2017

The Effects of a 12-Week Custom Foot Orthotic Intervention on the Intrinsic Muscles of the Foot, and Dynamic Stability During Unexpected Gait Termination in Healthy Young Adults

Katrina Protopapas
prot3480@mylaurier.ca

THE EFFECTS OF A 12-WEEK CUSTOM FOOT ORTHOTIC INTERVENTION ON THE INTRINSIC MUSCLES OF THE FOOT, AND DYNAMIC STABILITY DURING UNEXPECTED GAIT TERMINATION IN HEALTHY YOUNG ADULTS

Katrina Protopapas

Supervisor: Dr. Stephen D. Perry

Submitted to the Department of Kinesiology and Physical Education in partial fulfillment of the

requirement for Master of Kinesiology

Wilfrid Laurier University

Abstract

Introduction: Custom-made foot orthotics (CFO's) are a commonly prescribed intervention to help individuals that are suffering from foot pain and foot disorders. However, the mechanisms of CFO's are still poorly understood and are not well known. With the plantar intrinsic muscles of the foot being in direct contact with the CFO, it puts these structures at risk for disuse muscle atrophy as a result of being offloaded. Therefore, the purpose of the current study was to determine the effect of a 12-week custom-made foot orthotic intervention on the intrinsic muscles of the foot and dynamic stability during unexpected gait termination.

Methods: Eighteen healthy young adults participated in the study. Participants were allocated by stratified sampling into either the: (a) orthotic group (n= 9) or (b) control group (n= 9). Beginning of each testing session, participants' right foot was assessed by diagnostic ultrasound to measure the cross-sectional area (CSA) of the flexor digitorum brevis (FDB), abductor digiti minimi (Abd DM), and abductor hallucis (Abd H). Subsequently, participants completed an unexpected gait termination protocol and data was collected using force plates, motion capture, and electromyography (EMG) to assess dynamic stability. A total of 50 walking trials were completed at baseline, 6-weeks and 12-weeks, where 25% of the trials were unexpected gait termination. The variables used to measure dynamic stability were M/L COM-BOS and A/P COM-COP. Additionally, the amount of muscle activity was determined by average EMG magnitude and integrated EMG. The secondary outcome measures of interest were vertical force rate of loading (ROL), step width, step length and gait velocity.

Results: At the end of the 12-week intervention, the participants in the OG had significantly smaller CSA of the FDB (9.6%) ($p<0.001$), Abd DM (17.1%) ($p<0.001$) and Abd H (17.4%) ($p<0.001$) plantar intrinsic muscles. Despite muscle atrophy, individuals in the orthotic group showed an improvement of 1.1 cm in M/L COM-BOS ($p<0.001$) at 12-weeks and were as stable as the CG during gait termination. Additionally, there were significant differences of ROL between the groups during first ($p<0.001$) and second single stances ($p<0.001$) at the end of 12-weeks. Lastly, there was no significant difference in average EMG magnitude of the intrinsic muscles between the groups.

Discussion: The short-term use of CFO's created a decrease in CSA of the FDB, Abd DM and Abd H plantar intrinsic muscles. These findings help understand the adaptations that are occurring when you offload specific structures such as the plantar intrinsic muscles. Although both groups were similar in creating stability when exposed to the mechanical perturbation, the participants in the OG adapted a compensatory strategy to recover their balance. Therefore, these findings along with future research can help develop guidelines to enhance the use of CFO's by adding rehabilitative exercises to prevent disuse atrophy from occurring.

Acknowledgements

Foremost, I would like to thank my supervisor Dr. Stephen Perry for his mentorship through this incredibly humbling experience. Your knowledge, guidance and expertise has added a substantial element to my research and without your involvement I would have not been able to succeed. I look forward to collaborating with you in the future and working with you for my PhD in the next chapter of my academic journey.

I would like to thank my thesis advisory committee members Dr. Jayne Kalmar, Dr. Tom Hazell, and Dr. John Zettel for contributing additional guidance and expertise to strengthen my research. Additionally, I would like to thank Dr. Steven Brown and Kim Rau for helping by providing me the equipment necessary to perform my data collection, without you both my research could have not been possible.

I would also like to thank my lab mates and the undergraduate students in the Neuromechanics Research Laboratory, especially Colin Kirst for helping me during data collection and the occasional equipment malfunction.

To all the friends I made along the way and those especially in the Masters program, thank you for all the laughs, the venting sessions and the fun times to help keep me motivated during the 2 years. To someone I now call my best friend, Maxine Harvey-Burgess, who was also in the trenches completing her own Masters thesis but always found time for "friendship" and to help me when I needed it the most, thanks dawg! You're a day one real OG, a Microsoft office and excel queen, and not too bad at Blokus.

Lastly, I would like to give a big thank you to my parents and "Seeeeeester" for your unconditional love and support throughout my time at Laurier. I will never be able to thank you enough for your great understanding of what it truly means to sacrifice your own life goals so that I could pursue my life dreams and academic goals. The many accomplishments and achievements I have obtained over the years are really because of you and I'm forever grateful. Thank you for always believing in me, when sometimes I didn't believe in myself, and for also supporting my long academic journey when others would discourage me and think I was crazy for pursing my 4^{th} degree.

Research reported in this document was supported by the MS2Discovery Institute Research & Travel Grant.

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Abd DM	Abductor digiti minimi
Abd H	Abductor hallucis
ANOVA	Analysis of variance
A/P	Anterior posterior
BOS	Base of support
CFO	Custom-made foot orthotic
CG	Control Group
COM	Centre of mass
COM-BOS	Centre of mass—Base of support
COM-COP	Centre of mass—Centre of pressure
CSA	Cross-sectional area
EDB	Extensor digitorum brevis
EHB	Extensor hallucis brevis
EMG	Electromyography
FDB	Flexor digitorum brevis
Fz	Vertical force
M/L	Medial lateral
MOS	Margin of stability
MVC	Maximum voluntary contraction
Mx	Moment of x-axis
My	Moment of y-axis
OG	Orthotic group
ROL	Rate of loading

1. Introduction

The foot orthotic insole industry has generated $2.5 billion globally in 2014, and has projections of reaching $3.5 billion by 2020 (IndustryARC, 2015). North America is the leading contributor with 45% of the market (IndustryARC, 2015), suggesting North Americans are utilizing foot orthotic insoles more compared to the rest of the world. It is important for research to keep up to date with the latest technology put out by the foot orthotic companies in order to understand their implications on specific populations utilizing them. Custom-made foot orthotics (CFO's) are a commonly prescribed intervention for individuals suffering from foot disorders and pain. However, the mechanisms of CFO's are still poorly understood and the implications of their use are not well known.

Foot pain has become an increasingly large problem throughout the world, with varying reports affecting many different geographical regions. The prevalence of foot pain ranges from 10-34% in countries such as the United Kingdom, United States, Denmark, and Australia (Hill, Gill, Menz, & Taylor, 2008; Mølgaard, Lundbye-Christensen, & Simonsen, 2010; Roddy et al., 2011; Thomas et al., 2011). Thomas et al. (2011) identified that two thirds of the individuals with foot pain reported an associated disability in activities of daily living. It is well documented that foot disorders and foot pain lead to poor foot function that result in changes in biomechanics that contribute to an increased risk of falls in the elderly population (Menz, Morris, & Lord, 2006). Although the prevalence of foot pain remains high, many researchers attribute this to anthropometric characteristics of the foot and footwear worn (Paiva de Castro, Rebelatto, & Aurichio, 2010). Previous research has established that poor fitting footwear can lead to these disorders (Barnish & Barnish, 2016; Burns, Leese, & McMurdo, 2002; Menz & Morris, 2005; Rossi, 2001) and effect gait (Doi et al., 2010; Menant et al., 2008). Despite great technological advances to footwear and footwear devices added into the shoe, foot disorders and foot pain remain at staggering high numbers.

1.1 Theories of Mechanisms of Orthotics

Currently, there are two theories that are commonly used in the clinical setting when prescribing orthotics that involve either correcting biomechanical alignment of specific foot structures and/or off loading soft tissue structures: (a) subtalar joint axis neutral (Rootian) theory and (b) tissue stress theory.

1.1.1 Subtalar Joint Axis Neutral (Rootian) Theory

The subtalar joint axis neutral (Rootian) theory was first proposed in the early 1970’s by Merton L. Root and has since continued to be used by many clinicians. The premise of this theory is to identify whether excessive motion occurring at the subtalar joint will produce abnormal foot function to potentially increase the risk of foot disorders. Excessive motion includes any deviation from neutral in either pronation or supination (Daniel & Colda, 2012; Harradine & Bevan, 2009; McPoil & Hunt, 1995). The practitioner first measures the degree of the deformity with a goniometer and casts an impression, using plaster material, of both feet by positioning each foot in a non weight-bearing subtalar neutral position. A “functional” foot orthotic is created by positioning wedges or posts based on the specific foot deformity present (Harradine & Bevan, 2009).

Contrary to the high utility of this paradigm, there is minimal evidence in the scientific literature that supports the notion of the theory. Previous kinematic studies have shown that foot orthotics have reduced rearfoot eversion during walking and running, however, it only contributed a small reduction of 1º to 4.1º (Bates, Osternig, Mason, & James, 1979; Branthwaite, Payton, & Chockalingam, 2004; Eslami et al., 2009; Mills, Blanch, Champman, McPoil, Vicenzino, Cornwall, & Collins, 2009; Stacoff et al., 2007; Zifchock & Davis, 2008). The minimal change in rearfoot range of motion makes it unlikely that correcting biomechanical alignment of the rearfoot is a possible explanation of the mechanism. To coincide with the rest of the literature many kinematic studies were unable to show that custom-made foot orthotics (CFO's) had any effect on controlling rearfoot motion (Garbalos et al., 2015, Mündermann et al., 2003; Nigg, Khan, Fisher, & Stefanyshyn, 1998; Stacoff et al., 2000). More recently the theory has been questioned with many criticizing the lack of reliability of measurements, controversial definition of normal, and whether correcting biomechanical alignment into subtalar neutral actually prevents foot disorders from manifesting.

Additionally, using the biomechanical alignment approach has been applied to other areas of the foot and another commonly targeted structure is the forefoot. A metatarsal pad is placed proximal to the five metatarsal heads to try and increase the space between the metatarsals as a result of a dropped transverse arch. A biomechanical study was done to determine if an increase structural space occurred to the forefoot during gait with a metatarsal pad, however the study resulted in only a small (0.64 mm) increase in forefoot width in static stance and a small increase (0.74 mm) in forefoot width during mid-stance of gait (Koenraadt, Stolwijk, van den Wildenberg, Dusysens, & Keijers, 2012). Again, these minimal changes in structural suggest that other possible mechanisms exist to explain the effectiveness of CFO's.

1.1.2 Tissue Stress Theory

The second theory that is also eminently practiced is the tissue stress theory. This theory was applied to describe the mechanism of orthotics in 1995 by Tom McPoil and Gary Hunt (Daniel et al., 2012; Harradine et al., 2009; McPoil et al., 1995). The basis of the theory focuses on the forces or pressures (kinetics) placed on the lower limb during gait rather than analyzing joint position or motion (kinematics). Theoretically, the purpose of the foot orthotic intervention is to reduce or redistribute forces to eliminate the stress on the painful structure. This can be explained by the load deformation curve (Figure 1). As a force is applied, for example to a specific muscle, and that force exceeds the capacity of the muscle to withhold the force, the integrity of the muscle will go from the elastic region and approach the plastic region. In between the elastic and plastic regions is the microfailure zone where the muscle is suspect to injury. Therefore, if the load is maintained for a prolonged period, the increased amount of deformation to the muscle will be irreversible. The purpose of a custom-made foot (CFO) is to unload the structures experiencing increased forces and redistribute the force in order to remain in the elastic region.

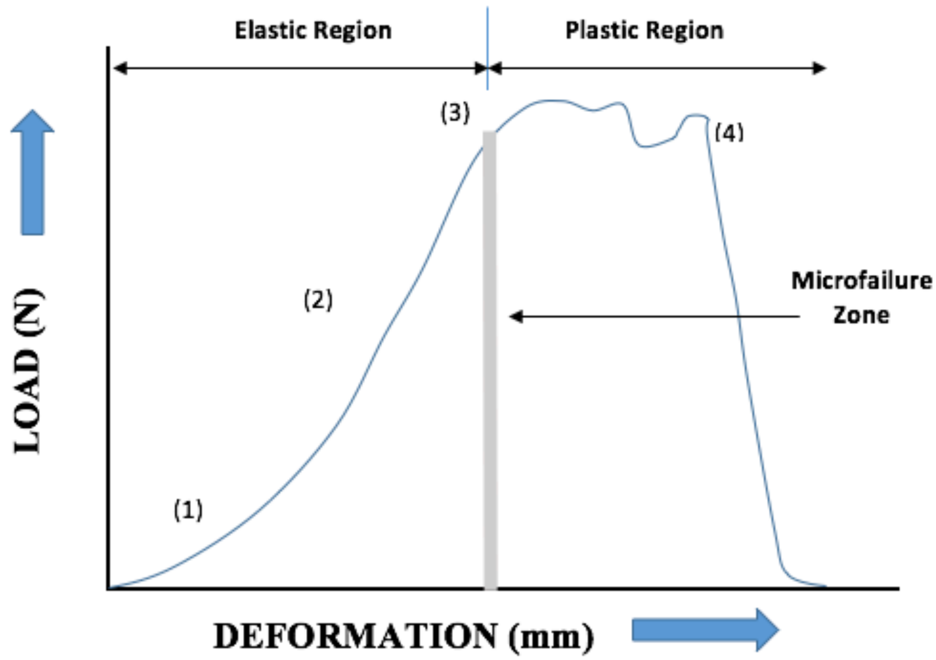

Figure 1. The load-deformation curve of soft tissue structures. The graph is a generalization of deformation that occurs as load is increasingly applied to soft tissue structures. The curve is represented by (1) Toe region, (2) elastic region, (3) plastic region, and (4) failure point. (Adapted with permission from JOSPT, 1995. Doi:10.2519/jospt.1995.21.6.381. Copyright ©Journal of Orthopaedic & Sports Physical Therapy®).

Common areas where the CFO is manipulated to alter plantar pressures is in the rearfoot and forefoot regions. Metatarsal pads and bars are commonly prescribed and customized to foot orthotics when individuals exhibit pain in the forefoot. Individuals with foot pain have associated higher plantar pressures (Burns, Crosbie, Hunt, & Ouvrier, 2005; Hodge, Bach, & Carter, 1999; Mickle, Munro, Lord, Menz, & Steele, 2011; van der Leeden, Steultjens, Dekker, Prins, & Dekker, 2006; Waldecker, 2002). The theory of the metatarsal apparatus is to reduce and redistribute plantar pressures of the foot and has been shown to reduce pressures by 11.8% to 60% in various studies (Hähni, Hirschmüller, & Baur, 2016; Hayda, Tremaine, Tremaine, Banco, & Teed, 1994; Hodge et al., 1999; Holmes & Timmerman, 1990; Jackson, Binning, & Potter, 2004; Hackney, Hunt, Lerche, Voi, & Smith, 2010; Kang, Chen, Chen, & His, 2006; Lee, Landorf, Bonanno, & Menz, 2014; Postema, Burm, Zande, & Limbeek, 1998). Although many studies have shown decreased plantar pressures in the forefoot, there is conflicting evidence demonstrating that changes in peak plantar pressures are correlated with changes in pain scores (Kang et al., 2006; Postema et al., 1998). Secondly, the midfoot region is another common targeted location to alter plantar pressures. A medial arch support is placed along the medial longitudinal arch to alter the forces and peak plantar pressures on the midfoot structures. A study by Farzadi et al. (2014) suggests that when adding a prefabricated orthotic with a medial arch support to the medial longitudinal arch of the foot, it increased both the peak force (N) and peak plantar pressures (kPa) by 2.2 times in the midfoot compared to when wearing shoes only. This was apparent at both the initial assessment and 1-month follow-up after enduring the 4-week foot orthotic intervention. Additionally, another study by McCormick et al. (2013) found similar results of increased peak plantar pressures by 15% and 12% in the medial midfoot as a result of wearing CFO's compared to wearing shoes only at week 0 and 4 respectively. It is apparent from the literature that wearing CFO's creates changes in plantar pressures compared to wearing normal shoes. However, those differences (increased or decreased) in plantar pressures are dependent on the specific region of the CFO being manipulated.

Lastly, numerous muscle electromyography (EMG) studies have been conducted to evaluate the effectiveness of the tissue stress paradigm. Within the literature there is conflicting evidence demonstrating whether the effects of wearing CFO's induce changes of EMG magnitude in the various leg muscles. Some studies have shown decreases in specific shank muscle EMG activity (Garbalosa, Elliott, Feinn, & Wedge, 2015; Murley, Landorf, & Menz, 2010), while others have shown increases in shank (gastrocnemius medialis, peroneus longus, tibialis anterior) muscle EMG activity (Barn et al., 2014; Mündermann, Wakeling, Nigg, Humble, & Stefanyshyn, 2006; Murley & Bird, 2006; Nawoczenski & Ludewig, 1999; Tomaro & Burdett, 1993). Moreover, there is additional evidence that exhibits change in onset and duration of the muscular activity of the tibialis anterior, soleus, gastrocnemii (medialis and lateralis) and peroneus longus as a result of wearing CFO's (Dedieu, Drigeard, Gjini, Dal Maso, & Zanone, 2013). The variability of maximal EMG muscle activity and timing across studies may imply that individuals motor control systems adapt differently. Although findings from these studies partly support the tissue stress theory, the evidence does not conclusively validate the theory. A new paradigm called the preferred movement pathway has been proposed as an alternate explanation to the mechanism of CFO's. This paradigm may help to explain the wide variability in the previous experimental findings of the kinematic, kinetic and muscle EMG activity data in the literature and it may also suggest there is a more complex interaction with multiple systems of the human body. The preferred movement pathway attributes the locomotor system as choosing a path of least resistance by recruiting specific muscles that will maintain the movement in the most efficient path (Nigg, 2001). For example, when a CFO is added into an individual's shoe, Nigg et al. (1999) assert that if the CFO maintains the preferred movement path then muscle activity will be reduced, and the opposite affect is seen if the intervention counteracts the preferred pathway. Despite this revelation, few experimental designs have focused on testing this hypothesis, therefore future research needs to thoroughly explore this paradigm.

1.2 Benefits and Risks of Orthotics

The main goal of health practitioners in administering an effective intervention is to ensure that the benefits of the intervention out weigh the potential risks associated with the applied intervention. The estimated cost of custom-made orthotics (CFO's) ranges from $300 to $700 per pair (Rao, Riskowski, & Hannan, 2012), therefore it is important practitioners provide evidence-based research to allow individuals to make an informed choice for wearing CFO's. Currently in the literature a Cochrane review delineates only high-level evidence for the use of CFO's for reducing pain in pes cavus, rheumatoid arthritis, juvenile idiopathic arthritis (JIA), and hallux valgus conditions (Hawke, Burns, Radford, & Du Toit, 2007). Due to a lack of high-level research designed studies, inconclusive findings have been drawn for the use of CFO's on the various other foot disorders and accordingly the literature does not support their use at this time. A second benefit shown in the scientific literature is that CFO's are beneficial for enhancing balance parameters for the elderly population. Previous studies have displayed significant improvements in balance measurements in individuals with impaired balance and at risk for falls (de Morais Barbosa et al., 2013; Gross, Mercer, & Lin, 2012). Overall, the research literature insinuates improvements in outcome measures will be obtained if CFO's are dispensed properly and used for the appropriate condition. In this study, the focus is to disrupt balance by unexpected gait termination in order to observe how individuals respond to mechanical perturbations. Unexpected gait termination is a dynamic task and is one of many ways to perturb gait; gait termination was chosen as it mimics a situation people encounter in everyday life.

While the efficacy of CFO's remains unclear, there is a level of uncertainty of the potential negative side effects CFO's may impose on the structure and function of the foot. To date, there is sparse evidence that demonstrates the safety of orthotics, although they have been acknowledged as having few side effects (Rao et al., 2012). The known side effects are predominantly self-reported by the individuals wearing the CFO's and include discomfort, additional pain and/or skin irritation. Generally, the CFO's are returned to the practitioner that prescribed the orthotic to make the appropriate adjustments to the areas of concern or recommend the individuals discontinue using them. Previous literature has not objectively measured physiological changes that may occur to the foot as a result of wearing CFO's. Additional research focusing on this area is needed to provide further insight into the overall safety and to strengthen the current clinical guidelines. There are currently no definitive evidence-based clinical guidelines recommending a timeline on the duration or frequency CFO's should be worn for the various foot disorders utilizing CFO's as an intervention. This postulates immediate concern to the small plantar intrinsic muscles of the feet, since these muscles and surrounding joints are in direct contact with the CFO. According to Nigg (2010), there are potential consequences that may occur by reducing the functional demand on those muscles and may be associated with the deterioration of muscle structure and performance.

1.3 Intrinsic Muscles of the Foot

The intrinsic muscles of the foot are compartmentalized into dorsal and plantar intrinsic muscles. The plantar intrinsic muscles consist of 4 layers starting from superficial to deep (Figure 2). The superficial layer consists of the abductor hallucis (Abd H), flexor digitorum brevis (FDB), and abductor digiti minimi (Abd DM). The second layer contains the quadratus plantae and lumbrical muscles. The third plantar layer encompasses the flexor hallucis brevis, adductor hallucis, and flexor digiti minimi brevis. The deepest layer comprises of the dorsal and plantar interosseous muscles.

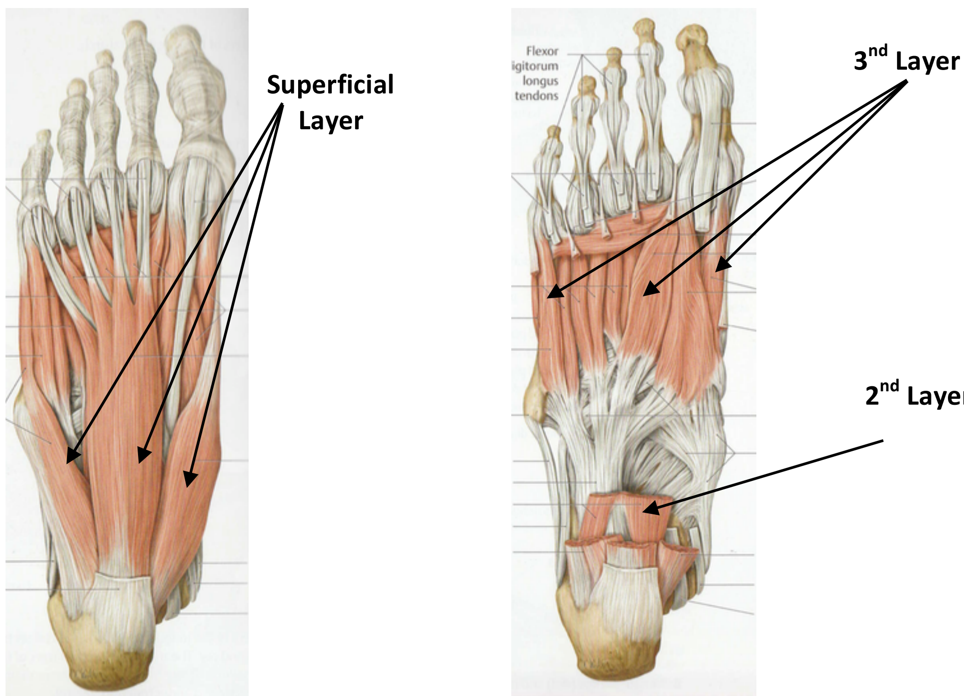

Figure 2. Plantar view of the superficial, 2nd and 3rd layer of the plantar intrinsic muscles. (Adapted from Figure 26.16. Gilroy, MacPhearson, & Ross, 2008. Atlas of Anatomy; Thieme).

The role of the intrinsic muscles in foot function has been vastly underestimated. These muscles are viewed as not bearing importance in foot function and are frequently disregarded due to their small size. An early electromyography (EMG) study by Mann & Inman (1964) identified during ground level walking the plantar intrinsic muscles were the most active during mid-stance up until toe-off, where the plantar intrinsic muscles then acted to stabilize the foot during propulsion. Recent studies have further investigated the functional role of the plantar intrinsic muscles and confirmed they play a vital role in controlling foot posture (Fiolkowski, Brunt, Bishop, Woo, & Horodyski, 2003; Headlee, Leonard, Hart, Ingersoll, & Hertel, 2008; Mulligan & Cook, 2013), the stiffness of the longitudinal arch and buttressing effect during foot loading (Caravaggi, Pataky, Günther, Savage, & Crompton, 2010; Kelly, Cresswell, Racinais, Whiteley, & Lichtwark, 2014). Deformation of the medial longitudinal arch was noted by an increase in navicular drop test when muscles were disrupted by lidocaine injection into the tibial nerve (Fiolkowski et al., 2003) and a fatiguing protocol in static stance (Headlee et al., 2008). Whereas a study by Mulligan & Cook (2013) demonstrated the opposite affect by maintaining support to the medial longitudinal arch by performing 4-weeks of short foot exercises of the intrinsic foot muscles to increase navicular height. The magnitude of muscle activity for plantar intrinsic muscles is variable and is dependent on the type of tasked performed, load applied and walking speed. Kelly et al. (2012) found performing single legged stance task showed greater average EMG muscle activity for the abductor hallucis, flexor digitorum brevis and quadratus plantae compared to the double leg stance. Thus, they concluded that increases in postural demand created increases in the plantar intrinsic muscle activity. A follow up study by Kelly et al. (2014) established muscle activity of the plantar intrinsic muscles were detected when loads between 50% and 150% of body mass was applied to the foot statically. Lastly, Caravaggi et al. (2010) observed when faster walking cadences were performed it increased stiffness in the medial longitudinal arch. The investigators attributed the increased stiffness as a result of the recruitment of the plantar intrinsic muscles that become activated to absorb the higher ground reaction forces the foot sustains with quicker walking speeds and was later confirmed by a study done by Kelly, Litchtwark, & Creswell (2015).

The plantar intrinsic muscles like any other muscle in the body are susceptable to injury. Disuse muscle atrophy of the intrinsic foot musculature has recently been suggested as a possible source for acquired foot disorders. Observations from a cadaveric study revealed the flexor digitorum brevis muscle had reduced cross-sectional area in the feet with claw toe deformities (Locke, Baird, & Frankis, 2010). A more recent study by Mickle & Nester (2017) compared cross-sectional area (CSA) of the plantar intrinsic muscles to older adults with foot deformities and healthy older adults. They found that CSA decreases in abductor hallucis and flexor hallucis brevis muscle size in participants with hallux valgus and decreases in CSA for abductor hallucis, quadratus plantae, flexor hallucis brevis and flexor digitorum brevis in participants with lesser toe deformities compared to the healthy older adults. Since foot disorders are acquired over a length of time, it may be possible for the atrophy to be present prior to the development of the foot disorder. There is a paucity of research investigating possible mechanical adaptations to the plantar intrinsic muscles as a consequence of wearing custom-made foot orthotics (CFO's). Although it is known that wearing CFO's alter the distribution of plantar pressures, no previous study has investigated if disuse muscle atrophy ensues as a consequence of offloading specific plantar intrinsic muscles.

1.4 Disuse Muscle Atrophy

Disuse muscle atrophy occurs as a consequence of short-term and long-term muscular inactivity, immobilization, and unloading of the surrounding structures. It results in a loss of muscle mass, increase in fatty infiltration into the muscle (Borkan, Hults, Gerzof, Robbins, & Silbert, 1983; Forsberg, Nilsson, Werneman, Bergström, & Hultman, 1991; Overend, Cunningham, Paterson, & Lefcoe, 1992), changes in structural components of the neuromuscular system (Hather, Adams, Tesch, & Dudley, 1992), decrease in strength (Deschenes, Holdren, & Mccoy, 2008; Hvid et al., 2010), and adaptations in neural drive (Dudley et al., 1992; Seki, Taniguchi, & Narusawa, 2001), which collectively affect the functional capacity and performance of an individual (Aagaard, Suetta, Caserotti, Magnusson, & Kjaer, 2010; Coker, Hays, Williams, Wolfe, & Evans, 2015; Kortebein et al., 2008; Suetta et al., 2009). The rate at which muscle atrophy occurs from disuse depends on the degree of unloading and inactivity, the muscle group involved and anatomical location (Miokovic, Armbrecht, Felsenberg, & Belavy, 2012; Psatha et al., 2012). The degree which a joint is limited or restricted in movement, and the position that the joint is immobilized in will have an effect on the rate the muscle atrophies. The rate of muscle atrophy is also greater when a muscle is immobilized in a shortened position rather than a lengthened position (Spector, Simard, Fournier, Sternlicht, & Edgerton, 1982). Furthermore, the rate the muscle atrophies is also influenced by anatomical location. During lower limb immobilization and unloading, the posterior calf muscles deteriorate at a faster rate and undergo a greater amount of disuse muscle atrophy than the knee extensors (vasti, rectus femoris) and ankle flexors (tibialis anterior, extensor digitorum longus). Studies by Miokovic et al. (2012) and Psatha et al.

(2012) demonstrated that the medial gastrocnemius and soleus atrophy the quickest. They hypothesize that the order in which atrophy occurs in the muscle coincides with the recruitment patterns during locomotion. Additionally, they found that many muscles do not atrophy uniformly along the length of the muscle, which is likely related to the specific use of each muscle. The earliest onset of disuse muscle atrophy observed in the literature is 72 hours (Lindboe & Platou, 1984). However, this was done by a more dramatic unloading methodology, where they immobilized the lower limb with a cast, while simultaneously on bed rest. An additional study found that 4 days of complete unloading via lower limb immobilization led to a 10% decrease in mean muscle fibre cross-sectional area (Suetta et al., 2012). It is important to note there is a lack of research that focuses on other mechanisms of inducing atrophy, where it may be beneficial to understand if disuse muscle atrophy can be influenced by assistive devices used on an everyday basis while mobile.

Investigators are faced with the difficult task to decipher if the changes from disuse muscle atrophy are associated to natural progression of aging, or as a result of unloading. Therefore, it is imperative to clarify if age is a dependent factor to the rate of disuse atrophy, and the effects it may have on recovery. Two recent studies have compared old and young men after 2 weeks of immobilization of the lower limb followed by a 4-week retraining period (Hvid et al., 2010; Suetta et al., 2009). An apparent difference between young and older men at baseline measurements existed, with older men exhibiting lower scores in maximal muscle strength, quadriceps muscle volume, and cross-sectional area of the compared to younger men. After 2 weeks of immobilization of the lower limb, the older individuals were more affected in neural activation and function, whereas the younger group had different adaptive mechanisms that only caused changes to the muscle size and architecture. Moreover, it was evident that after 4 weeks of retraining the younger men were able to recover from the impairments experiences as a result of short-term immobilization, and return back to baseline values. The older men had similar recovery in isometric strength and dynamic strength, however they remained deficient in force rate capacity, impulse, muscle volume, and cross-sectional area of the muscle following the retraining period. These results indicate that older individuals have an impaired ability to recover from disuse muscle atrophy and may need to undergo longer retraining periods in comparison to younger individuals (Tanner et al., 2015). The older men's inability to recover to their original baseline values corresponds to the evidence that suggests sarcopenia causes muscle loss of ~0.5 to 1% per year (Mitchell et al., 2012). Contrary to the evidence indicating sarcopenia as a potential factor to the rate of disuse muscle atrophy, there is opposing evidence against sarcopenia and ascribe the decline in muscle mass and strength to a sedentary lifestyle adopted with the progression of age. Wroblewski et al. (2011) examined master level athletes between the ages of 40 to 81 years, subdivided them into 4 age groups based on decade and assessed muscle mass and strength using magnetic resonance images (MRI) and functional strength tests. They found that chronic exercising preserved the quadriceps muscle mass and prevented fatty infiltration from occurring from the measurements on the MRI. There were no differences across the age groups in measured mid-thigh total area, subcutaneous adipose tissue, and intramuscular adipose. In addition, they did find that peak torque of the quadriceps at the age of 60 years, however did not decline with further aging. The authors concluded that individuals with sedentary physical activity levels contribute to the effect of chronic disuse rather than muscle aging.

1.5 Purpose, Objectives and Hypotheses

In the current literature, there is a lack of evidence to explain whether mechanical adaptations occur to the structure of the foot as a result of wearing custom-made foot orthotics (CFO's). Due to the poor understanding of the mechanisms of orthotics, it unknown if the plantar intrinsic muscles are affected since they are in direct contact with the CFO's. The purpose of this study was to explore the effect of a 12-week custom-made foot orthotic intervention on the intrinsic muscles of the foot and dynamic stability during unexpected gait termination. The objectives of the study are to determine if the use of CFO's cause: (a) changes to the structure of the plantar intrinsic muscles, (b) alteration to the magnitude and duration of the intrinsic muscles during the gait cycle and (c) changes in dynamic stability during gait.

It was hypothesized that individuals in the foot orthotic group will have decreased cross-sectional area measurement of the plantar intrinsic muscles at the end of the 12-week intervention. Secondly, it was hypothesized that individuals in the orthotic group will have decreases in average magnitude of electromyography (EMG) muscle activity for the dorsal and plantar intrinsic muscles. Additionally, it was hypothesized the muscle burst activity duration of the orthotic group will remain the same at the end of the intervention. Lastly, it was hypothesized that individuals in the orthotic group will exhibit a decrease in dynamic stability from their baseline measurements to the end of the intervention during gait termination trials. More specifically, the orthotic group will have a decrease in lateral stability margin and the centre of mass (COM) trajectory will approach closer to the lateral border of the base of support during gait termination trials. Using the additional measure of instability, the centre of mass—centre of pressure (COM-COP) relationship, it is hypothesized that the orthotic group maximum anterior-posterior direction COM-COP differences will increase over time during gait termination.

2. Methodology

2.1 Participants

Eighteen healthy young adults between 21-33 years of age voluntarily participated for this study. Participants were recruited with posters displayed in the Kitchener-Waterloo and Wilfrid Laurier University communities. Once they volunteered each individual attended a screening session prior to inclusion into the study. The screening session consisted of each participant completing the screening questionnaire (Appendix A), their foot posture was evaluated by a single examiner using the Foot Posture Index (FPI) (Appendix B), while weight bearing as described by Redmond et al. 2006 and Navicular Height (NH) (Appendix C) was measured to confirm a pronated foot posture (Mueller, Host, & Norton, 1993). The NH measurement was taken a total of three times, and then averaged. The screening questionnaire included general information of demographics, previous history of medical and lower limb injuries, and dietary protein intake consumption. The dietary protein food frequency questionnaire was only administered at baseline. After the screening session, the main researcher determined if each participant met the inclusion criteria of the study. The participants were included into the study if they did not meet the exclusion criteria: (a) worn custom foot orthotics (CFO) in the past year, (b) scored less than +5 on the FPI or had NH greater than 3.6 cm, (c) had a current lower limb injury, leg or foot pain, (d) neurological or musculoskeletal disorders affecting balance and coordination, (e) previous history of lower limb surgery, (f) dietary protein consumption exceeding Health Canada's recommended daily intake (0.8 g/kg/d), and (g) on any medications affecting balance.

After the inclusion criteria was met, participants were placed into one of two groups by stratified sampling and then were randomized into either the orthotic (n= 9) or control group (n= 9). The control group was added to determine the effect of task over time and the effect of the intervention. The orthotic group age ranged from 21 to 33 years old (24.2 ±3.5), height ranged from 1.60 to 1.85m (1.74 ±0.07) and mass ranged from 56.8 to 87.7 kg (70.4 ±9.4). The control group age ranged from 23 to 32 years old (25.3 ±3.0), height ranged from 1.57 to 1.88 m (1.77 ±0.09) and mass ranged from 59.1 to 91.8 kg (76.8 ±13.6) (Table 1). Each participant signed a written consent form that outlined and detailed the protocol along with any possible risks associated with the study prior to the first testing session. They were permitted to revoke their consent at any time and withdrawal from the study. The Wilfrid Laurier University Ethics Board reviewed and approved the study prior to data collection.

2.2 Custom-made Orthotic Casting, Fitting and Materials

Participants randomized into the orthotic group had a physical assessment session prior to data collection. Each participant was casted for a pair of custom-made foot orthotics (CFO's) by a certified Pedorthist with twenty-five years of clinical experience. The participants were seated and a negative foam box cast was taken optimizing arch height, subtalar joint posture and forefoot to rearfoot alignment. The design of the CFO's was standardized where all shell materials, liners and external postings were equivalent across all participants in the orthotic group, however they were customized to accommodate the varying degrees of the pronated foot postures. The CFO's were ¾ of their foot length ending proximal to the metatarsal (MT) heads of each subject, the shell material was composed of low pressure polypropylene, the external postings and liners made of ethylvinylacetate (EVA) (Figure 3). The participants in the orthotic group returned to the Pedorthist for a fitting session where minor adjustments were made if needed through heating and grinding to ensure proper fitting, comfort, and foot posture. All participants were then given an acclimatization period of one week to accommodate to the CFO's before the start of the study. Participants were instructed to wear the CFO's for a minimum duration of 6 hours a day or as long as possible throughout the twelve-week study period. At the end of each week, all participants in the orthotic group received and completed a follow-up questionnaire (Appendix D) via e-mail to ensure adherence to the protocol.

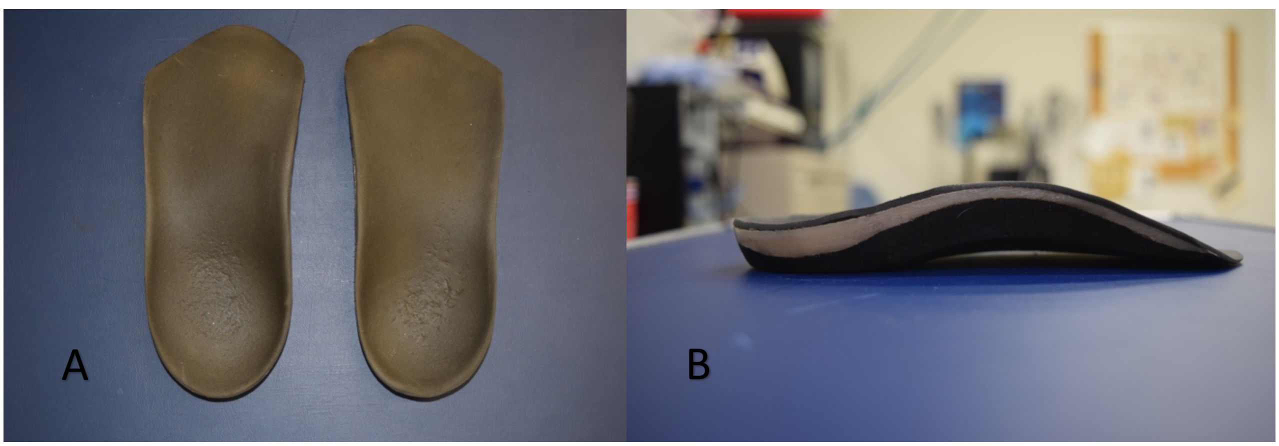

Figure 3. Custom-made foot orthotics (CFO's) worn by participants in the orthotic group. **(A)** Overhead view **(B)** Medial view.

2.3 Instrumentation and Data Processing

2.3.1 Kinetics

Three force plates (Advanced Mechanical Technologies Inc., Watertown, MA) embedded securely into the floor were used to record kinetic data collected at a sampling frequency of 1000-Hz (Figure 4). The spacing of the force plates was designed to collect data for walking and gait termination tasks. The horizontal and vertical forces and moments were recorded and used to calculate the centre of pressure (COP) and rate of loading (ROL). All force measurements were normalized to the participant's body weight in Newton's (N). A threshold of 10 N of vertical force was used to determine heel contact (HC) and toe-off (TO) of each force plate. The onset was determined when the vertical force exceeded 10 N of force and the offset was defined as when the vertical force fell below 10 N.

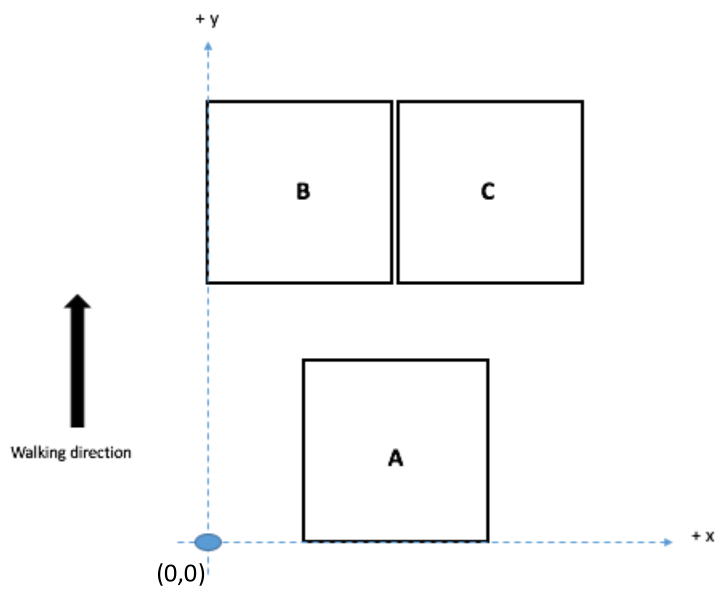

Figure 4. Setup of the three force plates embedded into the floor: **(A)** force plate one (FP1), **(B)** force plate two (FP2), and **(C)** force plate three (FP3). The kinetic and kinematic reference systems were aligned with an origin of (0,0) as indicated above.

2.3.2 Kinematics

Two OptoTrak 3020 motion capture banks (Figure 5) equipped with 6 cameras (Northern Digital Inc., Waterloo, ON, Canada) were used to locate the position of the markers placed on the body in three dimensional space during each task. One camera bank was positioned vertically and the other camera bank was positioned horizontally. A

12 smart marker setup was applied in the frontal plane of the participant as used previously by Perry et al., (2007) and was sampled at a frequency of 100-Hz. The markers were placed on the forehead, bilateral acromion processes, xiphoid process, bilateral anterior superior iliac spines (ASIS), bilateral tibial tuberosities, bilateral anterior distal tibias, and bilateral base of the third metatarsals (Figure 6). The participants were able to move freely as a result of using a wireless strober.

The kinematic data was processed using the Optofix (Mishac Kinetics, Waterloo, ON, Canada) program to fill in gaps of the missing data points using the cubic spline interpolation method. The cubic spline method calculated and completed the section of missing data by locating four points prior and four points after the gap to represent the actual motion trajectory of the specific marker position. The kinematic data collected was used to calculate the whole body centre of mass (COM) and the location of the lateral border of the base of support (BOS) in the transverse plane.

Figure 5. OptoTrak 3020 Motion Analysis Systems: (Left to Right: Vertical and horizontal configuration).

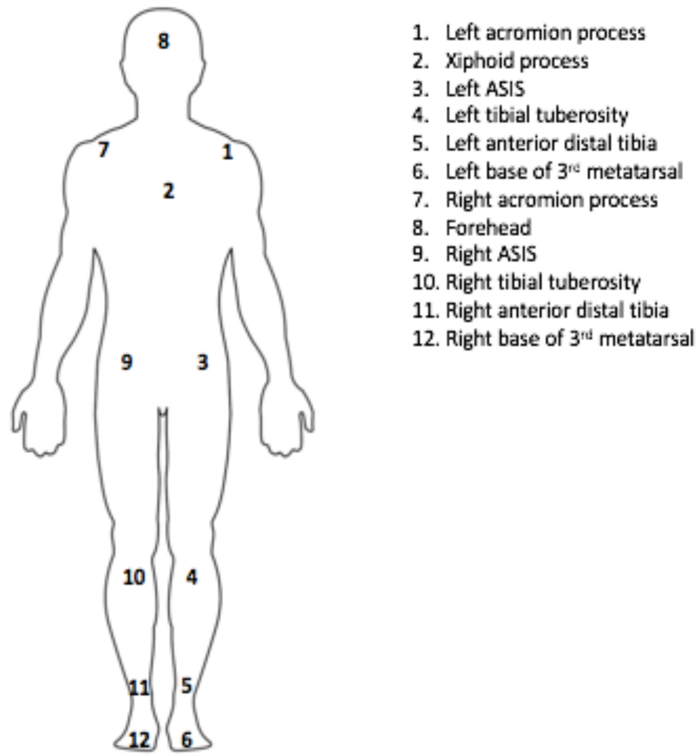

Figure 6. The kinematic 12 frontal smart marker setup (anterior placement).

2.3.3 Electromyography

To assess muscle activity during normal walking and gait termination trials, surface electromyography (EMG) recorded by the Bortec AMT-8 Octopus system (Calgary, AB, Canada) was collected from two dorsal and two plantar intrinsic foot muscles of the right foot. All participants had the surface of their skin cleaned and prepped with 70% isopropyl-rubbing alcohol over each muscle being evaluated. Two pairs of 2cm Kendall foam electrodes with conductive adhesive hydrogel (Covidien, Mansfield, MA, USA) were placed on the most superficial intrinsic muscles: extensor hallucis brevis (EHB), extensor digitorum brevis (EDB), abductor hallucis (Abd H) and abductor digiti minimi (Abd DM). The Abd H electrodes were placed 1-2 cm posterior to the location of the navicular tuberosity, the Abd DM electrodes were placed 1cm proximal to the styloid of the 5th metatarsal, the EDB electrodes were placed laterally to the extensor digitorum brevis longus tendon and anterior to the lateral malleolus, and the EHB electrodes were placed between the extensor hallucis longus and the extensor digitorum longus tendons (Arincini, Genc, Erdem & Yorgancioglu, 2003; Jung, Koh & Kwon, 2011; Kim, Kwon, Kim & Jung, 2013; La Scaleia, Ivanenko, Zelik & Lacquaniti, 2014). In addition, all muscles bellies were identified by palpation and muscle resistance testing, and electrodes were placed in the direction of the muscle fibres (Figure 7) (Kendall, McCreary, Provance, Rodgers & Romani, 2005). The ground electrode was placed on the medial malleolus. Measurements of electrode distance from bony landmarks and photographs were taken to ensure accuracy of electrode placement for the second and third testing periods. A maximal voluntary contraction (MVC) value was obtained by observing the maximum values of the peak EMG magnitude during three gait trials and taking the average. The investigator retrospectively assessed the data of each participant's fifty walking trials for that testing date and took three of the largest peak EMG magnitudes, averaged them and utilized it as that test date's MVC.

All EMG data were sampled at a frequency of 1000-Hz and amplified (Bortec, Calgary, AB, Canada) to maximize signal resolution. Raw EMG data were unbiased, full-wave rectified and filtered using a dual pass first order Butterworth filter with a low-pass cut off frequency of 20-Hz to create a linear envelope. The linear envelope EMG was normalized to the peak magnitude of each muscle on the specific test date and averaged from three walking trials. The EMG, kinetic and kinematic systems were synchronized to collect data at the same time.

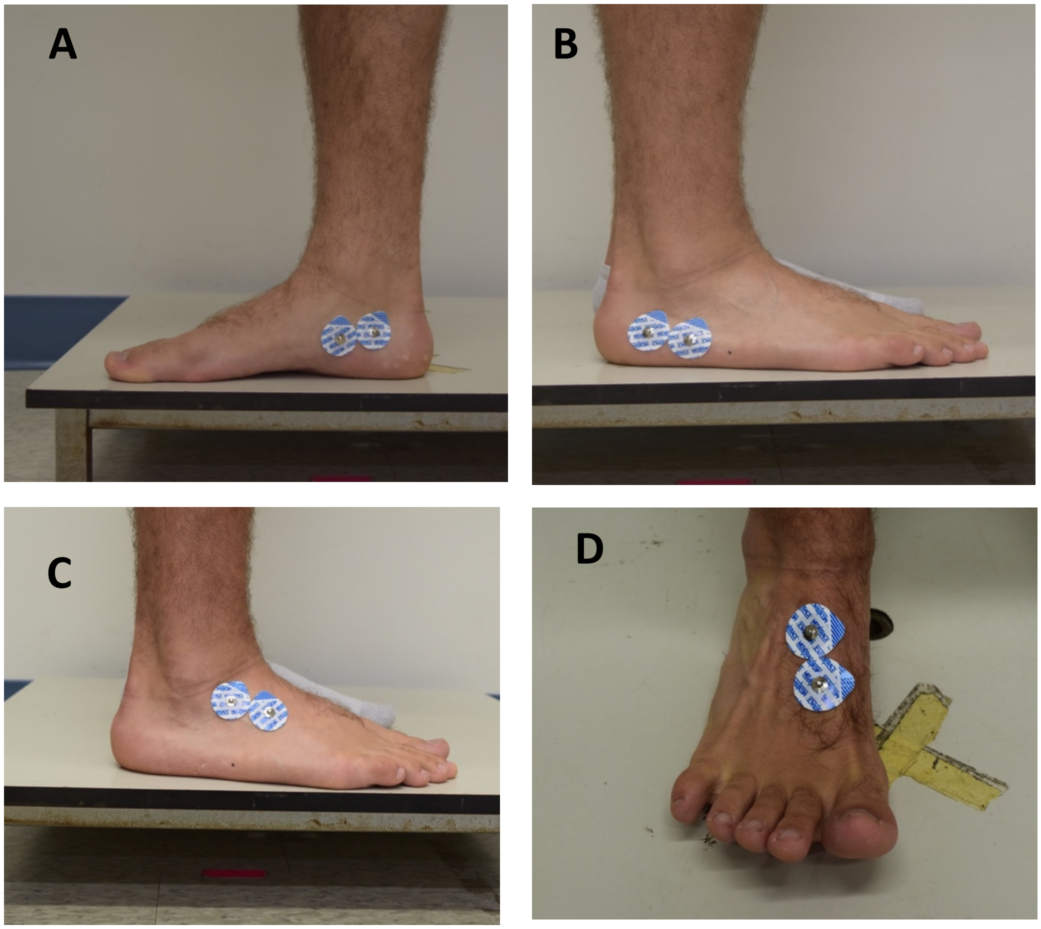

Figure 7. Electrode placement to the intrinsic muscles of the foot. **(A)** Abductor Hallucis (Abd H), **(B)** Abductor Digiti Minimi (Abd DM), **(C)** Extensor Digitorum Brevis (EDB), and **(D)** Extensor Hallucis Brevis (EHB).

2.3.4 Ultrasound

High-resolution ultrasound images of the plantar intrinsic muscles of the right foot were obtained using a 6-15 MHz linear transducer (Sonosite M-Turbo, Markham, ON, Canada) held by the research investigator on a marked location on the surface of the skin. Due to restrictive access to the ultrasound equipment, the plantar intrinsic muscles were only evaluated in 5 of 9 participants in both the OG and CG. Scanning lines developed by Mickle et al. (2013) and Angin et al. (2014) were used to obtain ultrasound images of the flexor digitorum brevis (FDB), abductor digiti minimi (Abd DM) and the abductor hallucis (Abd H) (Figure 8). The FDB measurement was taken from the proximal 1/3 of the scanning line on the plantar surface that went from the medial calcaneal tuberosity to the 3rd digit. The Abd DM scanning line was drawn from the lateral calcaneal tuberosity and angled toward the styloid of the 5th metatarsal. Lastly, the Abd H scanning line began from the medial calcaneal tuberosity and went toward the navicular tuberosity. In addition, the investigator referenced anatomy and ultrasound textbooks to confirm appropriate location. Images were completed while the participant laid prone on a chiropractic portable table with their ankles resting in a neutral position. The transducer was placed longitudinally along the scanning line and then was rotated 90° to obtain a cross-sectional image of the muscle.

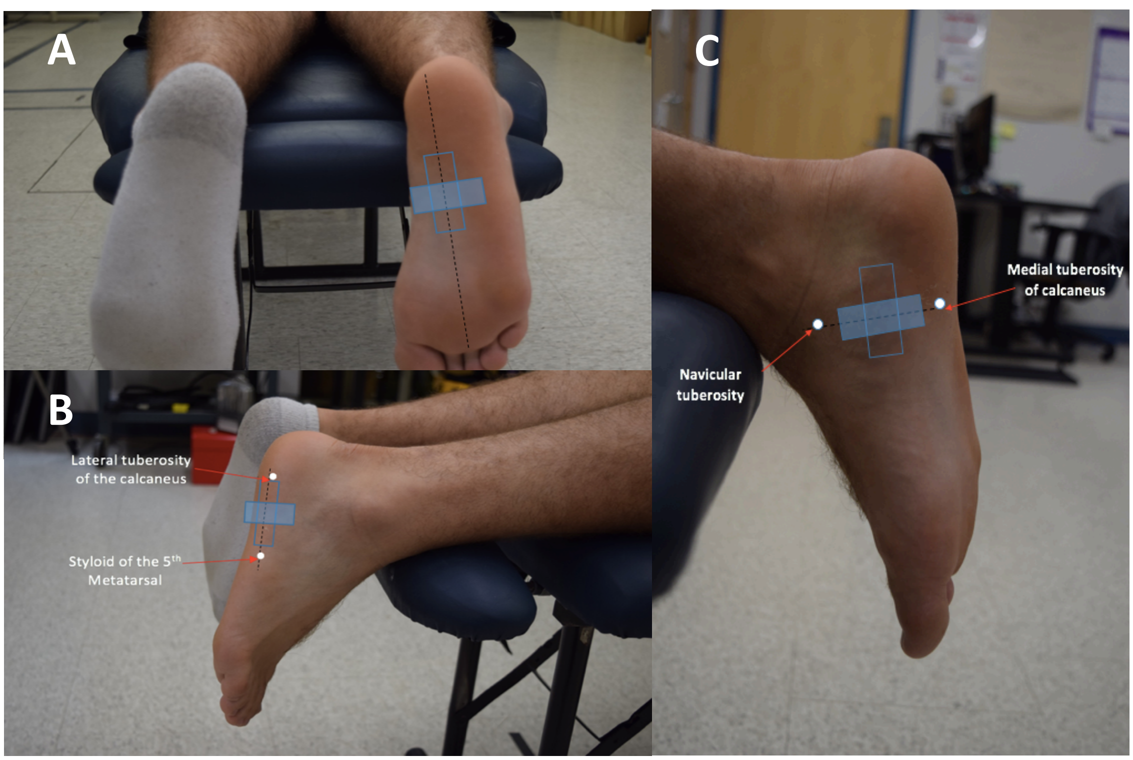

Figure 8. Scanning lines of plantar intrinsic muscles for obtaining the ultrasound images (A) FDB, (B) Abd DM, and (C) Abd H. The solid blue square represents the probe rotated to 90° to obtain a cross-section and the clear square is the probe placed longitudinally.

2.4 Experimental Protocol

Participants in both the orthotic group (OG) and control group (CG) completed baseline, 6-week and 12-week testing. Individuals in the orthotic group were expected to wear the orthotics for the duration of the study, whereas the participants in the control group were asked to continue wearing their normal footwear throughout the duration of the study. At the beginning of each testing session participants had cross-sectional diagnostic ultrasound images taken of three plantar intrinsic muscles of the right foot: flexor digitorum brevis (FDB), abductor digiti minimi (Abd DM) and abductor hallucis (Abd H). A gait termination protocol was adapted from Perry et al. (2001). All testing was completed barefoot and participants were not tested while wearing orthotics or any footwear. CFO's have been shown to be beneficial for reducing foot pain, however it is assumed they are withdrawn from the footwear after the pain has resolved. Offloading the plantar intrinsic muscles may result in deficits in muscular function and expose these individuals to an increased risk of injury when they no longer wear the CFO, therefore participants were tested barefoot. Participants were instructed to walk down an 8m walkway barefoot looking straight ahead (Figure 9). Participants were told they may or may not hear an audio buzzer sound to terminate their gait at a pre-determined area. The audio buzzer was triggered by a foot contact force of 10N over the first force plate and then during the next two steps gait termination took place over the next two force plates. If they did not hear an audio buzzer they were asked to continue to walk to the end of the walkway. A total of 50 trials were recorded and 25% (12 of 50) of those trials were randomly selected for gait termination. Participants were given 3-5 practice trials to familiarize themselves with the normal walking and gait termination protocol.

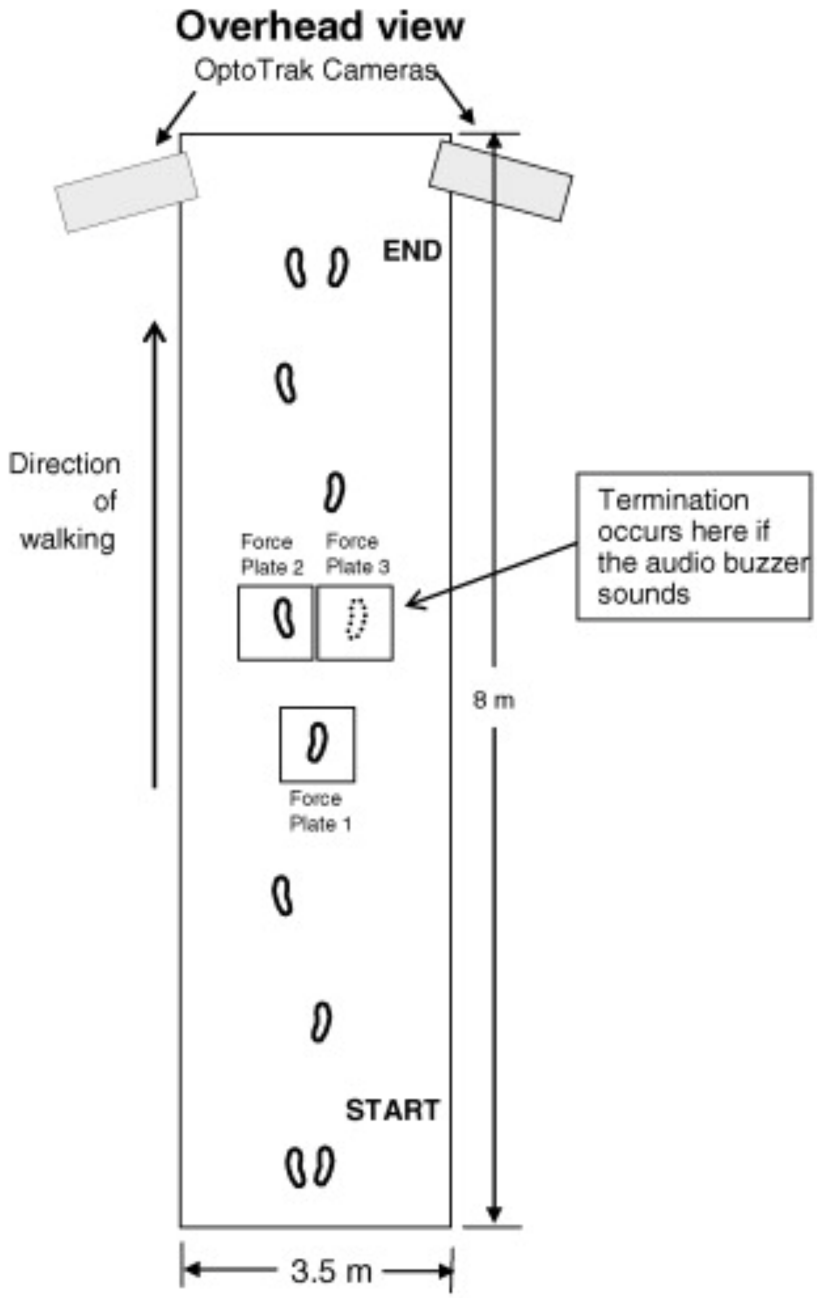

Figure 9. Overhead view of the 8m walkway with the experimental instrumentation configuration and pre-determined area where gait termination occurred.

2.5 Data Analysis

The primary outcome measures of the study were cross-sectional area (CSA) of FDB, Abd DM and Abd H of the right foot, the transverse plane projection of the minimum (lateral stability margin) centre of mass location relative to the lateral base of support (COM-BOS), the maximum of the centre of mass-centre of pressure (COM-COP) difference in the anterior posterior (A/P) direction, the vertical force rate of loading (ROL), the average EMG magnitude, integrated EMG and muscle burst activity duration. The secondary outcome measures of the study were gait velocity, step length and step width.

The analysis window for the COM-BOS and COM-COP measures were calculated during the first single stance phase on force plate 1 (FP1) and the second single stance phase on force plate 2 (FP2). The ROL was calculated during the first 100 m/s of contact with FP1, FP2, and if gait termination occurred force plate 3 (FP3). The analysis window for EMG measures during normal walking trials was defined as 100% of the gait cycle, the beginning being when the first right foot heel contact was made (0%) and the ending being when second right foot heel contact was made (100%). The analysis window for EMG measures taken during gait termination was defined as 100% of the gait cycle (first right heel contact on FP1 to second right heel contact on FP3) and for an additional 1 second after gait was terminated.

2.5.1 Ultrasound Analysis

Ultrasound Analysis was completed by a single investigator using ImageJ software (National Institute for Health, Bethesda, MD, USA). All images were

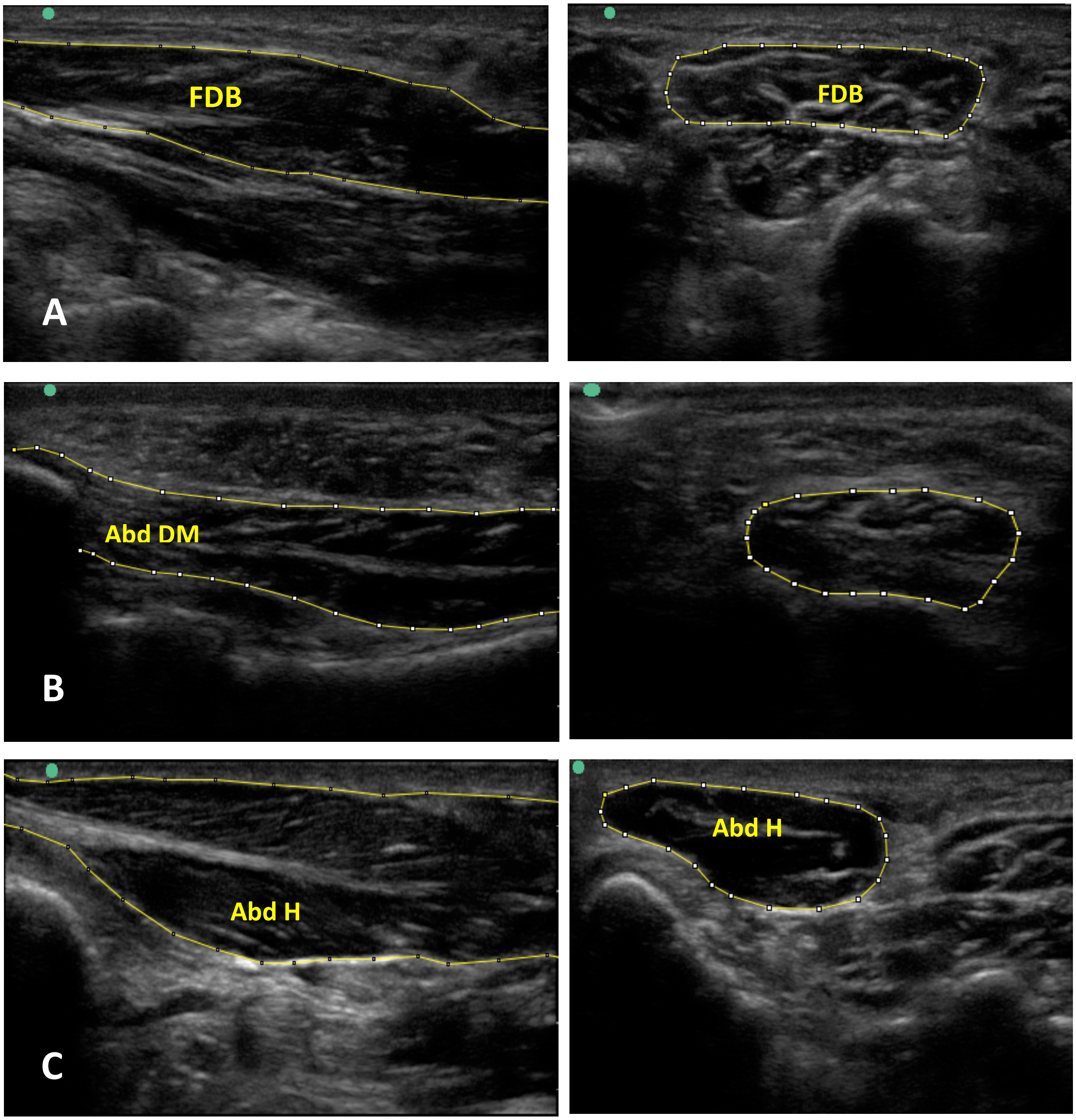

Figure 10. Longitudinal view (left) and cross-sectional area (right) ultrasound images of the plantar intrinsic muscles. **(A)** Flexor digitorum brevis (FDB), **(B)** Abductor digiti minimi (Abd DM) and **(C)** Abductor hallucis (Abd H).

randomized and assigned a numerical value by a second investigator so the primary investigator was blinded to the muscle and testing period of the image. At the end of data collection all images were analyzed all at once. The cross-sectional area (cm^2) measurement of the FDB, Abd DM, and Abd H of the right foot were taken three times for each muscle and then averaged (Figure 10). A measurement scale was calibrated in the software program by measuring a known distance of 1 cm on the image. A pilot study was performed on six subjects to determine the reliability and revealed a simple Pearson correlation of 0.999 for both FDB and Abd DM, and 0.997 for Abd H when images were taken over two collection periods.

2.5.2 Kinematic Analysis

The centre of mass (COM) was calculated taking the 12 smart marker positions from the OptoTrak Motion Analysis System and inputting their location in a customized program. The customized program calculated the COM by using a segmental average approach of seven segments as described by Winter (1995). The lateral base of support was defined by taking the smart marker location of the anterior distal tibia and base of the 3rd metatarsal of each foot and an estimated lateral border was calculated using the anthropometric distance from each marker to the lateral border of the foot. The minimum COM-BOS value was obtained by a customized analysis program using Microsoft Visual Basic. The lateral stability margin was calculated using trigonometry functions to find the distance between the COM to the lateral border. This variable was specifically selected since most falls occur in the M/L direction. The larger values of the displacement between the COM and the lateral base of support indicates greater stability, whereas the smaller the margin between the two suggests instability and a reduced biomechanical capacity to respond to lateral perturbations.

Additionally, the secondary outcome measures of gait velocity, step length and step width were calculated using the smart marker positions. Gait velocity (m/s) was calculated from the obtained centre of mass distance it travelled during the analysis window and averaged over the analysis time window. Step length (m) was calculated by the difference in distance from the first foot contact to the second foot contact of the opposite limb and step width (m) was calculated by measuring the mediolateral distance from the first foot contact to the second foot contact of the opposite limb.

2.5.3 Kinetic Analysis

Three force plates collected force measurements to calculate centre of pressure (COP) and vertical force rate of loading (ROL). The COP was calculated in the anterior posterior (A/P) and medial lateral (M/L) directions to give a spatial location. The A/P COP was calculated using the moment about the x axis (Mx, M/L) measurement and dividing it by the the vertical force (Fz) and the M/L COP was calculated using the moment about the y axis (My, A/P) measurement, multiplied by negative one (to correct for the default force plate axis) and then divided by the vertical force (Fz). The maximum COM-COP in the A/P direction was calculated in the customized analysis program, which measures the distance between the COM and COP during both single stance phases, the greater the distance between the two variables the larger the value, suggests instability. This difference in A/P maximum COM-COP was used to observe how far the participant was being perturbed. This measures dynamic stability as the COM is still accelerating forward even though the participant has terminated their gait.

Secondly, the ROL (BW/s) was calculated as the slope from the onset of foot contact to the force (N) reached at 100 ms divided by the change in time. All ROL data were normalized to the participant's body weight (BW) measured in Newton's (N) to allow for comparisons across all participants.

2.5.4 Electromyography Analysis

Each muscle burst was represented by average EMG magnitude, integrated EMG magnitude and activation duration as calculated during the analysis window. A muscle burst analysis window was defined when the onset of muscle activity had exceeded a 5% MVC threshold for each muscle consistently for 100 ms and cessation was determined when muscle activity fell below the 5% MVC threshold for 100 ms. Average EMG magnitude (v) was calculated by adding all the EMG magnitude data points within the specific muscle burst and dividing it by the total number of data points. The integrated EMG magnitude (v) was calculated by adding all the EMG data points within the defined muscle burst. Lastly, muscle burst duration (ms) was calculated by subtracting the time of onset from the cessation of the specific muscle burst. All EMG activity variables were normalized to the participants MVC. Timing variables were normalized to the time of the predefined gait cycle.

2.6 Statistical Analysis

Multiple three way repeated-measures analysis of variance (ANOVA) using SAS statistical software (University Edition, SAS Institute Inc., Cary, NC, USA) were performed to determine the effect of wearing custom-made foot orthotics on each of the dependent variables. The dependent variables were minimum centre of mass—base of support (COM-BOS), maximum anterior-posterior (A/P) centre of mass—centre of pressure (COM-COP), average EMG magnitude (aEMG), integrated EMG (iEMG), muscle burst activity duration (MD), vertical rate of loading (ROL), gait velocity (GV), step length (SL), and step width (SW). The statistical model was comprised of one between-participant factor (*participant group:* orthotic vs control) and two within-participant factors: *(i) testing session* (*test date:* baseline vs 6-weeks vs 12-weeks), and (ii) *walking task* (*task:* gait termination vs normal walking). Additionally, a two-way ANOVA was used to compare mean differences in cross-sectional area of the flexor digitorum brevis (FDB), abductor digiti minimi (Abd DM) and abductor hallucis (Abd H) muscles. The model had one between-participant factor (*participant group:* orthotic vs control) and one within-participant factor (i.e., test date: baseline vs 6-weeks vs 12-weeks). The assumptions of normality of ANOVA were tested for each statistical analysis and when appropriate the data was rank-transformed to ensure that normality assumptions were met. Outliers were determined by setting a criterion to identify measures that were greater than two standard deviations of the variable mean. The data of the identified outlier was then inspected and video was reviewed to note possible reasoning for measurement error (e.g. missed force plate contact, missing marker) and if exclusion of the trial was not warranted, then the data was retained for analysis. The least square means for multiple comparisons was the post-hoc test used to determine where differences occurred. For all statistical analysis, the significance level was set a priori to $\alpha = 0.05$.

3. Results

3.1 Participant's General Characteristics

There were no significant differences between the orthotic or control groups general characteristics for age (p=0.482), height (p=0.550), weight (p=0.263), FPI score (p=0.379) or navicular height (p=0.873). (Table 1).

Table 1. Mean (SD) of participant's general characteristics of the orthotic and control groups with p-values indicated. No significant differences between the groups (p>0.05).

	Orthotic Group (n= 9)	Control Group (n= 9)	p-value
Age	24.2 (3.5)	25.3 (3.0)	0.482
Height (m)	1.74 (0.07)	1.77 (0.09)	0.550
Weight (kg)	70.46 (9.36)	76.82 (13.55)	0.263
Range	56.8 to 87.7	59.1 to 91.8	
FPI score (+)	6.4 (1.5)	7.1 (1.6)	0.379
NH (cm)	2.36 (0.50)	2.31(0.66)	0.873
Shoe Size *	7.6 (2.0)	8.9 (2.5)	0.231
Range	5 to 11	5 to 11.5	
Gender	M=3, F= 7	M= 5, F= 4	

* Shoe sizes were according to men shoe sizes

3.2 Effect of CFO's on Cross-sectional Area of the Plantar Intrinsic Muscles

There was a main effect of group and test date for the right flexor digitorum brevis (FDB) (p<0.001), the right abductor digiti minimi (Abd DM) (p<0.001), and right abductor hallucis (Abd H) (p<0.001). There were statistically significant interactions for group and test date on cross-sectional area (CSA) of the FDB (η_p^2=0.941), the Abd DM (η_p^2=0.932), and Abd H (η_p^2=0.934) muscles (p< 0.001). Following the 12-week intervention period, individuals that wore the CFO's had a decrease in overall CSA from baseline measures for the FDB, Abd DM, and Abd H plantar intrinsic muscles.

For FDB, there was a statistically significant difference in CSA from baseline to 6-weeks (2.09 ± 0.50 cm^2 vs. 2.04 ± 0.55 cm^2; $p < 0.001$) 6-weeks to 12-weeks (2.04 ± 0.55 cm^2 vs. 1.89 ± 0.46 cm^2; $p<0.001$), and baseline to 12-weeks ($p<0.001$) for the orthotic group (Figure 14). The control group (CG) saw a slight increase in CSA of the FDB from baseline to 6-weeks (2.19 ± 0.46 cm^2 vs 2.24 ± 0.49 cm^2; $p<0.001$) and baseline to 12-weeks (2.19 ± 0.46 cm^2 vs. 2.23 ± 0.49 cm^2; $p<0.001$). There was no significant difference from 6-weeks to 12-weeks ($p=0.10$). The FDB CSA was smaller in the orthotic group (OG) compared to the control group (CG) at baseline ($p<0.001$), 6-weeks ($p<0.001$) and 12-weeks ($p<0.001$).

The CSA for Abd DM in the orthotic group were significantly lower from baseline to 6-weeks (1.23 ± 0.10 cm^2 vs. 1.15 ± 0.12 cm^2; $p<0.001$), 6-weeks to 12-weeks (1.15 ± 0.12 cm^2 vs. 1.02 ± 0.09 cm^2; $p<0.001$), and baseline to 12-weeks ($p<0.001$) (Figure 15). There was no significant difference in the CG from baseline to 6-weeks ($p=0.26$), baseline to 12-weeks ($p=0.71$) or 6-weeks to 12-weeks ($p=0.14$). The OG CSA in comparison to the CG CSA significantly differed at baseline (OG: 1.23 ± 0.10 cm^2 vs. CG: 1.30 ± 0.27 cm^2; $p<0.001$), 6-weeks (OG: 1.15 ± 0.12 cm^2 vs. CG: 1.30 ± 0.28 cm^2; $p<0.001$) and 12-weeks (OG: 1.02 ± 0.09 cm^2 vs. CG: 1.31 ± 0.27 cm^2; $p<0.001$).

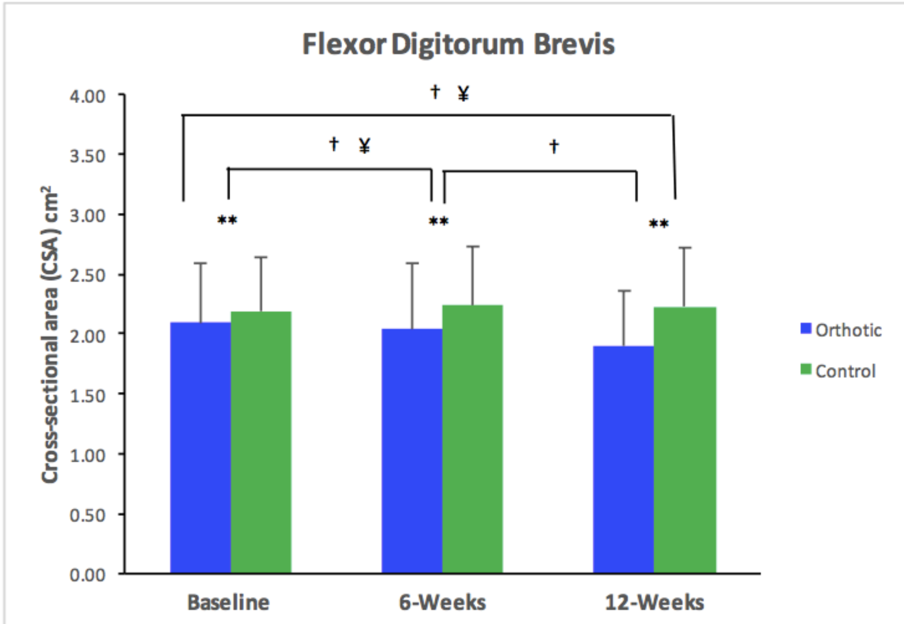

Figure 14. Effect of orthotics on cross-sectional area of the right FDB after a 12-week intervention. Standard deviation bars shown. Note: **= significance between groups, †= significance within orthotic group between test dates and ¥= significance within the control group between test dates. ($p<0.05$).

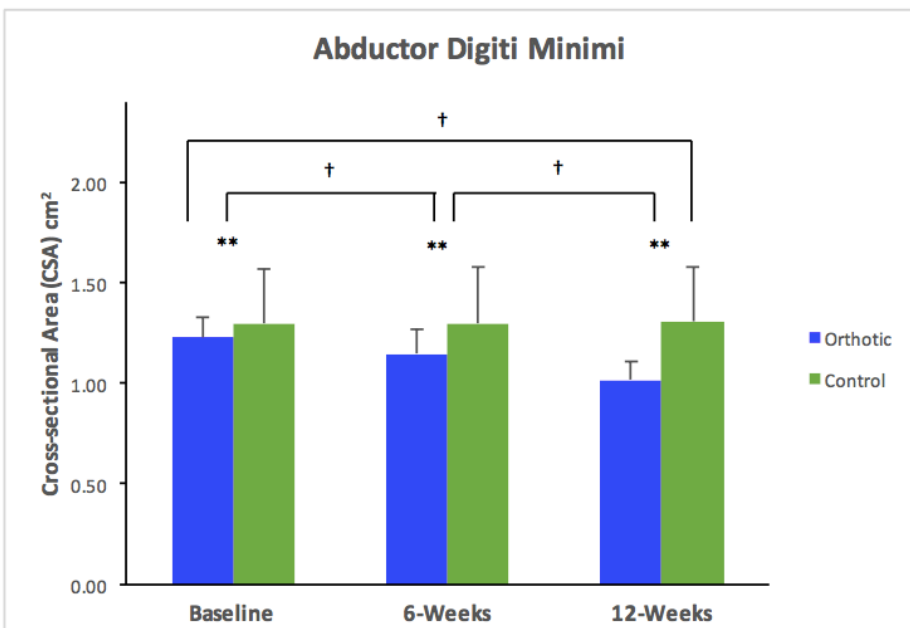

Figure 15. Effect of orthotics on cross-sectional area of the right Abd DM during a 12-week intervention. Standard deviation bars shown. Note: **= significance between groups, †= significance within orthotic group between test dates and ¥= significance within the control group between test dates. ($p<0.05$).

Lastly, the Abd H had significant changes in the OG CSA across the different test dates, with decreases occurring from baseline to 6-weeks (1.38 ± 0.51 cm^2 vs. 1.24 ± 0.42 cm^2; $p<0.001$), 6-weeks to 12-weeks (1.24 ± 0.42 cm^2 vs. 1.14 ± 0.38 cm^2; $p<0.001$), and baseline to 12-weeks ($p<0.001$) respectively (Figure 16). The CG had a slight decrease in CSA from baseline to 6-weeks (1.82 ± 0.20 cm^2 vs. 1.79 ± 0.21 cm^2; $p<0.001$), and baseline to 12-weeks (1.82 ± 0.20 cm^2 vs. 1.81 ± 0.21 cm^2; $p=0.01$). From 6-weeks to 12-weeks the CG CSA increased slightly (1.79 ± 0.21 cm^2 vs. 1.81 ± 0.21 cm^2; $p=0.02$). The CSA of the Abd H as time progressed was significantly smaller in the OG compared to the CG at 6-weeks (OG: 1.24 ± 0.42 cm^2 vs. CG: 1.79 ± 0.21 cm^2; $p<0.001$) and 12-weeks (OG: 1.81 ± 0.21 cm^2 vs. CG: 1.14 ± 0.38 cm^2; $p<0.001$).

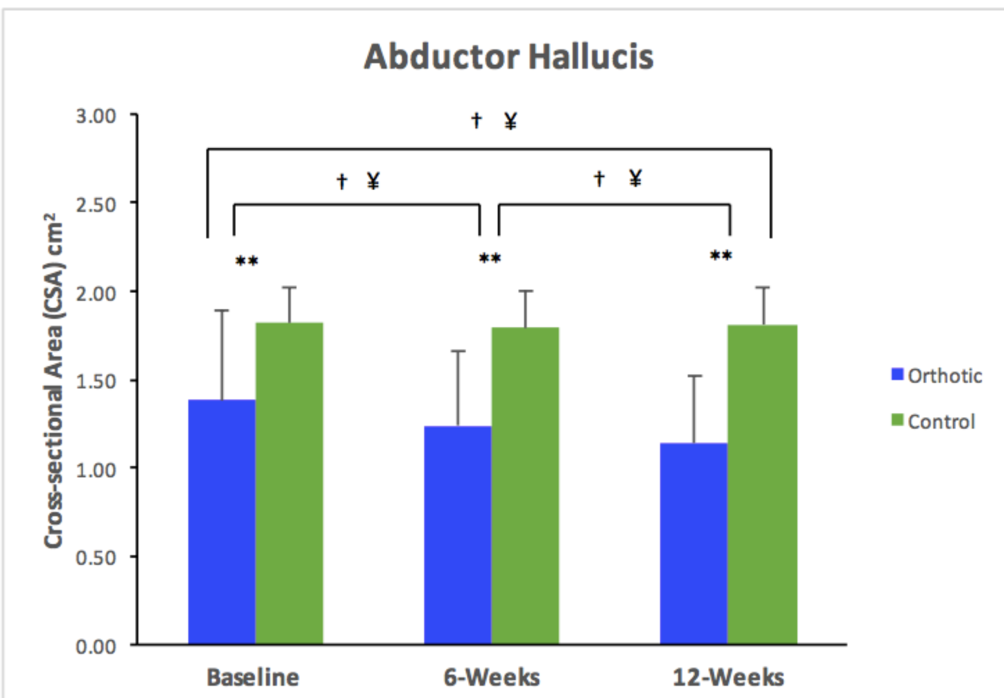

Figure 16. Effect of orthotics on cross-sectional area of the right Abd H during a 12-week intervention. Significant interaction between group, test date and task ($p<0.001$). Standard deviation bars shown. Note: **= significance between groups, †= significance within orthotic group between test dates and ¥= significance within the control group between test dates. ($p<0.05$).

3.3 Effect of CFO's on Balance Measurements

3.3.1 Minimum COM—BOS (Lateral Stability Margin)

There was no significant main effect for group on the lateral stability margin ($p=0.071$). There were significant main effects for test date ($p=0.002$) and task ($p<0.001$). A significant interaction was observed for the effect of group, test date and task on the first single stance lateral stability margin ($p= 0.028$) (Figure 17). The LSMeans comparisons revealed the OG lateral stability margin measurements significantly differed between the three test dates in gait termination trials. The lateral stability margin for the OG increased from baseline to 6-weeks (6.4 ± 3.8 cm vs. 7.1 ± 3.4 cm; $p<0.001$) and baseline to 12-weeks (6.4 ± 3.8cm vs. 7.5 ± 3.8 cm; $p<0.001$), however there was no significant difference from 6-weeks to 12-weeks (7.1 ± 3.4 cm vs. 7.5 ± 3.8 cm; $p=0.359$). The CG lateral stability margin showed significant differences from baseline to 6-weeks (9.1 ± 3.4 cm vs. 6.7 ± 3.1 cm; $p<0.001$), baseline to 12-weeks (9.1 ± 3.4 cm vs. 7.7 ± 3.9 cm; $p<0.001$) and 6-weeks to 12-weeks (6.7 ± 3.1 cm vs. 7.7 ± 3.9 cm; $p<0.001$). Additionally, at baseline the OG had a significantly smaller lateral stability margin (6.4 ± 3.8 cm) compared to the CG (9.1 ± 3.4 cm; $p<0.001$), whereas at 6 weeks the OG had a slightly higher mean lateral stability margin of 7.1 cm (± 3.4) compared to the CG of 6.7 cm (±3.1) ($p=0.034$). However, it then remained similar between the groups at 12-weeks ($p= 0.246$).

There were significant main effects for group ($p<0.001$), test date ($p=0.039$), and task ($p<0.001$) on the second single stance lateral stability margin. No significant interaction occurred for the effect of group, test date and task on the second single stance lateral stability margin ($p=0.487$). These findings are summarized in Table 2.

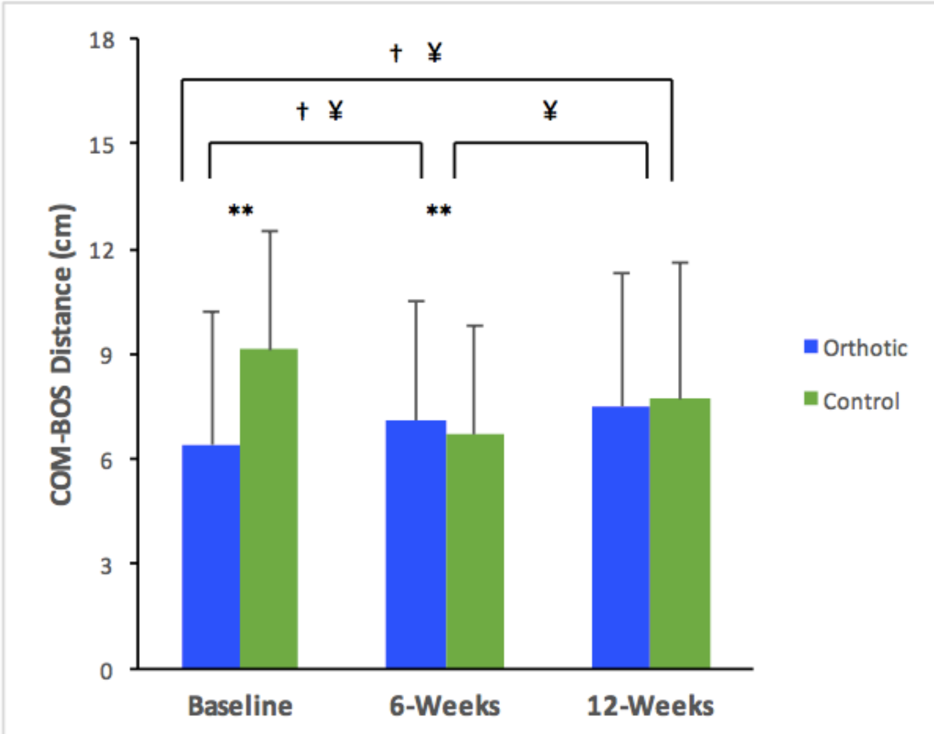

Figure 17. Effect of orthotics on first single stance minimum COM-BOS during gait termination. Significant interaction between group, test date and task (p=0.03). Standard deviation bars shown. Note: **= significance between groups, †= significance within orthotic group between test dates and ¥= significance within the control group between test dates.

Table 2. Mean (SD) of the second single stance lateral stability margin (min COM-BOS distance in cm) during gait termination. No significant interaction between group, test date and task (p>0.05).

Group	Baseline	6-Weeks	12-Weeks
Orthotic	0.35 (0.21)	0.33 (0.16)	0.28 (0.17)
Control	0.42 (0.19)	0.40 (0.19)	0.35 (0.18)

**All values are in (cm)*

3.3.2 Maximum A/P COM—COP

There were significant main effects for group (p<0.001), test date (p<0.001), and task (p<0.001) on maximum A/P COM—COP. No significant interaction was revealed for the effect of group, test date and task on the maximum anterior-posterior centre of mass—base of support (COM—COP) model (p=0.569). These findings are summarized in Table 3.

Table 3. Mean (SD) of maximum AP COM-COP distance (cm) during gait termination. No significant interaction between group, test date and task (p>0.05).

Group	Baseline	6-Weeks	12-Weeks
Orthotic	20.7 (8.0)	18.0 (1.9)	17.4 (1.9)
Control	19.2 (2.7)	18.2 (2.0)	18.3 (1.5)

*All values are in (cm)

3.4 Effect of CFO's on Rate of Loading

There were significant main effects for group (p<0.001) and test date (p<0.001) on the first stance phase of ROL. There was no main effect of task (p=0.725) on first stance ROL. A significant interaction was shown for the effect of group, test date and task on force plate rate of loading for the first foot contact (p=0.042) (Figure 18). The analysis revealed that during the first foot contact to signal gait termination the OG had an initial decrease in loading rate from baseline to 6-weeks (14.79 ± 2.49 BW/s vs. 14.23 ± 2.80 BW/s; p=0.004) and then returned to a similar loading rate as baseline from 6-weeks to 12-weeks (14.23 ± 2.80 BW/s vs. 14.70 ± 2.06 BW/s; p=0.014). There was no significant difference for rate of loading in the OG from baseline to 12-weeks (p=0.644). The CG increased single stance ROL from baseline to 6-weeks (15.21 ± 2.09 BW/s vs. 16.63 ± 23.8 BW/S; p<0.001) and baseline to 12-weeks (15.21 ± 2.09 BW/s vs.16.86 ± 2.61BW/s; p<0.001). There were no differences in ROL in the CG from 6-weeks to 12-

weeks ($p=0.101$). Moreover, the OG demonstrated significant differences in rate of loading of the first foot contact as gait termination was initiated compared to the CG at baseline ($p=0.027$), 6-weeks ($p<0.001$) and 12-weeks ($p<0.001$). At the 6-week test date the OG had a lower rate of loading (14.23 ± 2.80 BW/s) compared to the CG (16.63 ± 23.8 BW/s) while being signaled to terminate gait. Similarly, at 12-weeks the OG had lower rate of loading (14.70 ± 2.06 BW/s) compared to the CG (16.86 ± 2.61 BW/s).

There were significant main effects for group ($p<0.001$) and task ($p<0.001$) on the second stance ROL. There was no main effect for test date ($p=0.702$). The force plate rate of loading at the second foot contact had a significant interaction between group, test date and task ($p<0.001$). The OG displayed significant differences in rate of loading across the different test dates when gait termination occurred (Figure 19). The rate of loading decreased from both baseline to 6-weeks (23.32 ± 3.45 BW/s vs. 21.66 ± 4.96 BW/s; $p<0.001$) and baseline to 12-weeks (23.32 ± 3.45 BW/s vs. 21.81 ± 3.96; $p<0.001$), though no changes resulted from 6-weeks to 12-weeks ($p=0.247$). The CG second single stance ROL significantly differed from baseline to 6-weeks ($p=0.002$) and baseline to 12-weeks ($p<0.001$). There was no significant difference from 6-weeks to 12-weeks ($p=0.618$) for the CG. In comparison to the CG, the OG had an initially had a higher rate of loading at baseline (OG: 23.32 ± 3.45 BW/s vs. CG: 22.56 ± 3.44 BW/s; $p=0.026$) an then had significantly lower rate of loading forces on the second force plate during gait termination trials at 6-weeks (OG: 21.66 ± 4.96 BW/s vs. CG: 23.75 ± 3.47 BW/s; $p<0.001$) and 12-weeks (OG: 21.81 ± 3.96 vs. CG: 23.86 ± 3.56 BW/s; $p<0.001$).

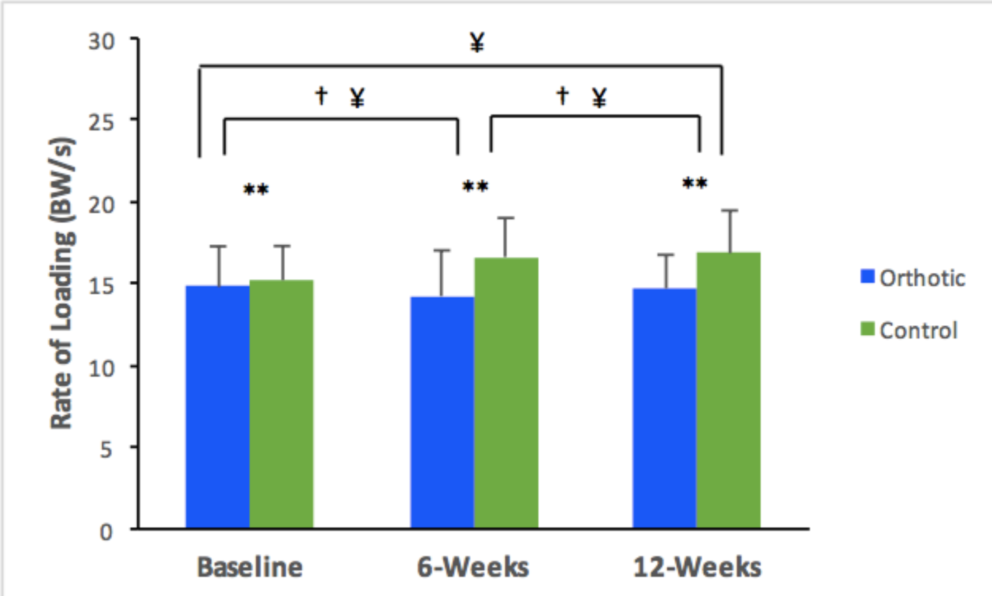

Figure 18. Effect of orthotics on first stance ROL (BW/s) during gait termination across the three test dates. Significant interaction between group, test date and task ($p=0.042$). Standard deviation bars shown. Note: **= significance between groups, †= significance within orthotic group between test dates and ¥= significance within the control group between test dates. ($p<0.05$).

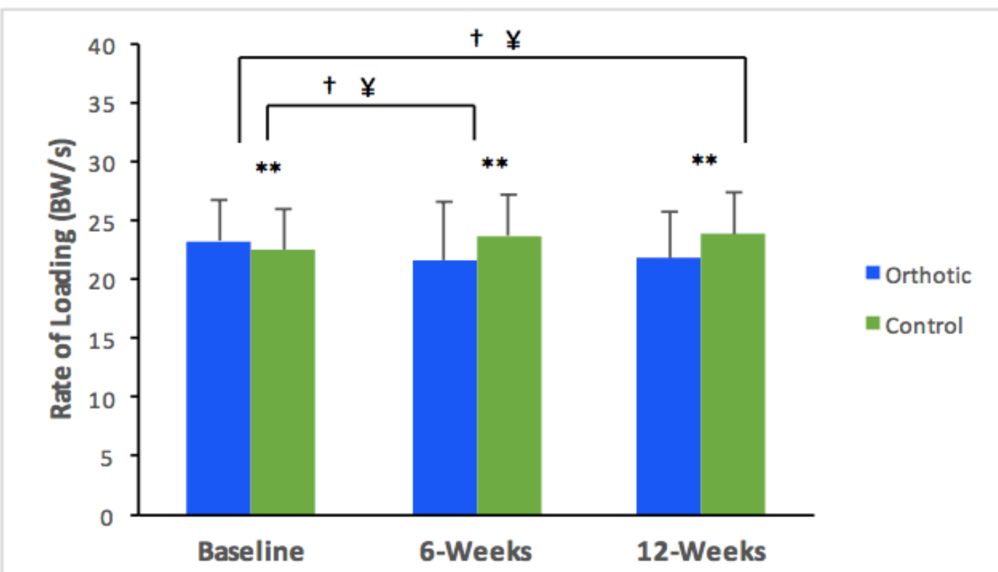

Figure 19. Effect of orthotics on second stance ROL (BW/s) during gait termination across the three test dates. Significant interaction between group, test date and task ($p<0.001$). Standard deviation bars shown. Note: **= significance between groups, †= significance within orthotic group between test dates and ¥= significance within the control group between test dates. ($p<0.05$).

3.5 Effect of CFO's on Intrinsic Foot Muscles EMG

3.5.1 Normalized average EMG magnitude

There were significant main effects for group (p<0.001) and test date (p<0.001) on average EMG magnitude of the AbdH. There was no main effect of task (p=0.727). A significant interaction was shown for the effect of group, test date and task on normalized average Abd H EMG magnitude (p=0.018) and normalized average EMG magnitude of EDB muscles (p=0.024). For the Abd H, the OG saw a significant change in average EMG magnitude across the test dates (Figure 20). A decrease in average EMG magnitude for the OG was seen from baseline to 6-weeks (14.9 ± 5.7% MVC vs. 12.8 ± 4.2% MVC; p=0.001), baseline to 12-weeks (12.8 ± 4.2% MVC vs. 12.0 ± 5.3% MVC; p<0.001), and 6-weeks to 12-weeks (14.9 ± 5.7% MVC vs. 12.0 ± 5.3% MVC; p=0.019). A decrease in average Abd H EMG magnitude was shown in the CG from baseline to 6-weeks (16.7 ± 7.0% MVC vs. 14.9 ± 5.7% MVC; p< 0.001) and baseline to 12-weeks (16.7 ± 7.0% MVC vs. 12.1 ± 4.0% MVC; p<0.001). There was no significant difference from 6-weeks to 12-weeks (p=0.142). However, no significant difference in average Abd H EMG magnitude existed when comparing the OG to the CG at baseline (p=0.077), 6-weeks (p=0.216) or 12-weeks (p=0.754).

For the EDB muscle, the OG group had no significant differences in average EMG magnitude from baseline to 6-weeks (p=0.652), baseline to 12-weeks (p=0.222), or 6-weeks to 12-weeks (p=0.926). The CG did not show differences between each test date's average EDB magnitude from baseline to 6-weeks (p=0.585), baseline to 12-weeks (p=0.722) or 6-weeks to 12-weeks (p=0.364). Additionally, the OG did not significantly differ from the CG average EDB EMG magnitude at baseline (p=0.900), 6-weeks (p=0.388) or 12-weeks (p=0.618).

There was a significant main effect for task on average EMG magnitude of the Abd DM ($p<0.001$). There was no main effect of group (p=0.440). No significant interaction existed for the effect of group, test date and task on normalized average Abd DM EMG magnitude (p=0.348).

There were significant main effects of group ($p<0.001$), test date ($p<0.001$), and task ($p<0.001$). No significant interaction existed for the effect of group, test date and task on normalized average EHB EMG magnitude (p=0.919). These findings are summarized in Table 4.

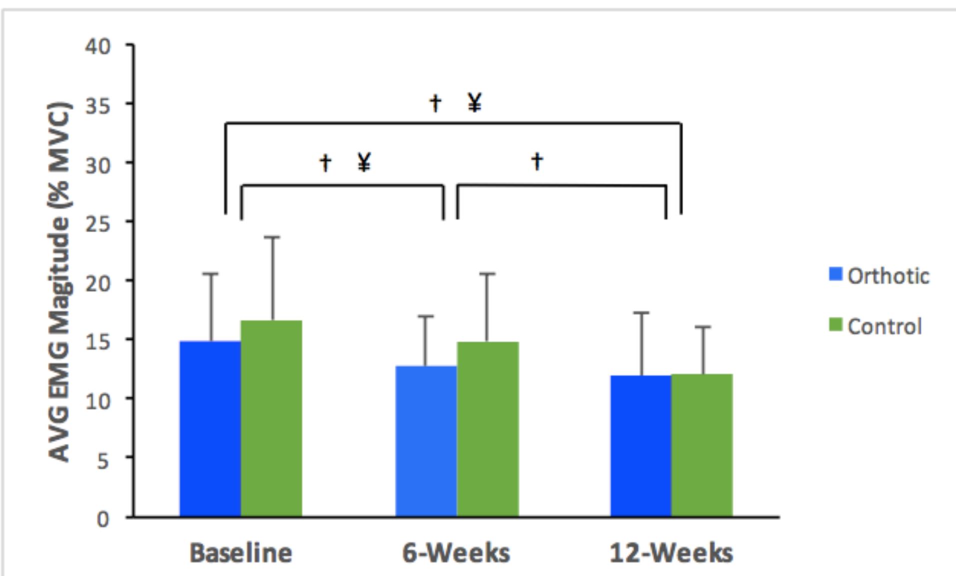

Figure 20. Effect of orthotics on the average right Abd H magnitude during gait termination. Significant interaction between group, test date and task (p=0.018). Standard deviation bars shown. Note: **= significance between groups, †= significance within orthotic group between test dates and ¥= significance within the control group between test dates. ($p<0.05$).

3.5.3 Normalized EMG Muscle Duration

There were significant main effects for group ($p=0.008$), test date ($p<0.001$) and task ($p<0.001$) for Abd H muscle burst duration. No significant interaction was observed for the effect of group, test date and task ($p=0.080$) (Table 4).

There were significant main effects for group ($p=0.029$), test date ($p<0.001$) and task ($p=0.044$) for Abd DM muscle burst duration. No significant interaction was observed for the effect of group, test date and task ($p=0.513$).

There were significant main effects for group ($p<0.001$) and test date ($p<0.001$) for EDB muscle burst duration. There was no significant interaction for the effect of group, test date and task ($p=0.229$).

There were significant main effects for group ($p<0.001$), test date ($p=0.028$), and task ($p<0.001$) for EHB muscle burst duration. There was no significant interaction shown for the effect of group, test date and task on normalized EMG muscle duration of EHB ($p= 0.459$). These findings are summarized in Table 4.

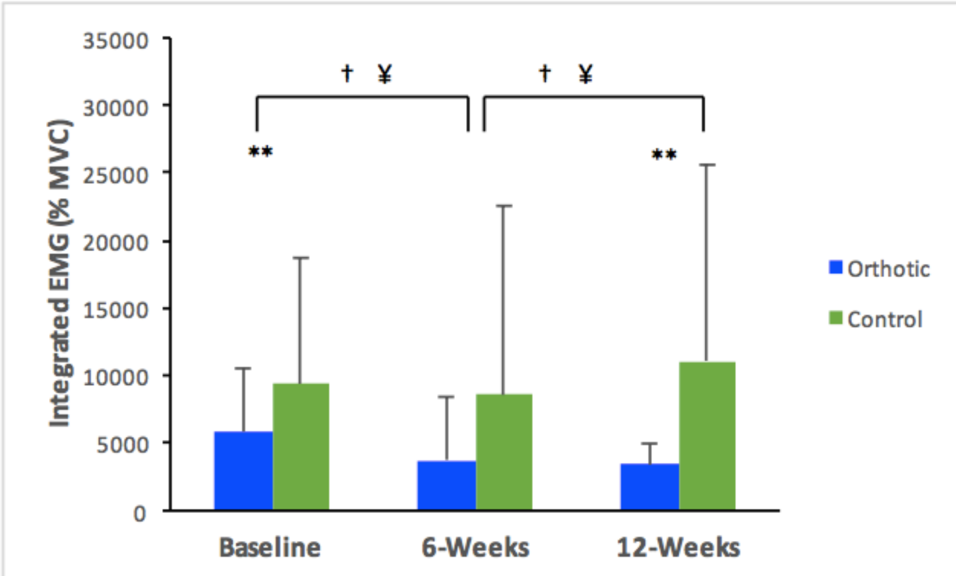

Figure 21. Effect of orthotics on integrated EDB EMG (% MVC) during gait termination. Significant interaction between group, test date and task (p=0.008). Standard deviation bars shown. Note: **= significance between groups, †= significance within orthotic group between test dates and ¥= significance within the control group between test dates. (p<0.05).

Table 4. Mean (SD) of average EMG magnitude (% MVC) and muscle burst duration (% of the gait cycle) during gait termination. No significant interaction between group, test date and task (p>0.05).

	Muscle	Group	Baseline	6-Weeks	12-Weeks
Average EMG magnitude (% of MVC)	Abd DM	Orthotic	11.9 (4.9)	10.8 (3.3)	11.6 (3.5)
		Control	11.5 (4.2)	11.4 (3.7)	11.6 (3.5)
	EHB	Orthotic	12.9 (3.9)	13.5 (3.8)	13.1 (3.0)
		Control	13.3 (3.2)	14.0 (2.9)	14.7 (3.7)
EMG Muscle Duration (% of the Gait Cycle)	Abd H	Orthotic	52.5 (65.4)	32.5 (30.6)	61.3 (69.5)
		Control	97.2 (115.9)	32.5 (22.9)	76.9 (1.36.2)
	Abd DM	Orthotic	49.4 (69.4)	22.6 (23.5)	61.2 (73.8)
		Control	70.5 (89.1)	29.3 (28.6)	152.1 (194.1)
	EDB	Orthotic	49.4 (38.7)	33.2 (35.6)	28.4 (14.9)
		Control	79.4 (79.2)	54.9 (70.5)	108.2 (143.1)
	EHB	Orthotic	60.7 (36.9)	59.4 (38.2)	60.6 (43.0)
		Control	102.0 (80.1)	90.5 (62.7)	120.0 (140.6)

3.6 Effect of CFO's on Secondary Outcome Measures

3.6.1 Step Width

There were significant main effects for group ($p<0.001$) and test date ($p<0.001$) for the first single stance step width. There was no main effect task ($p=0.069$). Group, test date and task had a significant interaction on second single stance step width ($p=0.025$). The OG step width during second single stance significantly differed between the different test dates (Figure 22). Step width in the OG decreased from baseline to 6-weeks (26.8 ± 2.4 cm vs. 25.5 ± 2.9 cm; $p<0.001$) and baseline to 12-weeks (26.8 ± 2.4 cm vs. 25.8 ± 2.2 cm; $p=0.005$). There was no significant difference in step width from 6-weeks to 12-weeks ($p=0.360$). The CG increased their second single stance step width over time. A significant increase was shown from baseline to 12-weeks (25.2 ± 2.9 cm vs. 26.7 ± 2.1 cm; $p<0.001$) and 6-weeks to 12-weeks (25.4 ± 2.3 cm vs. 26.7 ± 2.1 cm; $p<0.001$). However, no significant difference was seen in the CG from baseline to 6-weeks ($p=0.967$). In contrast to the CG, the OG differed in step width in the second single stance at baseline ($p<0.001$) and 12-weeks ($p=0.001$). At baseline the groups differed in second single stance step width by 1.6 cm (OG: 26.8 ± 2.4 cm vs. CG: 25.2 ± 2.9 cm) with the OG having a larger step width. Whereas at 12-weeks, the difference in step width between the two groups became smaller and only differed by 0.9 cm (OG: 25.8 ± 2.2 cm vs. CG: 26.7 ± 2.1 cm) with the OG taking a smaller step width on the next foot contact after being signaled to terminate gait compared to the CG. No significant changes in step width occurred between the two groups at 6-weeks ($p=0.575$).

There were significant main effects of group ($p<0.001$), test date ($p<0.001$), and task ($p<0.001$) for second stance phase step width. There was no significant interaction was shown for first single stance step width ($p=0.614$) (Table 6).

Table 6. Mean (SD) of first single stance step width (cm) during gait termination. No significant interaction between group, test date and task ($p>0.05$).

Group	Baseline	6-Weeks	12-Weeks
Orthotic	24.3 (4.3)	24.0 (2.3)	24.9 (1.8)
Control	24.6 (3.2)	23.6 (2.9)	24.0 (2.4)

**All values are in (cm)*

3.6.2 Step Length

There were significant main effects of group ($p<0.001$), test date ($p<0.001$) and task ($p<0.001$) for first and second stance phase of step length. No significant interaction was observed for the effect of group, test date and task on first stance step length ($p=0.731$) or second stance step length ($p=0.136$). These findings are summarized in Table 7.

3.6.3 Gait Velocity

There were significant main effects of group ($p<0.001$), test date ($p=0.019$), and task ($p=0.009$) for first stance average gait velocity. There were significant main effects of group ($p<0.001$), test date ($p=0.054$), and task ($p<0.001$). No significant interaction was observed for the effect of group, test date and task on average gait velocity of the first single stance (p=0.219) or average gait velocity of the second single stance (p=0.207). These findings are summarized in Table 7.

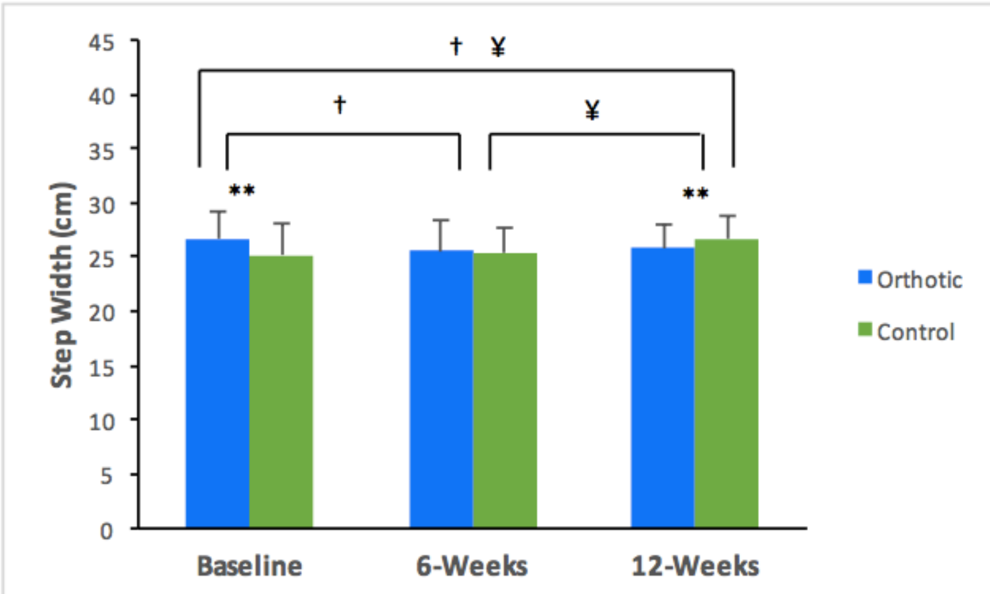

Figure 22. Effect of orthotics on second single stance step width (cm) during gait termination. Significant interaction between group, test date and task (p=0.025). Standard deviation bars shown. Note: **= significance between groups, †= significance within orthotic group between test dates and ¥= significance within the control group between test dates. ($p<0.05$).

3.7 Adherence of CFO's

There was 100% response rate in completing weekly reports over the course of the 12-week intervention for those in the orthotic group (n= 9). The average days per week that participants wore the CFO's was 6.0 days (± 1.19) and the average hours per day the participants wore the CFO's was 6.7 hours per day (± 1.03). Over the 12-week intervention, only 2 of 9 participants wore the CFO's less than 5 days a week, and all the participants on a weekly average wore the CFO's > 6 hours per day. In the first week, 3 of 9 participants reported mild discomfort and 1 of 3 of those participants reported blistering in the arch. After the 6-week test date, 3 of 9 participants reported mild to moderate discomfort for only one of the weeks out of the 6-weeks remaining. All participants continued using the CFO's and no dropouts were reported.

Table 7. Mean (SD) of first and second single stance step length (cm) and first and second single stance average gait velocity (m/s) during gait termination. No significant interaction between group, test date and task ($p>0.05$).

	Phase	Group	Baseline	6-Weeks	12-Weeks
Step Length (cm)	1st stance phase	Orthotic	68.1(6.2)	69.1 (7.2)	70.0 (7.2)
		Control	72.0 (4.3)	74.4 (5.6)	74.7 (4.4)
	2nd stance phase	Orthotic	50.6 (4.4)	50.3 (5.9)	49.1 (5.4)
		Control	52.6 (4.3)	52.8 (4.0)	51.6 (4.6)
Gait Velocity (m/s)	1st stance phase	Orthotic	1.30 (0.12)	1.22 (0.21)	1.27 (0.14)
		Control	1.31 (0.13)	1.36 (0.12)	1.37 (0.12)
	2nd Stance phase	Orthotic	0.74 (0.09)	0.70 (0.12)	0.74 (0.14)
		Control	0.77 (0.07)	0.79 (0.10)	0.79 (0.07)

4. Discussion

4.1 Purpose and Hypotheses Revisited

Custom-made foot orthotics (CFO's) are a common intervention used to treat foot disorders and pain. However, the mechanisms of CFO's are poorly understood and the side effects associated with CFO's have not been investigated. The purpose of this study was to examine the effect of a 12-week CFO intervention on the adaptations to the plantar intrinsic muscles of the foot and dynamic stability during gait termination in young adults with a pronated foot posture. It was hypothesized that individuals in the foot orthotic group would have decreased cross-sectional area (CSA) measurement of the plantar intrinsic muscles at the end of the 12-week intervention. The orthotic group did result in decreased CSA at the end of 12-weeks to three plantar intrinsic muscles compared to the control group: flexor digitorum brevis (FDB), abductor digiti minimi (Abd DM), and abductor hallucis (Abd H). Secondly, it was hypothesized that the orthotic group would exhibit a decrease in dynamic stability. Contrary to our hypothesis the results yielded an increase in lateral stability margin for the orthotic group during second single stance of gait and no significant changes in maximum A/P COM-COP differences compared to the control group. Thirdly, it was hypothesized that the orthotic group would have decreased average EMG magnitude of the plantar intrinsic muscles and the duration of the muscle burst activity would result in no change. The orthotic group resulted with a significant decrease in average EMG magnitude of only the Abd H muscle compared to the control group. No changes were observed in the duration of muscle burst activity of the plantar intrinsic muscles in either the orthotic group or control group. A decrease in their average EMG magnitude suggests that the orthotic group did not have to engage their plantar intrinsic foot muscles as actively and may explain why changes in the secondary measures of vertical force rate of loading and step width behaviours when attempting to terminate their gait.

4.2 Effect of CFO's on the CSA of the Plantar Intrinsic Muscles of the Foot

As hypothesized, the orthotic group saw significant decreases in cross-sectional areas of the FDB (9.6%), Abd DM (17.1%), and Abd H (17.4%) at the end of the 12-week intervention. It is apparent that the mechanical effect of offloading structures on the plantar foot, as a result of wearing CFO's, caused disuse muscle atrophy, an adaptation which changed muscle mass. Often the goal of CFO's is to decrease plantar pressures to help modify symptoms of pain. A study by Chia et al. (2009) showed a reduction in rearfoot peak pressure by 34.4% as a result of wearing CFO's. However, these reductions in plantar pressures over the long-term may be related to offloading muscle function and causing muscle disuse atrophy. One of the proposed theories of CFO's is the tissue-stress theory, where the CFO intent is to offload specific structures and redistribute the load to other areas of the plantar aspect of the foot. With no specific clinical guidelines in place for frequency or duration of CFO use, disuse atrophy can occur according to the theory. Therefore, the current study results should be used to assist in the development of appropriate clinical guidelines to help guide practitioners prescribing CFO's in their clinical decision making process for their long-term use. While the difference may appear minuscule, it is important to interpret the results in context to the normal mass of the plantar intrinsic muscles. The plantar intrinsic muscles are small muscles in relation to the extrinsic muscles of the foot and their main function is to stabilize the foot during static and dynamic movements (McKeon, Hertel, Bramble, & Davis, 2014). The amount of atrophy that resulted in this study of each plantar intrinsic muscle may be detrimental to their ability to function optimally and may require muscle strengthening exercises to be prescribed in adjunct to wearing CFO's in the first 12 weeks. Additionally, in the present study there were differences in cross-sectional area at baseline measures between the orthotic group and control group, these differences may have resulted due to differences in anatomy and variability of shoe sizes or due to the varying degree of pronated foot postures between the groups.

4.3 Effect of CFO's on Dynamic Balance Stability

Contrary to the proposed hypothesis, the orthotic group demonstrated a slight increase in the mean lateral stability margin of 0.70 cm in the first single stance phase. The second single stance phase is the next step to occur after gait termination is triggered. The orthotic group was able to make a small adjustment in their COM-BOS relationship initially and then maintained that change throughout the remainder of the intervention. This finding suggests that the participants in the orthotic group may have perceived that they were unstable without wearing the CFO while being tested and developed a protective strategy when adapting to terminating their gait. The results also indicate that the orthotic group participants did not allow their COM to approach the limits of the lateral border of their BOS in order to safely terminate their gait. Previous study by Marigold & Patla (2002) suggested that repeated exposures of unexpected slip perturbations allowed the central nervous system to adapt quicker to the next perturbation and participants applied proactive strategies to increase dynamic stability when anticipating the next perturbation. Whereas the control group saw the opposite effect and overall had a moderate decrease in the mean lateral stability margin compared to baseline scores. The control group showed an initial decrease at 6-weeks of 2.4 cm and then slightly increased back another 1 cm, however still remained lower compared to baseline. This finding suggests that a learning effect occurred from baseline to 6-weeks of testing. It appears the control group took a cautious approach to executing the gait termination task and might have been a result of them consciously knowing they did not receive the CFO’s in their footwear at the beginning of the study. This is apparent by the large differences in the minimum COM-BOS distance between the control and orthotic groups at baseline. Once the control group became comfortable after the baseline testing date, they improved their mean lateral stability margin from 6-weeks to 12-weeks, which may be the actual representation of their true dynamic stability during gait termination. At the end of the 12-week intervention the control group achieved slightly greater stability than the orthotic group during second single stance of gait termination.

In postural control there is constant communication between the central nervous system, muscular and sensory systems that determines how we respond to various perturbations by either controlling COM motion or altering our base of support (Horak, 2006; Maki & McIlroy, 2006). Although the participants in the orthotic group of the current study saw deficits of the plantar intrinsic muscle CSA’s, they may have overcome the deficit by relying on other resources of postural control to increase stability. For example, if muscle atrophy occurs in the plantar intrinsic muscles of the foot, our body adapts by relying on other systems such as the somatosensory system more heavily to help attain information on body position and therefore is one of the many components of balance.

The secondary measures of first and second stance phase vertical force rate of loading and second stance phase step width confirm altered approaches to achieving dynamic stability during gait termination between the two groups. The orthotic group decreased their mean ROL of the first stance phase as gait termination was being signaled to 14.23 BW/s at 6-weeks and then returned back to baseline values of 14.70 BW/s at 12-weeks. There are two possible explanations for why this result may have occurred. First, since there was disuse atrophy occurring to the plantar intrinsic muscles, it may have prevented the muscular system to generate muscular torque from the joints in the foot and may have relied on other muscle torque to be generated from other areas such as the ankle, knee or hip joints. Secondly, this result also suggests that the individuals in the orthotic group developed a dependency for the orthotic and because testing was done without the orthotic they walked over the first force plate anticipating the signal to terminate gait. Although mean gait velocity did not result in a significant interaction, the orthotic group did decrease from 1.30 m/s (baseline) to 1.22 m/s (6-weeks) and then returning near baseline values 1.27 m/s (12-weeks). Addison & Lieberman (2015) compared impact loading rates between walking and running tasks and showed that changes in velocity effect impact loading rates. The higher impact loading rates were a result of higher velocities. This is also apparent in the results of the first single stance mean ROL of the control group, where the participants were able to achieve higher mean ROL from baseline (15.21 BW/s) to 6-weeks (16.63 BW/s) and 12-weeks (16.86 BW/s). Additionally, it seems the control group increased their walking gait velocity, although no significant interaction existed, from baseline (1.31 m/s) to 6-weeks (1.36 m/s) and remained similar at 12-weeks (1.37 m/s). Moreover, during second stance phase the orthotic group decreased the mean ROL only from baseline (23.32 BW/s) to 6-weeks (21.66 BW/s), whereas the control group only showed an increase in mean ROL from baseline (22.56 BW/s) to 6-weeks (23.75 BW/s). Overall, this suggests that the control group had to generate more force per second during the first and second stance phase to slow down their COM in order to terminate their gait compared to the orthotic group.

Despite the orthotic group showing a small increase in lateral stability margin, the second single stance step width resulted in a significant difference from baseline to 6-weeks by 1.2 cm and then no changes at 12 weeks. Our results were different from two studies that found a narrower step width was associated with a reduction in the medial-lateral (M/L) margin of stability (MOS) in younger adults (Arvin et al., 2016; McAndrew Young & Dingwell, 2012). Although according to Arvin et al. (2016), having reduced M/L COM displacement and velocity together with taking a narrower step can be a strategy used to more tightly control the COM over the narrower BOS. Additionally, the control groups strategy to increase second stance step width agrees with the approach of the above studies showing increases in step width influences the system to be more stable. Moreover, the mean ROL may help to explain the significant differences in second stance phase step widths between the orthotic and control groups. Since the control group was able to generate more forces per second and able to slow down the COM quicker compared to the orthotic group, the control group was able to take a wider second step on average following the initiation of gait termination.

4.4 Effect of CFO's on the Average EMG Magnitude of the Plantar Intrinsic Muscles

Although it was hypothesized that all four intrinsic muscles of the orthotic group would decrease in average EMG magnitude during gait termination trials, the current study demonstrated that only the Abd H muscle had decreased changes in magnitude. The remaining three muscles showed no changes across the 12-week intervention testing. The orthotic group average Abd H EMG magnitude showed decreased differences of 2.1% MVC (baseline to 6-weeks) and 0.8% (6-weeks to 12-weeks). This finding may suggest that due to mechanical effect of the CFO of decreased muscle CSA it could have impeded the function of the Abd H to fully engage. Another explanation for the decreases may have been as a result of a learning effect. Since both groups have never been exposed to gait termination protocols before it's possible that at baseline because it was a newer activity that may help explain that initially more muscle activity was required to perform the task before becoming familiar and adjusted accordingly, hence the small decrease over time. Similarly, the control group had only an initial decrease of 1.8% MVC (baseline to 6-weeks) and then did not differ from 6-weeks to 12-weeks. Previous research has demonstrated that the Abd H muscle has increases in activation patterns with increased postural demands (Kelly et al., 2012) and is important in creating stiffness in the medial longitudinal arch when exposed to increased load (Kelly et al., 2014). Therefore, the gait termination task may have not been a difficult task to perform for the participants in this study. Increased muscle activity was not required from the Abd H in assisting to bringing the COM velocity to zero but rather there may have been an increase in muscle torque from the knee or hip joints. Muscles such as the extrinsic muscles (e.g. gastrocnemius, tibialis anterior) of the lower limb may be contributing a substantial amount of muscle activation to create stability when trying to perform gait termination in addition to Abd H muscle.

4.5 Limitations

The main limitation in the current study was the participants were tested only in a barefoot condition. Testing participants in barefoot on its own may have hindered the overall effect CFO's had on dynamic stability outcome measures, as previous studies have shown that testing in barefoot provided greater increases in dynamic stability in A/P and M/L directions during single-leg jump landings compared to minimalist footwear and normal footwear (Bowser, Rose, McGrath, & Davis, 2017). The knowledge of the results from barefoot, normal footwear, and footwear with CFO's could have provided a complete understanding of what is occurring to dynamic stability in those conditions and mimicked real life footwear selections. There are many different options for selecting variables to measure dynamic stability, therefore the two stability measures used to analyze balance control in this study may have been a limitation. Another limitation was that surface EMG can only measure muscle activity of superficial muscles, which our study was limited to the muscles selected for this study. The design of the study having repeated measures of EMG perhaps also was a limitation of using EMG due to the difficulty of placing the electrodes in the exact location every test date and the difficulty for participants to create MVC's of the plantar intrinsic muscles. However, precautionary measures were taken with the same investigator applying the electrodes based on photographs and measurements taken from anatomical landmarks to ensure consistency. Another limitation of instrumentation was the amount of pressure applied to the skin with the ultrasound probe. Again, precautionary measures were taken with one assessor conducting all measurements and applied the same consistent pressure across all participants. The use of ultrasound to assess the intrinsic muscles has shown to be cost-effective and reliable measure (Crofts, Angin, Mickle, Hill, & Nester, 2014; Mickle, Nester, Crofts, & Steele, 2013) and is an alternative to magnetic resonance imaging. Other limitations noted are the selection of gait termination protocol as the mechanical perturbation to challenge young healthy adults balance parameters. Although it is perceived that a ceiling effect might have occurred, the observations made while participants performed the unexpected gait termination protocol showed that many trials were not performed successfully (i.e. participants could not control COM within the base of support and took an extra step off the force plate). This suggests that the task was not too simple to perform and the protocol addressed that by being unexpected. There also appeared to be a practice effect due to the control group having changes in their dynamic stability over time. Further limitations were that the control group was aware they did not receive CFO's and this knowledge may have altered their normal walking strategies and behaviours during testing. Additionally, stratifying participants by age alone was a limitation of the study. Future research should stratify groups with a combination of matching age, weight and gender. A final limitation was that this study did not control for current physical activity levels of participants and the main investigator was not aware if participants were performing in exercises that may have enhanced their responses to increase dynamic stability.

4.6 Future Research Considerations

The current study provided important information regarding the effect CFO's create on structural and functional adaptations of the foot after short-term use, as no previous research has explored this avenue. The results of this study demonstrated that disuse muscle atrophy of specific plantar intrinsic muscles occurred as a result of offloading these structures and altered function by adopting compensatory strategies to maintain dynamic stability. Therefore, future research should look at adaptations that occur over the long-term use of wearing CFO's to see if disuse muscle atrophy continues to progress over a longer period of time (e.g. 6-months, 1 year). Currently, there are no current clinical guidelines that provided any evidence to practitioners who prescribe CFO's on the frequency and duration they should be worn. As future research continues to explore this avenue, employing appropriate guidelines can ensure safety of their use. A second consideration to enhance the findings from the current study would be to measure CSA and EMG magnitude of the plantar intrinsic and extrinsic muscles of the lower limb over the long term wearing CFO's and measure if any strength deficits exist to depict changes in muscle function. Thirdly, it would be beneficial for future research to look at more specific populations such as older adults with foot deformities. Previous research has shown that individuals with specific foot deformities have changes in muscle mass of specific plantar intrinsic foot muscles, the same population that may utilize CFO's as an intervention. Future research should focus on whether applying a CFO to a foot deformity associated with muscle atrophy either creates no change, exacerbates the symptom or further progresses the foot disorder and what those effects may impose on dynamic stability and muscle strength.

5. Conclusion

The current study examined the effect of a 12-week CFO intervention on the adaptations to the plantar intrinsic muscles of the foot and dynamic stability during unexpected gait termination in young adults with a pronated foot posture. The short-term use of CFO's appeared to decrease muscle CSA of the FDB, Abd DM and Abd H plantar intrinsic muscles and altered the approach these individuals incorporated to respond to the mechanical perturbation from unexpected gait termination. It is well documented in the literature that young adults show better responses to recover balance compared to older adults (Maki, Edmondstone, & McIlroy, 2000; Rogers, Hedman, Johnson, Cain, & Hanke, 2001). However, it is not well known the extent of compensatory strategies used by young adults to respond to perturbations when the muscular system incurs a deficit due to wearing CFO's. This study demonstrated that when the muscular system is impeded negatively by disuse atrophy, the compensatory strategies to achieve increased stability differs between the individuals with an impeded muscular system and individuals with an intact muscular system. Therefore, this study improves our understanding of the negative consequences that might arise from wearing CFO's and the effects it has on dynamic stability during gait termination in young healthy adults.

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Appendix A

SCREENING QUESTIONNAIRE

VOLUNTEER EXCLUSION CRITERIA **Date: (MM/DD/YYYY): _____, _____, _____**

Name: _____

Address:_____

_____

City, Prov:_____ Postal Code _____

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

Age: _____yrs. Height: _____cm Weight _____kg Shoe Size _____

Gender: M☐ F☐

Please check (√) if applies

	Y/N	How much does the condition interfere with your activities? little or none	mod	a great deal
Do you have any conditions that limit the use of your arms or legs?	Select	☐	☐	☐

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)	diabetes	☐
i)	problem with your vision that isn't corrected by glasses	☐
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?	Select
Have you had a concussion within the last three months?	Select
Do you have or ever had recurrent ear infections?	Select
Have you ever had frostbite in the lower extremities?	Select

Do you have or have you ever had :

		Y/N	How much does the condition interfere with your activities? little or none	mod	a great deal
a)	problems with your heart or lungs	Select	☐	☐	☐
b)	high blood pressure	Select	☐	☐	☐
c)	blood circulation problems (generally)	Select	☐	☐	☐
	(specifically lower extremities)	Select	☐	☐	☐

d)	cancer	Select	☐	☐	☐
e)	arthritis	Select	☐	☐	☐
f)	rheumatism	Select	☐	☐	☐
g)	back problems	Select	☐	☐	☐
h)	a joint disorder	Select	☐	☐	☐
i)	a muscle disorder	Select	☐	☐	☐
j)	a bone disorder	Select	☐	☐	☐
k)	spina bifida	Select	☐	☐	☐

Have you ever severely injured or had surgery on your

a)	head	Select	☐	☐	☐
b)	neck	Select	☐	☐	☐
c)	back	Select	☐	☐	☐
d)	pelvis	Select	☐	☐	☐
e)	ankle, knee, or hip joints?	Select	☐	☐	☐

		How much does the condition interfere with your activities?		
	Y/N	little or none	mod	a great deal
Have you ever broken any bones?	Select	☐	☐	☐

Which ones? : _____

Have you had any recent (specify)

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

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

Which activities?: _____

Are you currently taking any medications (prescription or over-the-counter), or other drugs?

Medication   Ailment   Frequency of use

DIETARY PROTEIN INTAKE

Please check (√) all questions with either **YES or NO.** Check YES **ONLY** if you consume any of the following **ONCE or MORE per week** for an **entire YEAR.**

If you check **YES** for any of the following questions, please specify the **number of times per week consumed** and an **approximate amount you have at each sitting for a typical week.**

Food Item	Yes	No	Frequency of Consumption/Week
SUPPLEMENTS			
a) Whey Protein			# days ______ X Amount per DAY ________
b) Soy Protein			# days ______ X Amount per DAY ________
(**Please specify the brand and scoops/day)**			
FISH			
c) Tuna			# days ______ X Amount per DAY ________
d) Salmon			# days ______ X Amount per DAY ________
e) Halibut			# days ______ X Amount per DAY ________
f) Talapia			# days ______ X Amount per DAY ________
(**References**: 1 palm= ~3 oz)			
RED MEAT			
g) Beef			# days ______ X Amount per DAY ________
h) Pork			# days ______ X Amount per DAY ________
i) Veal			# days ______ X Amount per DAY ________
j) Lamb			# days ______ X Amount per DAY ________
k) Mutton			# days ______ X Amount per DAY ________
(**Referemces:** 1 palm = ~3 oz)			
POULTRY			
l) Chicken			# days ______ X Amount per DAY ________
m) Turkey			# days ______ X Amount per DAY ________
(**Reference:** 1 palm= ~3 oz)			
NUTS/SEEDS			
n) Peanuts			# days ______ X Amount per DAY ________
o) Almonds			# days ______ X Amount per DAY ________
p) Cashews			# days ______ X Amount per DAY ________
q) Pumpkin Seeds			# days ______ X Amount per DAY ________
r) Chia Seeds			# days ______ X Amount per DAY ________
s) Flax Seeds			# days ______ X Amount per DAY ________
(**Reference:** 1 thumb length = 1 oz)			

Appendix B

Foot Posture Index Datasheet

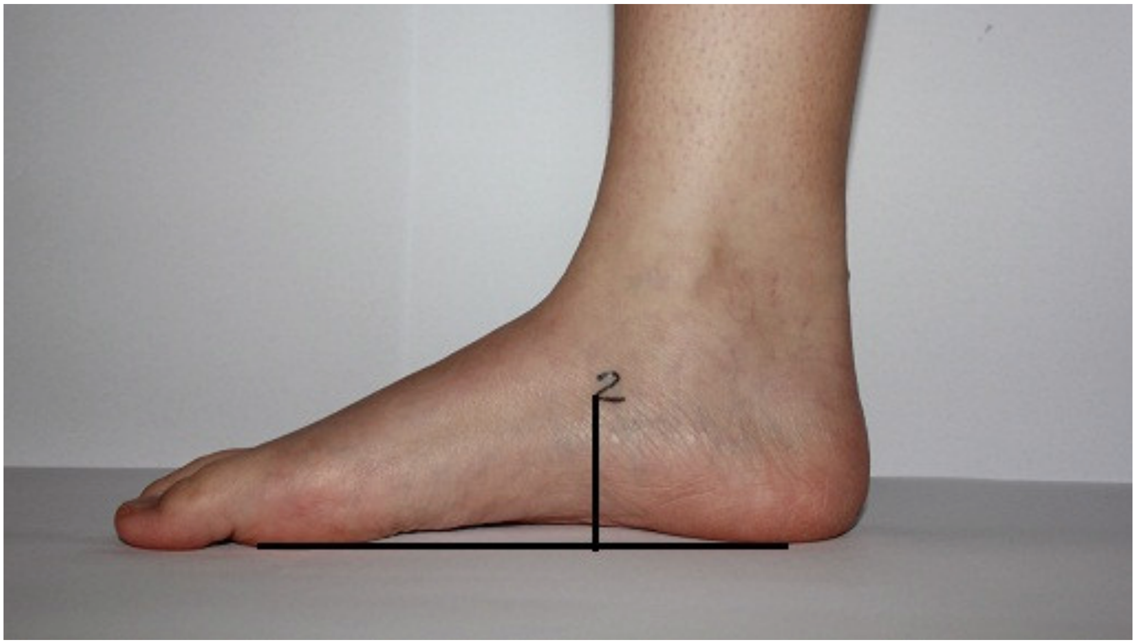
Patient name ***ID number***

	FACTOR	PLANE	SCORE 1 Date______________ Comment__________		SCORE 2 Date______________ Comment__________		SCORE 3 Date______________ Comment__________	
			Left -2 to +2	**Right** -2 to +2	**Left** -2 to +2	**Right** -2 to +2	**Left** -2 to +2	**Right** -2 to +2
Rearfoot	Talar head palpation	*Transverse*						
	Curves above and below the lateral malleolus	*Frontal/ transverse*						
	Inversion/eversion of the calcaneus	*Frontal*						
Forefoot	Prominence in the region of the TNJ	*Transverse*						
	Congruence of the medial longitudinal arch	*Sagittal*						
	Abd/adduction forefoot on rearfoot	*Transverse*						
	TOTAL							

Reference values
Normal = 0 to +5
Pronated = +6 to +9, Highly pronated 10+
Supinated = -1 to –4, Highly supinated –5 to -12

Appendix C

NAVICULAR HEIGHT (NH)



NH- The position of the navicular bone has implications on the medial longitudinal arch of the foot. The individual stands up in a static weight bearing position with feet staggered (right foot in front of left) and is asked to maintain a relaxed position. The examiner identifies and landmarks where the navicular tuberosity is located via palpation. In this position, the examiner takes an index card and lines it up from the floor and against the medial area of the foot and makes a mark on the index card. The perpendicular distance measured from the navicular tuberosity to the ground is then recorded.

Arch Classification	**Navicular measurement (cm)**
Severely Low	< 2.7
Low	2.7 to 3.5
Normal	3.6 to 5.5
High	5.6 to 6.4
Severely High	>6.4

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Appendix D

The weekly follow-up questions sent to participants at the end of each week via e-mail.

Week 1

(a) How many days did you wear your orthotics?

(b) On average, how many hours in a day did you wear your orthotics?

(c) Did you experience any pain or discomfort while wearing your orthotics?

(d) What type of foot wear did you wear your orthotics in? (i.e. boots, running shoes, slippers, etc.) *You can have multiple responses to this question.*

Appendix E

Table Ei. Mean (SD) integrated Abd H EMG (% MVC) during gait termination. No significant interaction between group, test date and task ($p>0.05$).

Group	Baseline	6-Weeks	12-Weeks
Orthotic (n= 9)	7,778 (10,393)	4,407 (5492)	9,363 (17,709)
Control (n= 9)	18,030 (28,764)	4,503 (3512)	7,866 (13,454)

** All values are in % MVC*

Table Eii. Mean (SD) integrated Abd DM EMG (% MVC) during gait termination. No significant interaction between group, test date and task ($p>0.05$).

Group	Baseline	6-Weeks	12-Weeks
Orthotic (n= 9)	7,628 (8502)	4,230 (2981)	7,638 (7770)
Control (n= 9)	7,884 (9279)	5,288 (4543)	15,486 (17,637)

** All values are in % MVC*

Table Eiii. Mean (SD) integrated Abd DM EMG (% MVC) during gait termination. No significant interaction between group, test date and task ($p>0.05$).

Group	Baseline	6-Weeks	12-Weeks
Orthotic (n= 9)	7,102 (4,065)	7,750 (4,868)	7,533 (5,418)
Control (n= 9)	12,936 (10,360)	12,134 (8,793)	14,198 (12,060)

** All values are in % MVC*