothotics insoles displayed greater COM-BOS lateral distances. A smaller margin demonstrates that the body’s COM is closer to the BOS lateral border, signifying the individual may be more compromised in their ability to control their balance in the lateral direction. Furthermore, the overall temporal COM-BOS medial-lateral stability margin indicated that wearing normal insoles produced a significantly shorter time to hypothetically reach the BOS than when wearing the Prothotics insole. When the COM reaches the BOS in a short amount of time, the individual may be forced to make balance control adjustments in less time. Thus, descending the stair wearing normal insoles may be a more of a destabilizing task, while wearing Prothotics insoles may be a better option with respect to an individual’s COM control. While an argument can be made that compromised ability to control for balance may not directly result in a fall, these outcome measures may still provide a better understanding of one’s ability to control their body during stair negotiation.

A limitation of the study was that foot structure was not assessed or excluded from the study; in particular pes planus, pes cavus, plantar tissue thickness, as it has been found that foot structure may affect pressure (Morag & Cavanagh 1999). However, due to limited assessment time prior to the study, structural foot components were not evaluated.
The findings of this study demonstrate that CPO insoles may not provide adequate pressure offloading in comparison to normal insoles. With respect to balance, wearing normal insoles indicated a worse ability to control for an individual's COM compared to Prothotics insoles, especially during stair descent. The design and hardness of insoles, particularly the Prothotics insoles may provide some more balance control especially during the hazardous task of stair descent. While CPO insoles continue to be manufactured and sold, consumers should be critical of CPO insole product claims and attentive to additional foot problems.

5.6. Conclusion

Popular prefabricated commercial pressure offloading insoles during stair negotiation did not provide significant pressure offloading compared to the normal insoles. Moreover, the balance measures revealed that wearing normal insoles may compromise an individual’s ability to control their balance, especially during stair descent. This study provides the necessary information that popular CPO insoles, were virtually similar to normal insoles in their pressure offloading capacity. Evidence based findings of these insoles may help inform consumers with appropriate commercial insoles for the purpose of alleviating their specific condition.
5.7. References


37. Bus S. (2008). Foot structure and footwear prescription in diabetes mellitus. *Diabetes / Metabolism Research and Reviews, 24*(Suppl. 1), S90-S95


Chapter 6: General Discussion

The overall objective of this dissertation was to examine the dynamic balance, plantar pressure distribution and foot sensitivity of individuals with DPN, while considering the added influence that intrinsic (health) and extrinsic (stairs and insole) factors may play. Specifically, this dissertation set out to 1a) examine if severity of sensation loss may contribute to changes in plantar pressure distribution during stair gait, 1b) examine the contribution of various health factors on the severity of sensation loss, and 1c) examine if these health factors may help contribute to increased relative pressure during the task of stair gait (Chapter 3). Further, the dissertation examined whether differences existed in stair gait dynamic balance control and plantar pressure of individuals with DPN compared to an age-matched control group (Chapter 4). Lastly, the dissertation observed the influence of wearing CPO insoles on balance and plantar pressure of individuals with diabetes, while negotiating stairs (Chapter 5).

6.1. Background

It has long been established that increased foot pressure can lead to foot ulcerations during gait (Tang et al. 2015; Frykberg et al. 1998; Veves et al. 1992). Foot ulcerations are very common for individuals suffering from diabetes and peripheral neuropathy. A study by Masson et al. (1989) displayed that individuals with rheumatoid arthritis demonstrated high pressures in the feet during gait, similarly to individuals with diabetes, however, only individuals with diabetes presented with foot ulcerations thus demonstrating that diabetes may be an indicator of foot ulceration. While, sensation is used to diagnose neuropathy, it can also shed light on the interaction of the foot and the
contact surfaces. As mentioned in the introduction, plantar pressure can be influenced by the individual (sensation, age, and body weight) (Perry 2006; Menz et al. 2004; Yumin et al. 2016), task (walking speed) (Burnfield et al. 2004), and environment (stairs and insoles). Mobility is an important facet to daily life and raises many concerns when interacting with environmental factors such as stairs and insoles.

6.2. Overview of Findings and Relevance

The overall results of this dissertation set out to examine the plantar sensation and pressure of individuals with diabetes during the activity of stair gait. The regression model in Chapter 3 found that for the big toe, medial and lateral MT, the model’s predictive capacity improved ($r^2$ change = 10%, 22%, and 15%, respectively) when sensation and blood glucose were included as factors. This model was created to determine changes to plantar pressure during stair gait, by using quick, easily obtainable information such as age, weight, height, self-reported blood glucose level (HbA1c), stance time during stair gait, and plantar sensation levels (at 4 regions of the feet). The results of this model suggested that changes in relative pressure are associated with, and depends on changes to factors such as age, blood glucose level, stance time, and BMI. As indicated, age was also found to possibly contribute to changes in plantar pressure. One of the biggest contributions of mobility impairment is age-related changes to the foot structure (Menz et al. 2014; Scott et al. 2007; Bus 2008). During gait, the foot interacts directly with the contact surface therefore even slight structural changes to the foot may substantially influence gait. Foot deformities
(Kernozek et al. 2003), reduced range of motion and muscular strength (Kumar et al. 2015; Rao et al. 2010) have been demonstrated to change the musculoskeletal characteristics of the foot. Further, research of plantar soft tissue at the heel and metatarsal region showed that the thickening of the soft tissue can lead to loss of tissue compliance and problems with gait in elderly individuals (Kwan et al. 2010).

As mentioned previously, Morag & Cavanagh (1999) utilized complex structural and functional measures of the foot to predict regional plantar peak pressures while level walking. The comprehensive inclusion of foot structure in their model accounted for 48.5 – 56.6 % of the variance in peak plantar pressure, depending on the region. Their findings showed an improved predictive capacity to previous research findings (Cavanagh et al. 1997), however, the authors still determined additional factors have yet to be explored. While their study explained a great proportion of variance, the study was conducted on 55 healthy subjects without diabetes, therefore sensory deficit with respect to pressure was not accounted for. With the findings in Chapter 3, the models predicted 22 – 39% of the variance in pressure, depending on the region. It would be intriguing to see the combined contribution of health-related factors and foot structure in how they may indicate a change in foot pressure, especially for individuals with diabetes.

In Chapter 4, there was some evidence to show that individuals with diabetes with sensation loss demonstrated lower pressure during stair gait compared to the age-matched control group. Individuals with DPN may have utilized a cautious walking behaviour to reduce the risk of mobility and foot impairments because they were aware of their sensory impairment. It is a possibility that individuals with diabetes were more
purposeful in their movement which led to their reduced pressures exhibited during stair gait. As highlighted by Pai et al. (2003), feedforward control is one strategy to maintain balance where the central nervous system (CNS) integrates afferent inputs to monitor and continuously updates the COM state. The CNS can select and execute an appropriate action in a feedforward method to counter the intentional self-perturbation of stair gait. Individuals with diabetes may have been anticipating the requirements of the task and operating with feedforward control of gait to control their stepping, whereas individuals without diabetes may have been employing more feedback control since they may have perceived the task to be simple. When somatosensory systems are impaired, the visual system is more relied upon to maintain stability. Referring to the study by Horak et al. (1990), despite the loss of one sensation, individuals may rely on alternative senses. In their classic example, individuals with reduced somatosensory information still maintained their balance because they could rely on visual and vestibular information. It is possible that individuals with DPN relied on the visual system to proactively plan the stepping behaviour during stair gait. In a classic study by Rothwell et al. (1982), one male individual was presenting severe sensory neuropathy in all four limbs. This individual successfully performed the experimental motor control tasks, however when vision was removed, his performance quickly deteriorated. This suggests that when somatosensory was reduced, vision contributed to the successful action. Although the activity of gait may present different mechanical processes from the upper body task employed by Rothwell et al. (1982), this highlights the possibility of sensory organization in action. For the present study, all participants had complete vision of the stair gait, however their gaze behaviour was not observed. Research has
shown that older adults compared to young adults needed more time fixating on the stairs to process visual information and generate an accurate stepping movement (Zietz & Hollands 2009). This gaze behaviour found in older adults is a strategy for feedforward control, allowing them to maintain safe stair negotiation.

If individuals with DPN generated less plantar pressure during stair gait, these individuals are still susceptible to developing ulcers. According to Brand, the "repetitive moderate stress" placed on the plantar foot may still cause ulcerations (1978). During normal gait, sensory feedback will alter an individual's gait in response to foot discomfort, but with impaired sensation individuals are unable to alter their gait in response to the foot issue (Laing et al. 1998). In addition, if there is cumulative load placed on more bony prominences such as the metatarsal heads, the likelihood of tissue trauma is higher due to the lack of cushioning tissue (van Deursen 2004). Lastly, Reiber et al. (1999) proposed that when a participant presents with the 'critical triad' (neuropathy, minor foot trauma and foot deformity), they are likely to develop ulcerations. While it seems like ulcerations are inevitable regardless the intervention, it still is vitally important that clinicians strive to offload pressure because preventative methods will help in reducing the risk of development and recurrence of ulcerations.

Findings from Chapter 4 also showed that individuals with diabetes demonstrated less plantar pressure and were in a better position to control their COM control during the task of stair gait. As stated above, individuals with diabetes may have demonstrated a cautious walking pattern which could have resulted in reduced pressure. The increased attention to stair gait may be enabling these individuals with more purposeful feedforward stepping. The intentional stepping may also affect their
COM control, allowing them to produce greater COM-BOS medial-lateral stability margins.

For this study, it is important to note that balance was mainly considered in the medial-lateral direction, as denoted by the COM-BOS minimum lateral stability margin. Research by Zachazewski et al. (1993) found the largest lateral separation between the COM and the COP, during the stance phase of stair gait, occurred at the initiation of single limb stance. Their findings also confirmed large COM-COP anterior divergence during the single leg stance of stair ascent and descent. In Chapters 4 and 5, the COM-BOS displacement was measured in the medial and lateral direction, but not for the COM anterior-posterior direction. Since the COM naturally moves forward with the progression of stair gait, it becomes difficult to discern purposeful movement of the COM in the anterior-posterior direction with potential control deficits in COM anterior position. Consequently, Chapter 4 and 5 introduced the temporal component of the COM in both the COM anterior-posterior, and medial-lateral directions to determine the temporal COM-BOS ‘stability margin’ (measured in seconds) (Hof et al. 2005). Shorter time would indicate less time for the ability to adjust to changes in balance as a consequence of the activity. This shortened time was demonstrated for the task of stair descent compared to stair ascent, across all the sample participants, thus the task of descending the stairs may introduce issues in one’s attempt to control their balance, as shown in Chapter 4.

Lastly, Chapter 5 addressed the pressure offloading capacity of various commercial insoles. The study found that for the common activity of stair gait, commercial pressure offloading (CPO) insoles did not reduce pressure any better than
normal insoles. As previously discussed, research has demonstrated that plastazote foam can offload foot pressure, but the combination of foam materials such as plastazote and Poron have a better capacity to offload foot pressures (Fauli 2008; Sobel & Levitz 2001; Tong & Ng 2010). The stress-strain relationship of various insole materials demonstrated that plastazote material did not reduce the pressure as well as Poron material, an open-cell urethane foam (Sanders et al. 1998; Bowker & Pfeifer 2001; Sobel & Levitz 2001). This relationship defines the pressure placed on the insoles and the material deformation (Sanders et al. 1998). For plastazote, the material was found to be less compliant, while the Poron material was more compliant. When pressure was placed on the plastazote material, the foam deformed but was more resistant to the deformation when compared to the Poron material, as the material did not effectively contain the pressure. It is important to distinguish the difference between solely testing the material and testing the foam material within an insole for the purpose of full body weight pressure offloading, as there might be a discrepancy in the material performance. This dissertation demonstrated that plantar pressures in the foot are dependent on 1) task, 2) region, 3) condition, and 4) repetition. So, when these factors are involved, the compliancy of the materials alone during the mobility task may not be representative in the findings.

6.3. Limitations

There were some limitations that could have confounded our research. First, the classification of neuropathy was not identified. There are many classifications of neuropathy such as motor, predominantly sensory, or a combination of both sensory-
motor neuropathy. While no motor problems were observed, there were no tests conducted to identify the potential for motor problems. However, conduction of touch-test monofilaments may have identified the presence of sensory neuropathy. Secondly, the participants with diabetes (10/14) were recruited from a diabetes exercise and education program and may be considered more active than the general population, thus they may not be representative of the general diabetes population. Third, the staircase in the laboratory was tilted 20 degrees to ensure adequate alignment of the staircase therefore; the vestibular system may have been affected (See Appendix E-2). To limit this possible phenomenon, participants were given adequate time (10-15 minutes) to acclimate to the altered angle. Lastly, as was alluded to in the discussion, the foot structure was an important element to consider with respect to pressure, however it was not feasible to assess the foot structure of the participants in detail due to cost of the high technology imaging equipment, foot assessment training, and time-constraints of the study. Visual inspection and foot tracing was completed to ensure there were no calluses, ulcerations, hammer/ claw toes or hallux valgus present. It is understood that altered foot characteristics become more evident as individuals age. Elderly individuals may present with flatter and more pronated feet and have been known to produce less loading in the lateral metatarsal head (Scott et al. 2007). Using an imaging technique called ultrasonography, this past study identified that older individuals had increased stiffness of plantar soft tissue especially at the region of the MT head. The soft tissue becomes less elastic and unable to adequately redistribute pressure under the feet during gait. Thus, stiffer tissues under the MT head were areas of high pressure during gait (Gefen 2003; Kwan et al. 2010).
Additionally, in the study by Morag & Cavanagh (1999), structural and functional components of the foot were manually measured as identifiers of changes to foot structure. While the findings found significant results, the manual assessments of the foot (such as hallux length, sesamoid height, Morton’s index) may be highly variable and dependent on researcher expertise. To accurately determine structural changes in the foot, high technology imaging equipment may be utilized, such as plane radiography, ultrasonography, and magnetic resonance imaging (Loredo et al. 2007; Agirman et al. 2016; Low & Peh 2015). In any case, there have been numerous studies that have focused specifically on the change in foot structure and clinical foot test with respect to plantar pressure (Payne et al. 2002; Menz & Morris 2006; Scott et al. 2007). Thus, the focus shifted to examine pressure using simple health information that clinicians can easily mimic in a rehabilitation setting.

6.4. Future Directions

This dissertation provided some interesting findings and also revealed new considerations for future research. First, researchers should continue to test plantar pressure regions based on task-specific criteria. When analyzing the pressure offloading insoles, the focus on metatarsal head or the heel allowed us to compare the interaction of the foot with various insole properties such as the metatarsal pad and the heel cups.

The participants of the study were diagnosed with type 1 or 2 diabetes and self-reported HbA1c blood glucose levels around the standard diabetes values of 7%. It is
recommended that future studies include participants with a wider range of blood glucose level, such as individuals with pre-diabetes and more severe cases of diabetes. The heterogeneity of widening the inclusion criteria would allow for better generalizability of the findings to the population. In addition, the regression model conducted in Chapter 3 would require a larger sample and the inclusion of a more heterogeneous group of individuals with diabetes and pre-diabetes for significant conclusions to be made.

The study in Chapter 3 provided some insight to the cumulative repetitive load during stair gait. Future research should continue to explore the cumulative load theory and how prolonged pressure may impact the foot during various important tasks of daily living, specifically during stair gait. As was also highlighted, ulcerations may still occur with low pressures as a result of foot structural changes. Future research would benefit from determining an easy, low-cost protocol to assess the changes in foot structure, as this may benefit the further understanding of how pressure can lead to ulcerations.

With respect to the insoles, the findings of this dissertation revealed that commercial pressure offloading insoles were no better in reducing foot pressure than normal insoles. While the study only tested three insoles, during a specific task of stair walking, it is recommended that general consumers continue to be critical of the claims companies make about their products and not rely on anecdotal statements and descriptions the company makes. Most importantly, individuals should consult with health care professionals regarding the manufacturing of customized insoles that target foot issues specific to the individual. With form-fitted footwear, high pressure and the chances of falling may be reduced.
6.5. Conclusions

For individuals with diabetes, high blood glucose levels have a significant, low positive relationship to impaired plantar sensation. Further, the changes in relative pressure are associated with, and depends on changes to factors such as age, blood glucose level, stance time, and BMI, especially at the big toe, medial and lateral metatarsal head regions. Knowing that stair gait is a complex and treacherous task, individuals with diabetes may have employed more of a cautious walking behavior which resulted in offloaded pressure and better ability to control their balance than the age-matched control. Lastly, commercial pressure offloading insoles performed no better in reducing foot pressure during the task of stair gait than normal insoles.
6.6. References


## Appendix A Participant Characteristics & Additional Data

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</table>

**Appendix A-1:** Chart with touch-test monofilament scores, calculated BMI and age of participants in the research study. Shaded participants were excluded from group data analysis of pressure and balance due to missing data or holding the handrail.
<table>
<thead>
<tr>
<th>Participant</th>
<th>BG Level (AIC)</th>
<th>Ulcers</th>
<th>Foot Deformities</th>
<th>Reported Desensitized Feet</th>
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<tr>
<td>D1</td>
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<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>D2</td>
<td>6.3</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>D3</td>
<td>6.1</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>D4</td>
<td>10</td>
<td>No</td>
<td>No</td>
<td>Yes - Tarsals</td>
</tr>
<tr>
<td>D5</td>
<td>7.2</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>D6</td>
<td>6.8</td>
<td>No</td>
<td>No</td>
<td>Yes - Soles/ball of feet</td>
</tr>
<tr>
<td>D7</td>
<td>6.9</td>
<td>No</td>
<td>No</td>
<td>Yes - Foot tingling</td>
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<tr>
<td>D8</td>
<td>7.3</td>
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<td>No</td>
<td>No</td>
</tr>
<tr>
<td>D9</td>
<td>7</td>
<td>No</td>
<td>No</td>
<td>Yes - Tarsals</td>
</tr>
<tr>
<td>D10</td>
<td>8</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>D11</td>
<td>6.7</td>
<td>No</td>
<td>No</td>
<td>Yes - Tarsals</td>
</tr>
<tr>
<td>D12</td>
<td>8.3</td>
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<td>No</td>
<td>Yes - Right Forefoot</td>
</tr>
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<td>D13</td>
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<td>No</td>
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<td>D14</td>
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<td>D15</td>
<td>7.1</td>
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<td>No</td>
<td>No</td>
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<tr>
<td>D16</td>
<td>6.6</td>
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<td>No</td>
<td>Yes - Tarsals</td>
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**Appendix A-2:** Chart of health information, such as the self-reported HbA1C level (%), foot inspections denoting presence of ulcerations and deformities, and self-reported foot areas of desensitization. Shaded participants were excluded from group data analysis of pressure and balance due to missing data or holding the handrail.
<table>
<thead>
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<th>Trials analyzed</th>
<th>Steps</th>
<th>TOTAL</th>
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<td>2</td>
<td>10</td>
</tr>
<tr>
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<td>10</td>
</tr>
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<td>5</td>
<td>2</td>
<td>10</td>
</tr>
<tr>
<td>7</td>
<td>5</td>
<td>2</td>
<td>10</td>
</tr>
<tr>
<td>8</td>
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<td>2</td>
<td>10</td>
</tr>
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<td>12</td>
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<td>2</td>
<td>10</td>
</tr>
<tr>
<td>13</td>
<td>5</td>
<td>2</td>
<td>10</td>
</tr>
<tr>
<td>14</td>
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**Appendix A-3**: Data Breakdown for Regression Analysis. For participant 8, 9, 10: Removal of 2 trials each due to either equipment error, or held onto the handrail.

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<th>SD</th>
<th>Mean PTI</th>
<th>SD</th>
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<td>22.38</td>
<td>1.5</td>
</tr>
<tr>
<td>2</td>
<td>9.62</td>
<td>3.6</td>
<td>25.35</td>
<td>4.7</td>
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<tr>
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<td>37.34</td>
<td>4.8</td>
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<tr>
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<td>13.06</td>
<td>3.8</td>
<td>55.3</td>
<td>7.4</td>
</tr>
<tr>
<td>5</td>
<td>7.04</td>
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<td>13.23</td>
<td>1.7</td>
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<td>6.15</td>
<td>1.4</td>
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**Appendix A-4**: Diabetes participant mean data of peak pressure (kPa) and pressure time integral (kPa·s), and standard deviations
<table>
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<tr>
<th>PV (Big Toe)</th>
<th>DV (Relative Pressure, %)</th>
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<tbody>
<tr>
<td>Body Mass Index (BMI)</td>
<td>-0.20†</td>
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<tr>
<td>Age</td>
<td>-0.17†</td>
</tr>
<tr>
<td>Stance Time</td>
<td>-0.08</td>
</tr>
<tr>
<td>Blood glucose level (BG)</td>
<td>-0.27*</td>
</tr>
<tr>
<td>Plantar Sensation (PS)</td>
<td>-0.19†</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PV (Medial MT)</th>
<th>DV (Relative Pressure, %)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Body Mass Index (BMI)</td>
<td>-0.23†</td>
</tr>
<tr>
<td>Age</td>
<td>0.33*</td>
</tr>
<tr>
<td>Stance Time</td>
<td>-0.31*</td>
</tr>
<tr>
<td>Blood glucose level (BG)</td>
<td>0.20†</td>
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<tr>
<td>Plantar Sensation (PS)</td>
<td>0.21†</td>
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<table>
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<tr>
<th>PV (Lateral MT)</th>
<th>DV (Relative Pressure, %)</th>
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<tr>
<td>Body Mass Index (BMI)</td>
<td>0.47*</td>
</tr>
<tr>
<td>Age</td>
<td>-0.21†</td>
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<tr>
<td>Stance Time</td>
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<tr>
<td>Blood glucose level (BG)</td>
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<td>Plantar Sensation (PS)</td>
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<table>
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<tr>
<td>Age</td>
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<tr>
<td>Stance Time</td>
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<tr>
<td>Blood glucose level (BG)</td>
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</tr>
<tr>
<td>Plantar Sensation (PS)</td>
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**Appendix A-5**: Pearson correlations of the predictor variables (PV) and the dependent variable (DV), separated by regions. Where: * = p < 0.001, † = p < 0.05
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<th>β</th>
<th>t</th>
<th>P value</th>
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<td></td>
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### Lateral MT

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### Medial Heel

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<th>$\beta$</th>
<th>t</th>
<th>$P$ value</th>
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**Appendix A-6:** Hierarchical regression model of relative pressure (%) separated by region. Region 1 = Big Toe, Region 3 = Medial MT, Region 5 = Lateral MT, Region 8 = Medial Heel.
# Appendix B Ethics

**University Health Network**
Research Ethics Board
10th Floor, Room 1056
700 University Ave
Toronto, Ontario, M5G 1Z5
Phone: (416) 581-7849

---

**Notification of REB Initial Approval**

**Date:** October 6th, 2015  
**To:** Dr. Stephen Perry

**Re:** 15-8761-DE  
Investigating Balance, Plantar Pressure, and Foot Sensitivity in Diabetic Individuals During Stair Gait

**REB Review Type:** Expedited  
**REB Initial Approval Date:** October 6th, 2015  
**REB Expiry Date:** October 6th, 2016

**Documents Approved:**

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<th>Version Date</th>
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The UHN Research Ethics Board operates in compliance with the Tri-Council Policy Statement; ICH Guideline for Good Clinical Practice E6(R1); Ontario Personal Health Information Protection Act (2004); Part C Division 5 of the Food and Drug Regulations; Part 4 of the Natural Health Products Regulations and the Medical Devices Regulations of Health Canada. The approval and the views of the REB have been documented in writing. The REB has reviewed and approved the clinical trial protocol and informed consent form for the trial which is to be conducted by the qualified investigator named in the letter.

Furthermore, members of the Research Ethics Board who are named as Investigators in research studies do not participate in discussions related to, nor vote on such studies when they are presented to the REB.

Best wishes on the successful completion of your project.

Sincerely,

Ann Heesters, BA MA BEd PhD (ABD)  
Co-Chair, University Health Network Research Ethics Board
PROTOCOL REFERENCE # 32637

February 5, 2016

Dr. Stephen Perry  
DEPT OF PHYSICAL THERAPY  
FACULTY OF MEDICINE

Mr. Patrick Antonio  
DEPT OF PHYSICAL THERAPY  
FACULTY OF MEDICINE

Dear Dr. Perry and Mr. Patrick Antonio,

Re: Administrative Approval of your research protocol entitled, "Investigating balance, plantar pressure, and foot sensitivity in diabetic individuals during stair gait"

We are writing to advise you that the Office of Research Ethics (ORE) has granted administrative approval to the above-named research protocol. The level of approval is based on the following role(s) of the University of Toronto (University), as you have identified with your submission and administered under the terms and conditions of the affiliation agreement between the University and the associated TAHSN hospital:

- Graduate Student research - hospital-based only
- Storage or analysis of De-identified Personal Information (data)

This approval does not substitute for ethics approval, which has been obtained from your hospital Research Ethics Board (REB). Please note that you do not need to submit Annual Renewals, Study Completion Reports or Amendments to the ORE unless the involvement of the University changes so that ethics review is required. Please contact the ORE to determine whether a particular change to the University’s involvement requires ethics review.

Best wishes for the successful completion of your research.

Yours sincerely,

Daniel Gyewu  
REB Manager
Appendix C Letter of Informed Consent Forms

CONSENT FORM TO PARTICIPATE IN A RESEARCH STUDY

Study Title: Investigating balance, plantar pressure, and foot sensitivity in diabetic individuals during stair gait

Investigator/Study Doctor: Stephen Perry, Ph.D.

Co-Investigator: Patrick J Antonio

Contact Information: Phone: 416-597-3422 x 7774 Email: Stephen.Perry@uhn.ca

Disclaimer: Please note that the security of e-mail messages is not guaranteed. Messages may be forged, forwarded, kept indefinitely, or seen by others using the internet. Do not use e-mail to discuss information you think is sensitive. Do not use e-mail in an emergency since e-mail may be delayed.

Introduction:
You are being asked to take part in a research study. Please read the information about the study presented in this form. The form includes details on study’s risks and benefits that you should know before you decide if you would like to take part. You should take as much time as you need to make your decision. You should ask the study doctor or study staff to explain anything that you do not understand and make sure that all of your questions have been answered before signing this consent form. Before you make your decision, feel free to talk about this study with anyone you wish including your friends, family, and family doctor. Participation in this study is voluntary.

Background/Purpose:
Diabetic peripheral neuropathy is a dysfunction of the nerves in the limbs that restricts feeling to the hands and feet. It can limit your mobility and reduce your quality of life. Furthermore your balance can be compromised because of the reduced feeling of your feet. To compensate for this, you apply greater foot pressures while walking, especially during stair walking, which can often lead to foot ulcers. If left untreated, foot ulcers can get infected and may lead to foot amputations. Currently, diabetic insoles available in the
market are prescribed to treat and prevent foot ulcers, without taking into consideration your mobility and balance.

The purpose of this research study is to observe your balance and foot pressures during stair walking. In addition you will test the performance of three diabetic insoles (market-available) with respect to balance and mobility. In completing this study, we hope to understand the falls risks people are exposed to, and the foot pressures associated with stair walking. In addition, this research study will give us more information about how diabetic insoles might influence your mobility and balance.

You are being asked to participate because you meet either criteria, 1) have diabetic peripheral neuropathy, or 2) meet the age-requirement to participate as a healthy individual with no physical issues that affect your balance or mobility.

The usual treatment for diabetic peripheral neuropathy is continuous foot monitoring and regular check-ups with your health care practitioner. Diabetic insoles may also be prescribed by the physician if it is deemed appropriate. You are being asked to test out the effects of three insoles readily available in the market meant for reducing high foot pressures placed on the feet.

Up to 40 people will participate in this study at Toronto Rehabilitation Institute and it will take 2 years to complete.

You are being invited to participate in this mobility research study. One of the investigators will read through this consent form with you, describe the procedures in detail, and answer any questions you may have. You may take as much time as required to review this document before deciding on participation.

**Study Visits and Procedures:**

The setup and testing will be completed in a (2 hour maximum) laboratory visit to the StairLab of the Challenging Environment Assessment Laboratory (CEAL), Toronto Rehabilitation Institute (University Centre). We will be testing your balance and foot pressures in two different staircases (described in detail below): (1) Stationary staircase and (2) Moving staircase. Participants with diabetic peripheral neuropathy will be asked to walk up and down the stationary staircase, while the healthy participants will walk up and down the moving staircase.

Upon your visit, small reflective ball markers will be placed on your feet, lower legs, thighs, upper body, arms and head using straps and non-allergenic tape so we can measure how your body moves as you walk up and down a flight of 8 stairs. Insole sensors will also be placed in the footwear to measure your foot pressures while you walk. Motion capture video cameras will be used to track your motion of the markers.
placed on your body. The motion capture video cameras are only capable of recording the marker movements and not your face or body. The conventional video cameras, on the other hand, will be able to fully record you while you walk up and down the stairs. You will be able to rest as needed to prevent fatigue. Since falls are being created by moving the stairs forward and backward, a loss of balance is likely. Thus, you will be asked to wear an overhead harness for your protection at all times. In addition, handrails will be mounted on both sides of the stairs in case of a potential slip, trip, or fall. A researcher will be present with you in the test laboratory at all times and will have an emergency switch that will stop movement of the stairs. If you wish to terminate the trials at any time for any reason, please inform the researcher in the room.

1. Stationary Staircase (Diabetic Peripheral Neuropathic Participants)

Prior to the start of the experiment, your diabetic peripheral neuropathy will be assessed for severity using a touch-test, a standard assessment tool used by physicians. Once completed and you are setup with the necessary equipment, you will be asked to stand at the bottom of the staircase. When given the signal, you will be asked to walk up the staircase (at a comfortable pace). Once you reach the top, you will turn around to face the staircase and walk down. You will be asked to walk up and down the stairs 15 times in each insole condition. You will go through 4 insole conditions - normal insoles which can be found in regular athletic footwear, and three diabetic insoles (market available insole inserts) to wear. Once all 4 insoles have been worn while walking up and down the stairs, you will have completed the study.

2. Moving staircase (Healthy Participants)

Prior to the start of the experiment, your foot sensitivity will be assessed using a monofilament touch-test, a standard assessment tool used by physicians. Once completed and you are setup with the necessary equipment, you will be asked to stand at the bottom of the staircase. When given the signal, you will be asked to walk up the staircase (at a comfortable pace). Once you reach the top, you will turn around to face the staircase and walk down. You will be asked to walk up and down the stairs 15 times in each insole condition. You will go through 4 insole conditions - normal insoles which can be found in regular athletic footwear, and three diabetic insoles (market available insole inserts) to wear. At certain times while walking up and down the stairs, the stairs will move and cause you to lose your balance. However, to minimize these risks, we have handrails and a harness system for your safety. Once all 4 insoles have been worn while walking up and down the stairs, you will have completed the study.

In order to assist our research, we will ask you for your permission to photograph and/or videotape while walking up and down the stairs. You will have the opportunity at the end of this form to refuse the use of photo or video records of you.

Risks:
Taking part in this study has risks. Some of these risks we know about. There is also a possibility of risks that we do not know about and have not been seen in humans to date. Please call the study doctor if you have any side effects even if you do not think it has anything to do with this study.

The risks we know of are:

- The nature of this study increases the chance of falls occurring since we are creating a movement of the staircase you will be standing on or walking on, steps to minimize the risks will be taken:

  a) You will be harnessed into an overhead track for safety at all times while walking up and down the stairs. This harness will catch your fall and prevent potential injuries to the knees, hip, back and head.
  b) The level of movement of the staircase used to create the balance loss will be chosen such that they will be sufficient to cause participants to rely on the handrail to recover, while still being tolerable for participants during ongoing gait over many trials.
  c) You will be constantly monitored by a researcher who will be positioned near an emergency switch to halt any stair movement and gently return the staircase to its neutral position if necessary.

In addition, since we will be introducing new diabetic insoles (market-available) participants may be unaccustomed to them and this may affect their balance. However, participants will be placed in a harness to prevent from potentially falling.

If you experience any discomfort related to this study, please tell a researcher immediately so that the problem can be addressed promptly. You are free to withdraw from the study at any time without providing reason. If the researcher feels that you are showing signs of pain, injury, or serious discomfort, the researcher may also withdraw you from the study.

**Benefits:**

There are no direct personal benefits from being in this study. Information learned from this study may help to address gaps in our knowledge of balance and foot pressures during stair gait. Furthermore, the results of this research should help with the development and manufacturing of an optimal insole device.

**Confidentiality:**

*Personal Health Information:*
If you agree to participate in this study, the research team will collect personal health information only required for the study. Personal health information is any information that could identify you and includes your name, partial date of birth (month and year), height, weight, foot size. Names and initials will not be used as identifiers on any of the data collection forms. You will only be identified by a code reflecting the project identifier (DP – Diabetic Participant) and your participant number. Data summary sheets and computer data files will identify your data by the code only. Documents containing your name and/or contact information (this consent form and a receipt of payment) will be separated from your data. You will not be identified in any publication, presentation or report and if video or photographs are used for presentation purposes, faces and any other recognizable physical features will be blurred out. Please note, University Health Network (UHN) Research Ethics Board may have access to study information for auditing purposes.

All study data and media files (video and photographs) will be stored in locked cabinets and secure computers that can only be accessed by researchers working on this project. All study data will remain at UHN and will not be transferred externally. All study data and media files (video and photographs) will be kept confidential and will not be shared with anyone outside the study unless required by law. After completing the project, this form will be kept for 10 years in a locked cabinet. Any study data and media files (video and photographs) collected will be destroyed at the end of a 10 year period.

**Voluntary Participation:**

Your participation in this study is voluntary. You may decide not to be in this study, or to be in the study now and then change your mind later. You may leave the study at any time with no consequences or impact on future care at UHN.

**Withdrawal from the Study:** You may choose to withdraw from the study at any time. If you decide to leave the study, you have the right to request withdrawal of information collected about you, let your study researcher know. The researchers can take you off the balance and foot pressures study, early for reasons such as an injury, foot ulceration or motion sickness during the experiment.

**Cost and Reimbursement:**

You will not have to pay for any of the procedures involved with this study. You will be compensated $10/hr to cover study related costs (such as travel, parking).

**Rights as a Participant:**

If you are harmed as a direct result of taking part in this study, all necessary medical treatment will be made available to you at no cost.
By signing this form you do not give up any of your legal rights against the investigators, sponsor or involved institutions for compensation, nor does this form relieve the investigators, sponsor or involved institutions of their legal and professional responsibilities.

**Conflict of Interest:**
Researchers have an interest in completing this study. Their interests should not influence your decision to participate in this study.

**Commercialization:**
The research investigators and the Toronto Rehabilitation Institute intend to claim ownership of any results that would come from this study. You will not receive any financial benefit that might come from the results of this study.

**Questions about the Study:**
If you have any questions, concerns or would like to speak to the study team for any reason, please call: *Stephen Perry or Patrick Antonio at (416) 597-3422 x7774*

If you have any questions about your rights as a research participant or have concerns about this study, call the Chair of the University Health Network Research Ethics Board (UHN REB) or the Research Ethics office number at 416-581-7849. The REB is a group of people who oversee the ethical conduct of research studies. The UHN REB is not part of the study team. Everything that you discuss will be kept confidential.

You will be given a signed copy of this consent form.
**Consent:**

*Videotape, Photography*

I am indicating that I give the research team permission to:

Videotape, and/or photograph my participation in this study.

☐ YES ☐ NO

Use videos and photos of me when they present this research in educational and professional venues, *as long as I am not personally identifiable*. In order to de-identify each participant, researchers will blur out faces and recognizable features about the participant.

☐ YES ☐ NO

This study has been explained to me and any questions I had have been answered. I know that I may leave the study at any time. I agree to the use of my information as described in this form. I agree to take part in this study.

______________________________   ___________________   ________________
Print Study Participant’s Name   Signature   Date

My signature means that I have explained the study to the participant named above. I have answered all questions.

______________________________   ___________________   ________________
Print Name of Person Obtaining Consent   Signature   Date
Appendix D Questionnaires

SCREENING QUESTIONNAIRE

VOLUNTEER EXCLUSION CRITERIA

Date: (MM/DD/YYYY): _____, _____, _____

Name: ___________________________ Email address: ___________________________

Tel #: (____)-____ Best time to call: _____

Age: _____ yrs. Height: _____ cm Weight _____ kg Shoe Size _____

Gender: M □ F □

Please check (√) if applies

**Absolute exclusion criteria questions**

Do you have diabetes as diagnosed by your doctor? Yes □ No □

Have you been diagnosed to have peripheral neuropathy in the feet? Yes □ No □

Do you have any of these issues:

- Foot pain Yes □ No □
- Foot tingling Yes □ No □
- Foot numbness (otherwise called sensation loss) Yes □ No □

Do you have any difficulties walking up and down stairs? Yes □ No □

- Alternating steps? Yes □ No □

Have you had any surgeries that now cause you pain or difficulty:

- When walking up and down stairs? Yes □ No □
- Holding a handrail? Yes □ No □

Do you have any muscle or joint problems that:

- Cause you pain or difficulty when walking up and down stairs? Yes □ No □
- Prevents you from holding a handrail? Yes □ No □
- Prevents you from being supported by a harness? Yes □ No □

Do you have any issues not discussed in this questionnaire that may prevent you from walking up or down stairs Yes □ No □

If so, explain: ____________________________________________________________

Are you left-handed? Yes □ No □ Both □
How much does the condition interfere with your activities?

Do you have any conditions that limit the use of your arms or legs?  
Yes ☐ No ☐

Describe:

Do you have or have you ever had:

Please check if applies

- a) paralysis ☐
- b) epilepsy ☐
- c) cerebral palsy ☐
- d) multiple sclerosis ☐
- e) Parkinson's disease ☐
- f) stroke ☐
- g) any other neurological disorder ☐
- h) problem with your vision that isn't corrected by glasses ☐
- i) cataract surgery ☐
- j) a balance or coordination problem ☐
- k) an inner ear disorder ☐
- l) hearing problems ☐
- m) constant ringing in your ears ☐
- n) ear surgery ☐

Have you ever had any serious problems with your memory?  
Yes ☐ No ☐

Do you have or ever had recurrent ear infections?  
Yes ☐ No ☐
Have you ever had frostbite in the lower extremities?  

Yes ☐  No ☐

Do you have or have you ever had:

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<th>mod</th>
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<td>☐</td>
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Have you ever severely injured or had surgery on your

How much does the condition interfere with your activities?

<table>
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<th>Y/N</th>
<th>little</th>
<th>mod</th>
<th>a great deal</th>
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</table>
d) pelvis


e) ankle, knee, or hip joints?

Have you ever broken any bones?
Yes ☐ No ☐

Which ones? _________________________

Have you had any recent (specify)

a) illnesses ☐ ☐ ☐ ☐
b) injuries ☐ ☐ ☐ ☐
c) operations ☐ ☐ ☐ ☐

Do you have difficulties performing any daily activities?
☐ ☐ ☐ ☐

Which activities? ____________________________

Are you currently taking any medications (prescription or over-the-counter), or other drugs that affects your balance or prevents you from walking up and down stairs?
Yes ☐ No ☐

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Characteristics Questionnaire

Do you have or have ever had:

a) Foot deformities     Yes □ No □
                         Which one(s)? : _______________________

b) Known desensitized areas of the feet     Yes □ No □
                             Where? : _______________________

c) A history of smoking?     Yes □ No □
                        How long? : _______________________ 

d) A history of hypertension     Yes □ No □


e) Previous ulcers     Yes □ No □
                        How long ago? : _______________________

f) Elevated Blood Glucose levels?     Yes □ No □
                         Current Blood Glucose level _____________________
Appendix E Photographs of Equipment & Diagrams

Appendix E-1: Image of ‘StairLab’ at Toronto Rehabilitation Institute. Total dimensions of the stair case were 1.96 m x 1.45m x 1.24 m (length x width x height), with step risings of 7 inches (17.8 cm) and step runners of 11 inches (27.95 cm)

Appendix E-2: Exterior of ‘StairLab’ in the Challenging Environment Assessment Laboratory (CEAL) at Toronto Rehabilitation Institute. The laboratory is tilted 20° to accommodate the proper stair angle.
Appendix E-3: Full Marker Setup. A) Markers placed on landmarks of the body during data collection, B) 12 Marker setup used for data analysis. COM 7-segment calculation using 12 markers. Segments consisted of the 1) head, 2) thorax and arms, 3) pelvis and abdomen, 4) right thigh, 5) left thigh, 6) right shank, and 7) left shank. The box demonstrates how the BOS lateral border was determined using the 5th metatarsal marker and the heel marker.

Appendix E-4: Medilogic pressure sensors (Medilogic, Schonefeld, Germany). Sensors were placed in between the foot and the insole. Various sizes of pressure insole were available.
Appendix E-5: Insole mapping of the right pressure sensor highlighting the 9 region masks; 1) big toe 2) tarsals 3) medial metatarsals 4) central metatarsal 5) lateral metatarsal 6) medial mid-foot 7) lateral mid-foot 8) medial calcaneus 9) lateral calcaneus

Appendix E-6: Picture of taped footwear used for the study. Various sizes of footwear were available. The standard athletic footwear consisted of a rubber-sole and synthetic upper material, and did not contain any additional footwear technology.
Appendix E-7: Touch-Test ® Sensory Evaluator monofilaments application on the plantar surface (North Coast Medical, Inc. Gilroy, CA, USA)

Appendix E-8: Depiction of the COM-BOS Temporal. The COM-BOS_{MLd} was found from the BOS lateral border at a perpendicular line. From the point where the perpendicular line and the COM intersect, the First Central Difference was found to determine the slope (COM_{AP}). The resultant COM_{MLv} was found and the COMBOS temporal value was determined using the equation.
Appendix E-9: Correlation plots of various variables. A) Age x BMI B) Age x Blood glucose C) Stance time x BMI D) Stance time x Blood glucose E) Stance time x Age. Where * denotes significance at p < 0.001, † denotes significance at p < 0.05.